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Screening for gestational diabetes

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PRIORITISING SUMMARY UPDATE 2008

REGISTER ID:	**000177**
NAME OF TECHNOLOGY:	**SCREENING FOR GESTATIONAL DIABETES**
PURPOSE AND TARGET GROUP:	**DETECTION AND TREATMENT OF GESTATIONAL DIABETES MELLITUS IN PREGNANT WOMEN**

2008 SAFETY AND EFFECTIVENESS ISSUES

Since the original prioritising summary was published, there have been two studies investigating gestational hyperglycaemia which have reported their findings.

A 5-year prospective observational study, the Hyperglycaemia and Adverse Pregnancy Outcome (HAPO) study, was conducted by the HAPO Study Cooperative Research Group, to investigate the associations between adverse pregnancy outcomes and various degrees of maternal glucose intolerance less severe than that in overt diabetes mellitus (level II prognostic evidence) (Metzger et al 2008). A total of 25,505 pregnant women at 15 centres in nine countries underwent a 75-g oral glucose-tolerance testing (OGTT), between 24 and 32 weeks of gestation. Primary outcomes included birth weight above the 90th percentile for gestational age, primary caesarean delivery, clinically diagnosed neonatal hypoglycaemia, and cord-blood serum C-peptide level (an index of foetal β-cell function) above the 90th percentile. Secondary outcomes were premature delivery (a delivery before 37 weeks of gestation), shoulder dystocia or birth injury, need for intensive neonatal care, hyperbilirubinemia, and preeclampsia. Data remained blinded if the fasting plasma glucose level was 5.8mmol/L or less, and the 2-hour plasma glucose level was 11.1mmol/L or less.

Data from 23,316 participants with blinded data were analysed to calculate adjusted odds ratios (ORs) for various adverse pregnancy outcomes in relation to an increase in the fasting plasma glucose level of one standard deviation (SD) (0.4mmol/L), an increase in the 1-hour plasma glucose level of one SD (1.7mmol/L), as well as an increase in the 2-hour plasma glucose level of one SD (1.3mmol/L). Results of the study are presented in Table 1. For the primary adverse pregnancy outcomes, there were strong, continuous associations of maternal glucose levels below those diagnostic of diabetes with increased birth weight and increased cord-blood serum C-peptide levels. Relationships between plasma glucose levels and primary caesarean section as well as clinical neonatal hypoglycaemia were also observed, although these tended to be weaker. Among secondary adverse pregnancy outcomes, relatively strong associations were identified for preclampsia and for shoulder dystocia or birth injury. Premature delivery, intensive neonatal care, and hyperbilirubinemia were related to the 1-hour and 2-hour plasma glucose levels, but to a lesser degree. There were no obvious thresholds at which risks of adverse pregnancy outcomes, both primary and secondary, increased. In addition, 130 perinatal deaths occurred during

the study period, however the HAPO study was underpowered to determine the effect of glucose levels on the risk of this outcome occurring.

Table 1 Relationship between plasma glucose level and adjusted ORs for adverse pregnancy outcomes

	Adjusted ORs [95% confidence interval] I-SD increase in glucose level		
	Fasting	1-hour	2-hour
Birth weight > 90th percentile	1.38 [1.32-1.44]	1.46 [1.39-1.53]	1.38 [1.32-1.44]
Cord-blood serum C-peptide level > 90th percentile	1.55 [1.47-1.64]	1.46 [1.38-1.54]	1.37 [1.30-1.44]
Preeclampsia	1.21 [1.13-1.29]	1.28 [1.20-1.37]	1.28 [1.20-1.37]
Shoulder dystocia or birth injury	1.18 [1.04-1.33]	1.23 [1.09-1.38]	1.22 [1.09-1.37]
Primary caesarean delivery	1.11 [1.06-1.15]	1.10 [1.06-1.15]	1.08 [1.03-1.12]
Neonatal hypoglycaemia	1.08 [0.98-1.19]	1.13 [1.03-1.26]	1.10 [1.00-1.12]

The authors concluded that maternal hyperglycaemia, which although less severe than overt diabetes, is associated with clinically important, harmful perinatal conditions and that these effects may be reduced by effective maternal treatment during pregnancy. The threshold level of maternal diabetes which would determine whether or not treatment would be required or offered has yet to be established (Metzger et al 2008).

Another observational study of 2,885 pregnant women assessed the risks of various adverse pregnancy outcomes at differing levels of *mild* maternal glucose intolerance in a 75-g OGTT (level II prognostic evidence). Since women with a 2-hour glucose level as 9.0mmol/L or above were treated for gestational diabetes mellitus (GDM), only those with a 2-hour glucose level *below* 9.0mmol/L were included in this study. Significant linear trends in multivariate analyses were demonstrated for shoulder dystocia (p <0.001), spontaneous preterm delivery (p=0.04), and macrosomia (large-for-gestational age infants) (p <0.001). None of these outcomes deviated significantly from linearity (p = 0.4-0.8). For caesarean section, the trend was only significant in the univariate analysis (p =0.02). After adjustment for confounders, no significance in linear trend was observed (p =0.09). There was no significant trend for hypertension, or for neonatal morbidity in terms of hypoglycaemia, respiratory distress and jaundice. Although the risk of adverse pregnancy outcomes increased with increasing glucose levels, there appeared to be no obvious threshold level to establish a cut-off point for treatment (Jensen et al 2008).

2008 COST IMPACT

A cost-consequence analysis was conducted on women enrolled in the randomised controlled ACHOIS trial, the initial findings of which formed the basis for the original Prioritising Summary . Women with mild gestational diabetes and a singleton pregnancy were treated with dietary advice, blood glucose monitoring and insulin therapy where required and compared to women who received standard obstetric care. The economic evaluation was conducted from the perspective of the health system and its patients, comparing the direct costs of additional resources used from time of randomisation until time of postnatal discharge from the hospital of both mother and child. For every 100 women with a positive OGTT who were offered treatment for mild gestational diabetes in addition to their usual obstetric care, additional direct hospital costs of $53,985 were incurred. In addition, costs of $6,521 were incurred by the women and their families. Although 9.7 additional women experienced induction of labour and 8.6 more infants were admitted to the neonatal nursery, 2.2 *fewer* babies experienced serious perinatal complications and 1.0 *fewer* babies died. When the perspective is taken over the whole life-span of the infant, the incremental per extra life-year gained was $2,988, which would appear sufficient to justify the reduction in perintal mortality and complications. It should be noted that this analysis examined the cost-consequences associated with treating screen-detected disease and did not therefore include the prior costs of screening.

2008 OTHER ISSUES

A recent letter to the BMJ emphasised the need to screen pregnant women for gestational diabetes not only as a means to prevent perinatal complications but as a means of identifying those at risk of developing Type 2 diabetes. Within 10-years of being diagnosed with gestational diabetes, 35-60 per cent of women will go on to develop Type 2 diabetes. In addition, their offspring are at an increased risk of developing the disease. Therefore, screening for gestational diabetes allows the monitoring of at least two individuals who may be at risk of developing Type 2 diabetes and may result in the implementation of interventions aimed at the prevention of the disease (Sillender 2008).

In June 2008, the funding of a new Victorian study, the STOP diabetes project, was announced and would be run in conjunction by Monash University and Southern Health. It is hoped that 250 women considered to be at high-risk of developing gestational diabetes will be identified and enrolled early on in their pregnancy. The project aims to implement lifestyle interventions to prevent the development of gestational diabetes (Miller 2008).

2008 SUMMARY OF FINDINGS:

The studies included for assessment in this Prioritising Summary update support those studies included in the original Summary, in that maternal hyperglycaemia, less

severe than that used to define overt diabetes, is associated with adverse pregnancy outcomes and that their effects may be ameliorated by treatment. Given that: screening for gestational diabetes is not universal in Australia or New Zealand, rates of Type 2 diabetes are increasing in Australasia, women with gestational diabetes and their offspring are at greater risk of developing Type 2 diabetes, and there is an effective treatment for gestational diabetes, the screening and treatment for gestational hyperglycaemia may have beneficial impact from a public health perspective.

2008 HealthPACT action:

The evidence for screening and the subsequent treatment of gestational diabetes is well developed. Therefore HealthPACT has recommended that this information should be forwarded to the Royal Australian College of General Practitioners (RACGP), the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) and to the National Screening Committee via CTEPC.

2008 Number of included Studies

Total number of studies	
Level II prognostic evidence	2

2008 References:

Jensen, D. M., Korsholm, L. et al (2008). 'Adverse pregnancy outcome in women with mild glucose intolerance: is there a clinically meaningful threshold value for glucose?' *Acta Obstet Gynecol Scand,* 87 (1), 59-62.

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Moss, J. R., Crowther, C. A. et al (2007). 'Costs and consequences of treatment for mild gestational diabetes mellitus - evaluation from the ACHOIS randomised trial', *BMC Pregnancy Childbirth,* 7, 27.

Sillender, M. (2008). 'Screen women with gestational diabetes for type 2 diabetes', *BMJ,* 336 (7656), 1263.

PRIORITISING SUMMARY 2005

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
- ☐ 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
- ☐ 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

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

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.

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

[2] Note, a wide confidence interval

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.
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.

RECOMMENDATION:

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. Based on the recent and ongoing high-level effectiveness data available and ethical issues that surround screening and treating GDM. Therefore HealthPACT recommended that this technology be monitored.

SOURCES OF FURTHER INFORMATION:

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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