

# **Gestational Diabetes Mellitus in New Zealand**

## **Technical Report**

**From the Gestational Diabetes Mellitus Technical Working Party**

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Organisations supporting this document

*Will be added once ratification received from organisations*

## 1.0 Executive Summary

1. In association with the epidemic of obesity and Type 2 diabetes in New Zealand, there are increasing numbers of women who will develop gestational diabetes (GDM) or who have undiagnosed Type 2 diabetes during pregnancy. GDM is associated with increased risks for the mother and baby during pregnancy and longer term risk of diabetes in both mother and offspring and obesity in the offspring.
2. Recent studies have shown that risks to mother and baby during and after pregnancy are reduced by treating women with GDM. The subsequent risk of developing Type 2 diabetes may be reduced with lifestyle or pharmacological interventions postpartum.
3. Currently in New Zealand, the approaches to screening women to detect GDM, and the way women with GDM are cared for are variable. In light of the current epidemic and the recent studies, a need was identified to review the evidence about relevant issues in screening of pregnant women for GDM and management of women with GDM in the context of the New Zealand health system.
4. A Working Party was created, involving representatives from organisations with an interest in GDM, to produce a Technical Report which could be used by the relevant Government and non-Government organisations to develop and implement a more consistent approach to GDM across New Zealand.
5. The Working Party made the following recommendations:
  - Care needs to be consumer centred and maintain the focus on women becoming mothers, and on the birth of healthy babies, only part of which is the management of their GDM
  - In general, women without known diabetes should be offered routine screening for GDM using a non-fasting, 1 hour 50g glucose challenge test at 24-28 weeks of pregnancy. This will require all pregnant women having the appropriate written information in order to make informed decisions about such screening.
  - The diagnosis of GDM should be by a fasting, 75g 2 hour oral glucose tolerance test. Currently the Working Party recommends that the criteria should remain as a fasting glucose  $\geq 5.5$  mmol/l and/or 2 hour  $\geq 9.0$  mmol/l. The Hyperglycaemia and Adverse Pregnancy Outcomes study<sup>27</sup> or HAPO study is investigating the relationship between different diagnostic cut offs and pregnancy outcomes. In future the Working Party acknowledge the increased need to collect local information relating to different diagnostic cut offs, to see how lower cut off levels would affect the New Zealand pregnancy population.
  - Some women will have significant risk factors for undiagnosed Type 2 diabetes at booking. These women require an early screen with their booking bloods. An HbA1c is recommended:
  - If the HbA1c is  $\geq 6.0\%$  women should be referred to the diabetes in pregnancy team for further assessment and management.
  - If the HbA1c is 5.3 – 5.9%, an early 75g OGTT is recommended (this will be implemented as a pilot strategy) If this is normal, repeat later in pregnancy (typically 26-28 weeks).
6. All District Health Boards require a recognised Diabetes in Pregnancy Team and should facilitate the local development of such a Team that best suits their region so that they address the issues/ principles raised in this report particularly.
7. All diabetes in pregnancy, including GDM, is associated with increased risks for the woman and the baby and needs careful monitoring (ultrasound, glucose, clinical). All LMCs should have access to a Diabetes in Pregnancy Team and ultrasound scanning facilities
8. The Diabetes in Pregnancy Team in conjunction with LMCs and primary healthcare in each District need to develop agreed standards of care and referral/communication pathways based upon the Australasian Guidelines. This would ensure that for the woman the management of diabetes in her pregnancy will be integrated between primary and specialist health carers.

9. Practitioners working in primary care need to be resourced to provide appropriate education about GDM implications overall and pregnancy specific management issues such as dietary and glucose monitoring advice.
10. Local audit, national monitoring and Australasian benchmarking systems should be in place to support continuous improvements in GDM care
11. Written material for both consumers and health professionals about GDM should be developed nationally with extensive input from consumer organisations.

## 2.0 Background of the Technical Report

A national workshop hosted by the Australasian Diabetes in Pregnancy Society and the New Zealand College of Midwives was held on 10 March 2006 to discuss screening for, and management of, gestational diabetes mellitus (GDM). Presentations included reviews of the current epidemic of obesity and diabetes in New Zealand and focussed on:

- recent evidence confirming benefits of treating women with GDM
- inter-generational effect of exposure of the fetus to maternal diabetes
- interventions that reduce progression to Type 2 diabetes in high risk populations
- potential long term health benefits for women and their children by identifying and treating GDM
- the rationale for promoting a general rather than selective screening approach for GDM
- controversies around the criteria for diagnosis of GDM and how these may be solved.

These presentations and report of the meeting are attached in Appendix 1 (Section 8.0).

During discussions it was agreed that a smaller working group, consisting of representatives from the stakeholder organisations form a Technical Working Party to meet and address the issues that were raised by developing a Technical Report. This would include recommendations about screening for GDM and what this would mean for the women when they presented with GDM in an attempt to model the type of care it was expected that they receive. The members of the Technical Working Party are shown in Appendix 2 (Section 9.0).

The Technical Working Party met on 01 June 2006 to consider GDM within the unique circumstances of the New Zealand demography and health services. It was agreed that representatives from the participating organisations would form four groups to address the main issues that had been identified with respect to screening and diagnosis of GDM. Each group would provide a written summary of the evidence and make recommendations based on the evidence. These documents would contribute to the body of a Technical Report, which could be used by stakeholder organisations to ensure that appropriate care is available for women during pregnancy.

The main issues are discussed in the four main sections of the report:

Section 3.0: Should all women be offered screening for gestational diabetes? If so, how?

Section 4.0: What does this mean for women and what models of care should be considered for the management of gestational diabetes?

Section 5.0: Which women should be screened early and how?

Section 6.0: What 2 hour cut-off should be used in the 2 hour glucose tolerance test?

This Technical Report is a collaborative effort, based on each member of the Working Party's submissions. Further consultation that led to the final draft of the report was as follows:

- The sections for the Technical Report were collated by the convenors of the working party.
- The draft Technical Report was distributed to the participating organisations for consultation, amendment and comment, to provide feedback to the Technical Working Party.
- The Technical Report was then revised based on the feedback received, with further discussions where necessary to address issues raised

- The final amended Technical Report was distributed to participating organisations as a final draft
- The Technical Report was then distributed to organisations asking for endorsement and for internal use.

It is important to note that this report has not reviewed budgetary considerations including cost effectiveness and health prioritisation. These are difficult to evaluate in the context of the limitations in existing data, current limitations in services for women who have had GDM and the putative inter-generational effects of GDM. Further work is needed in this area.

It is also important to note that all recommendations contained within this Technical Report are underpinned by the Health and Disability Consumers Code of Rights (Appendix 5 – Section 12.0) and Health Information Privacy Code.

Once the report has been reviewed by organisations, it will be summarised for submission to the New Zealand Medical Journal and circulated further within organisations (eg through professional and consumer journals) to inform policy. This will include the National Screening Unit, Public Health Directorate of the Ministry of Health and the Ministry of Health Expert Group on Diabetes and Cardiovascular Disease. We anticipate that the Ministry of Health Expert Group on Diabetes and Cardiovascular Disease will agree to forward the recommendations to the CEO's of District Health Boards for consideration on how to implement the document in their areas (including coordination of the different services).

We thank all parties for their constructive and collegial approach to this process. We thank the Ministry of Health for their support.



### 3.0 Should all women be offered screening using an oral glucose challenge test?

#### 3.1 Gestational Diabetes is an important condition

Gestational Diabetes Mellitus (GDM) is defined as glucose intolerance first diagnosed during pregnancy. GDM includes those with pre-existing undiagnosed diabetes, impaired fasting glucose (IFG) and impaired glucose tolerance (IGT), and those whose glucose tolerance is only transiently impaired during pregnancy. Diagnosis is based on a fasting 2-hour oral glucose tolerance test (OGTT) (see Section 5.0). As most pregnant women will not have GDM, a simpler preliminary screening test may be used. In New Zealand, current screening for GDM is based upon a 1 hour, non-fasting screening test, of a 50g oral glucose challenge test. Where the 1 hour result is  $\geq 7.8$  mmol/l, the fasting diagnostic test is undertaken. GDM identified in this way, was diagnosed in 3-8% of pregnancies in New Zealand depending on ethnic group in the mid 1990's<sup>1</sup>. With increasing rates of diabetes and obesity in the general populations, these rates are thought to have increased. National Womens Health's statistics for 2005 do show an increase in GDM amongst their birthing population<sup>2</sup>. The diagnosis of GDM is important, as it is associated with maternal and perinatal complications, including in the mother, pre-eclampsia, caesarean section and perineal trauma; for the baby there are risks of macrosomia, rarely stillbirth, shoulder dystocia, birth injuries and neonatal morbidity, such as hypoglycaemia, hypocalcaemia and jaundice<sup>3</sup>. Intervention during pregnancy for women with GDM will reduce the likelihood of these complications occurring.

Mothers who return to normal glucose tolerance postnatally have an increased risk of developing diabetes in the future, with further pregnancies potentially accelerating this risk<sup>4,5</sup>. There is increasing evidence that maternal diabetes in pregnancy is also associated with an increased risk of diabetes, obesity and the metabolic syndrome in the offspring<sup>6-8</sup>.

Importantly, for women who have had GDM, recent studies have shown that intensive lifestyle intervention or medications can prevent/delay progression to Type 2 diabetes in the mother<sup>9-11</sup>. Identifying women with GDM, could therefore not only flag the need for future testing for the early onset of diabetes (particularly among women who may again become pregnant), but would allow the early introduction of ways to prevent diabetes (and heart disease) in the future.

Recently, the results of a large multi-centre randomised controlled trial (ACHOIS) comparing "revealing" or "concealing" (ie not providing clinicians with the results to the OGTT) the diagnosis of "glucose intolerance during pregnancy" showed a lower rate of composite adverse perinatal outcomes in the revealed group<sup>12</sup>. Over 90% of the women who were recruited into the trial had GDM identified with routine screening rather than based on risk factors. The baseline characteristics of the women did not identify them as a high risk group, but they still benefited from treatment. This study supports universal screening as well as raising the issue of whether we should use a lower cut off to diagnose GDM (see Section 5.0). For the first time, prospective randomised data have shown benefits of treating women with GDM. Importantly, the diagnosis of GDM was not associated with increased caesarean section rates and led to decreased depression rates and anxiety scores in the mother. A summary of the trial and its context is given in Appendix 4 (Section 11.0).

Previous guidelines in New Zealand have recommended screening for GDM only among those women with risk factors<sup>13</sup>, which include maternal obesity, ethnicity, family history of diabetes, past GDM, maternal age 30+ years, past stillbirth and glycosuria among others. The Australasian Diabetes in Pregnancy Society (ADIPS) guidelines recommended screening all women unless there was a low prevalence of GDM<sup>14</sup>. The RANZCOG guidelines for screening in pregnancy endorse a policy of universal offer of screening<sup>15</sup>. In light of the ACHOIS trial, increasing numbers of women with obesity and diabetes and the potential benefits of intervention to reduce not only pregnancy risks, but longer term risks, it is timely to review recommendations and indeed some organisations have done this (NZCOM)<sup>16</sup>.

The discussion below addresses the following:

- Should we screen for GDM?
- Should screening be offered on a selective or universal basis?
- What recommendations can be made based on current evidence?
- What is the way forward?

### 3.2 Should all pregnant women be screened for GDM?

The Working Party considered the offer of screening for GDM within the context of the Ministry of Health “Screening to improve health in New Zealand”<sup>18</sup> criteria:

#### 1. The condition is important in the population being screened and may not be detected without screening

Using ADIPS guidelines and New Zealand diagnostic criteria for screening<sup>14</sup>, a significant and increasing number of pregnancies are complicated by GDM – it is not a rare disorder. It is usually asymptomatic and cannot be detected easily without screening.

#### 2. Treatment is associated with benefit.

- This has been shown regarding immediate obstetric and perinatal outcomes
- Public health benefits also need to be considered at a time when we have an epidemic of diabetes<sup>17,19</sup>

Relevant points:

- While there are no randomised controlled trials (RCTs) of screening, comparisons of treated and untreated women with GDM show major benefits from screening<sup>3</sup>, and women with GDM benefit from more intensive treatment<sup>29,30</sup>. The ACHOIS trial also provides relevant information<sup>12</sup>. The women randomised in ACHOIS were “low risk” with respect to risk factors, so most of them would not have been identified and treated in an environment of selective screening. In the control group (concealed results) they included at least 1 in 5 women with normal glucose tolerance. During the trial, the control group could be screened for GDM and treated if their LMC felt there were indications to do so. The control group was therefore similar to a group of women who were selectively screened, and this group had worse outcomes. There will not be a more definitive trial of screening, now that treatment has shown benefit, but ACHOIS strongly supports offering screening for GDM to all women.

- Pregnancies complicated by GDM are at increased risk of macrosomia (by all definitions) and large for gestational age babies and associated sequelae (shoulder dystocia, fractures, palsies), neonatal metabolic sequelae (hypoglycaemia, polycythaemia, respiratory complications) and late fetal death. These appear to occur independently of the effect of maternal obesity, age, gestational age and parity<sup>3, 12</sup>
- Women with past GDM are at increased risk of future Type 2 diabetes<sup>4,20</sup> and are likely to benefit from lifestyle and possibly pharmaceutical interventions<sup>9-11</sup>. Type 2 diabetes in New Zealand has reached epidemic proportions<sup>17,19</sup> and even without systematic screening for GDM, a significant proportion of New Zealand women with Type 2 diabetes had past GDM<sup>21</sup>. Identifying risk of future diabetes and then intervening is likely to reduce the magnitude of the epidemic in New Zealand.
- Women with past GDM are at increased risk of undiagnosed Type 2 diabetes, a condition associated with increased risk of fetal malformations and perinatal mortality in New Zealand<sup>22,23</sup>. A substantial number of women with GDM have permanent diabetes or IGT/IFG after pregnancy<sup>24</sup> and many of these will become pregnant again, possibly with unknown and unmanaged hyperglycaemia.
- There is growing evidence that exposure to hyperglycaemia in utero predisposes offspring to future diabetes and obesity<sup>6-8,25</sup>. Identifying GDM allows management of the hyperglycaemia to occur which may be associated with a reduced chance of future obesity and diabetes in the offspring<sup>26</sup>. At the very least it allows the parents to promote healthy eating and physical activity choices in their children.

### 3. There is a suitable test

The accepted approach, and that promoted by ADIPS in New Zealand, is the 50g non-fasting glucose challenge test followed by a diagnostic 75g 2 hour oral glucose tolerance test (OGTT) if the screening (non-fasting) glucose is  $\geq 7.8$  mmol/l<sup>14</sup>. This approach is already used across New Zealand<sup>27</sup>. The criteria for diagnosis using the OGTT are also already consistent across New Zealand (fasting glucose of  $\geq 5.5$  mmol/l and/or 2 hour glucose  $\geq 9.0$  mmol/l)<sup>27</sup>. However, the 2 hour cut-off is discordant with that used in Australia (fasting glucose of  $\geq 5.5$  mmol/l and/or 2 hour glucose  $\geq 8.0$  mmol/l) and that used in ACHOIS (fasting glucose of  $\geq 7.8$  mmol/l and/or 2 hour glucose  $\geq 7.8$  mmol/l). Indeed New Zealand has one of the highest 2 hour thresholds across countries with published guidelines for screening. A trial is currently underway to identify the diagnostic criteria with the optimal screening characteristics (called the Hyperglycaemia and Adverse Pregnancy Outcomes study<sup>27</sup> or HAPO). Section 4.0 discusses diagnostic criteria.

The sensitivity and specificity of the 50g GCT will vary according to the subsequent diagnostic criteria used to define GDM, but a recent report demonstrates that universal screening using this test is the most cost-effective approach to identifying women with GDM compared with using an OGTT alone or no screening.<sup>28</sup> This paper used the commonly reported sensitivity of the test as 80%, which means that 20% of women with GDM will have a screening result  $< 7.8$  mmol/l. Half of the women with a false normal result will have a result between 7.2 – 7.7 mmol/l. This is recognised, and it is recommended that women who have results in this range are further tested if there is also clinical suspicion for GDM. Using clinical risk factors in combination with the screening test leads to better identification of women with GDM.<sup>29</sup> The specificity of the test is reported as approximately 90%, which means that 90% of women without GDM have a normal screening result.

However, 10% of normal women have an elevated screening test, so they will undergo a 75g OGTT that gives a normal result. Several centres have shown that women with an elevated screening test and normal 75g OGTT have increased pregnancy risks.<sup>30, 31</sup> so it may be useful to identify these women anyway. It also raises the question whether current diagnostic thresholds are too high.

**4. The potential benefit from the screening programme should outweigh the potential physical and psychological harm.**

The broad health benefits of early GDM diagnosis and management for both mother and child in the current pregnancy, and in avoiding the future development of diabetes represents a significant health benefit for this screening programme. Potential harms must be kept in mind and steps taken to mitigate harm. Potential harms include: the increased medicalisation of pregnancy and the increased rate of intervention in pregnancies diagnosed with GDM (inductions<sup>12</sup>, possibly caesarean delivery<sup>12,32,33</sup>), increased anxiety for the woman and her whānau, possible adverse impacts on self-perceived health status<sup>12, 34, 35, 36</sup>, potential impacts of glucose loading during screening process (while no data exists indicating harm and the 75g glucose load is equivalent to 4 thick slices of white bread), and the potential affects of false positive results<sup>37</sup>. "While not a harm per se, it needs to be noted that the glucose load is unpalatable to many women."

**5. The health care system will be capable of supporting all necessary elements of the screening pathway, including diagnosis, follow up and programme evaluation.**

Screening for GDM is already in place across New Zealand, although some areas follow selective screening, and others follow a universal offer of screening. Each District Health Board in New Zealand already delivers a diabetes in pregnancy service to some degree. A universal offer of screening is likely to help with assessment and further planning of resources. Models of care are discussed in Section 5.0.

**6. There is consideration of social and ethical issues**

There are social and ethical issues related to screening or not offering screening for GDM. These include the need to balance the potential for preventing harm to mothers and their babies where this may be possible, with the possible impact of the screening, diagnostic and management process. A further consideration is the ability for screening to advise women of the risk to themselves and their current and future children. This is particularly the case at a time of an epidemic of Type 2 diabetes<sup>17,19</sup>.

Informed Consent

An offer of screening, with the provision of appropriate information, allows women to make the decision of whether or not to be screened. The Code of Health and Disability Rights states that, "Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including: b) An explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option"<sup>41</sup>.

When considering the universal offer of screening the relevant rights under The Code of Health and Disability Consumers Rights to consider are: (see Appendix 5 – Section 12.0):

- Right 5: Right to effective communication
- Right 6: Right to be fully informed
- Right 7: Right to make informed choice and give informed consent.

The introduction of a GDM screening programme must be in keeping with both the Code of Health and Disability Consumer Rights<sup>41</sup> and the Medical Council of New Zealand's Statement on Informed Consent<sup>42</sup> which states: *Doctors have a special duty of care when enrolling an apparently healthy asymptomatic person in screening programmes, to make him or her aware of the limitations of screening and the uncertainties, in particular the chance of false positive and false negative results. Before obtaining consent the doctor should explain, or give information to the patient that explains:*

- *The purpose of the screening*
- *The uncertainties*
- *Any significant medical, social or financial implications of the condition for which the screening is done and,*
- *Follow up plans, including availability of counselling and support services"*

#### **7. There is consideration of cost-benefit issues**

The cost benefit balance in ACHOIS is currently being analysed. Previous economic studies have suggested savings over time if GDM is followed by an intervention that could reduce new Type 2 diabetes by 10% per annum<sup>43</sup>. The latest interventions to prevent Type 2 diabetes by lifestyle approaches reduce new diabetes by 58% over 3-4 years<sup>9,10</sup>. No modelling has yet been undertaken of the benefits of preventing future diabetes and obesity in the offspring.

#### **8. There is responsiveness to Māori need**

The current screening guidelines in New Zealand<sup>13,14</sup> recommend that all Māori be offered screening for GDM on the basis of their high risk for GDM<sup>1</sup>, undiagnosed Type 2 diabetes in pregnancy<sup>23</sup> and adverse complications<sup>24</sup>. With such a high absolute risk, screening for GDM and the potential benefits for the mother and offspring (and possibly future generations) would provide major benefits to Māori. The evidence currently is that penetration of screening among Māori is not high<sup>1</sup>, and this may, in part be due to the current variety of views on screening for GDM.

### **3.3 Should screening be offered on a selective or universal basis?**

Most women do not develop GDM, but risk factor based approaches miss a sizable proportion of women with GDM<sup>44</sup> and selective screening has been associated with under-screening of those with risk factors, possible because of the complexity of the approach. The goal of offering screening for GDM is to:

- reduce harm to mother and baby during the pregnancy where GDM is found to be present
- reduce harm to future babies by increasing the likelihood of preconceptual identification and management of undiagnosed diabetes, thereby reducing the risk of malformations and early fetal loss
- inform women with GDM of their predisposition to Type 2 diabetes, such that they can act to reduce their risk
- inform women with GDM that their children are at increased risk of obesity and diabetes, such that they can act to reduce the risk of their children.

It is important to inform women of potential negative aspects of any test. This screening process must be cautious not to make a normal life event – pregnancy and childbirth - into a medically managed event as a result of screening. There is clearly a need for good information for women in which the rationale and goals of, screening as well as any potential negative consequences of participation are presented, so that they can make an informed decision in relation to being screened without anxiety being raised. See discussion under 'The potential benefit from the screening programme should outweigh the potential physical and psychological harm, (see page 8 and discussion under Models of care on page 22).

It is vitally important therefore that nationally consistent, evidence-based written material is produced in consultation with consumer organisations.

The key question within maternity has become whether screening should be undertaken by offering screening only to women with risk factors (selective offer of screening), or to all women (universal offer of screening). The advantages of each approach over the other is summarised below:

*A selective offer of screening has the following potential advantages over a universal offer:*

- it reduces the expectations/demands upon low risk women
- screening can be viewed as medical intervention and by not doing it this reduces the amount of medical intervention in low risk women
- it may be cheaper (This may not be true when considering benefits of treatment, and it is not the scope of this document to perform cost-analysis)

*A universal offer of screening has the following advantages over a selective offer:*

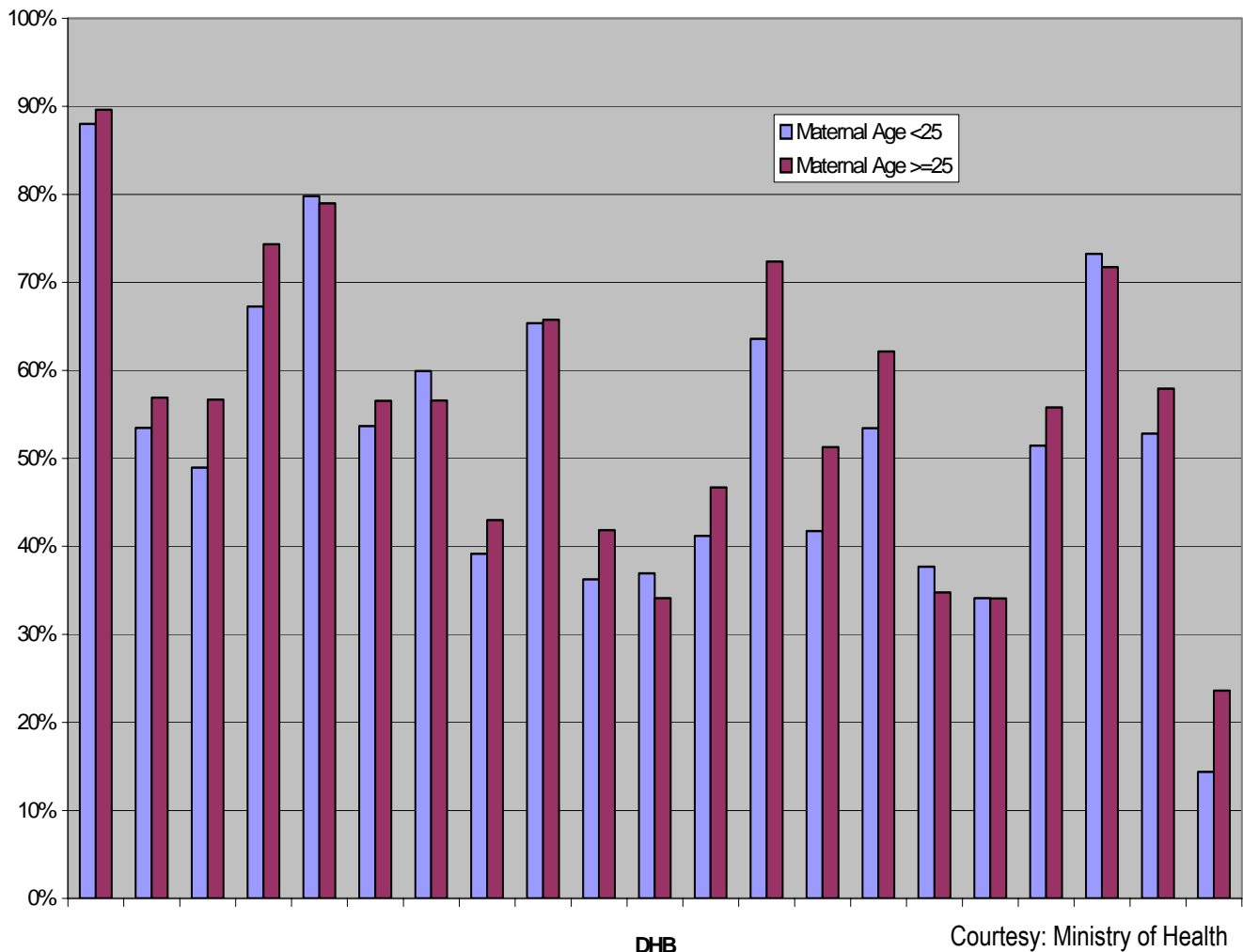
- risk factor screening is shown miss a significant number of women with GDM who (along with their babies) are at risk of harm during and after the current pregnancy (ACHOIS trial)
- it is simpler to offer it to all women. There is currently poor uptake of screening in pregnancy even among many of those with risk factors. There is evidence that the risk factors for GDM are not widely known or used<sup>45</sup>
- offering screening to all women avoids confusion over identifying risk factors especially in a population where diabetes is known to be increasing in prevalence
- it may help to reduce inequalities of care
- It identifies women who are likely to be at lower risk for later diabetes (normal test), which is a relevant positive outcome for many women.
- It ensures women are informed about an important and somewhat prevalent pregnancy complication so that women can participate in a decision about having the test, rather than it not being offered.

### **3.4 What are we doing currently in New Zealand?**

Data provided by the Ministry of Health (below) show that screening for GDM is very variable across the country and not consistent with the proportion of women from ethnic groups at high risk of GDM.

The proportions of women undertaking a glucose challenge test from the total number of women birthing in New Zealand by District Health Board ranges from 20% to 89%. The screening rates below and above 25 years of age are roughly comparable within each district, suggesting that risk factor screening is not currently being used systematically.

**Polyose (Glucose Challenge) Testing as a % of Live Births by District Health Board**



### 3.5 What recommendations can be based on current evidence?

*Recommendation of the Technical Working Party*

**“All women should receive a universal offer of screening for gestational diabetes with informed consent”**

### 3.6 What is the way forward?

In order for GDM to be offered universally, it is particularly important that women are able to make an informed decision about whether to be tested or not.

It is therefore crucial that:

- there is written information available that is nationally consistent and is easily understood by women that will raise general awareness about GDM
- benefits and disadvantages of screening are discussed with women and documented
- women are informed about screening in a timely and appropriate way during pregnancy

- relevant health professionals are aware of the benefits and disadvantages and are provided with resources to maintain currency so they are able to advise women and implement screening in a woman focussed manner.
- there is a system to ensure that screening and subsequent management if required are continuously improved
- Women are informed about their treatment options should they be diagnosed with GDM and remain the central focus of the model of care provided



## 4.0 What does this mean for the woman?

New Zealand population changes and proposed changes to screening and management of Gestational Diabetes Mellitus (GDM) will result in increased detection rates of GDM. As a result, systems that provide care to women with a positive diagnosis will need to expand on current levels of service. At the same time, services will need to ensure women are provided with care that not only manages and monitors their diabetes, but also ensures that care, of the quality demanded by this particular clinical problem, is delivered within the context of the NZ maternity framework. Such care needs to maintain the focus on these women becoming mothers with only part of it being the management of the GDM

### 4.1 Defining the GDM Management Team

The management of GDM is complex and requires involvement of health professionals across a number of different disciplines. This includes the woman's LMC, primary care services such as general practitioners and practice nurses, diabetes educators, dietitians, hospital midwifery services, ultrasonographers, physicians and obstetricians. Some services are hospital based while others are in the community. Who is involved, and at which point, will be determined by a number of factors including, availability of expertise, geographical considerations, funding considerations and the needs of each individual woman. There is agreement that the delivery of care for women needs to have the woman herself at the centre and that the services she requires need to be integrated to meet her needs. The details in this "models of care" report provide a framework which can then be considered by each DHB. Models will undoubtedly, vary across different communities but the principles (as detailed below) for a coordinated approach to care for the woman with GDM should be inherent in whatever service a DHB develops .

### 4.2 Key Principles for Responsibilities and Roles

While the nationally based maternity framework provides for clarity over responsibilities for services for women with uncomplicated pregnancies, a diagnosis of GDM requires an overlay of more specialised antenatal and perinatal services as well as the delivery of diabetes related services. Diabetes care for some women with GDM need not be complex and many of the tasks could be undertaken in a community based setting. However, poorly managed GDM risks an adverse outcome for mother and/or baby and for this reason a specialist service overview of all women who have a diagnosis of GDM is required. Many women with GDM will need to be exclusively managed within the context of a specialist service, while others will have their needs met by a shared care arrangement between specialists, the woman's LMC and other community based services. It must be recognised that at any time the status of the woman's GDM may change which in turn will change the level of care required. Effective and timely communication, mutual respect and collaboration will be the prerequisites of a successful GDM service.

A number of principles arise for the development of the following Models of Care:

- A key aim is to optimise services for women diagnosed with GDM, and to ensure that standards of care are equitable nationally (as far as possible).
- With the involvement of so many health professionals, approaches to co-ordination need to be agreed by all involved on both a local and interdistrict basis.
- The details of the inter-professional relationships required, need to have regional hospital and community health professional input. This includes referral criteria to access care.

- Some LMCs who are providing care may recognise that care has moved beyond their scope of practice, therefore there needs to be the capacity for LMCs to discuss this with the woman and to hand over the midwifery aspect of the woman's care to the secondary service. This is especially true when the woman's diabetes requires complex management.
- Community based services such as the woman's primary care team (in the context of general practice) can liaise with the LMC to provide timely initiation of management that includes further investigations, and instigation of dietary advice and glucose monitoring while the woman is waiting for a specialist appointment. The woman's primary care team may also be available for day to day advice and management including urgent referral should this need arise.
- Diabetes educators and dietitians having a special interest in diabetes in pregnancy are an essential resource for all pregnant women with GDM. As well as being members of the specialist team, they also need to be available for consultation in the community.
- Decisions regarding obstetric management need to be made by the woman following recommendations from Specialist Obstetricians experienced in GDM.
- Decisions regarding diabetes management need to have oversight by the diabetes team. Oversight includes ongoing audit of outcomes, and their relationship with referral pathways and processes of care.
- The expectation of the care that women with GDM receive as described need to be available in each DHB for all women who have been diagnosed as having GDM following screening. The thresholds for screening and diagnostic tests will be in line with that described earlier in the report.

### 4.3 Key Components of the Models of Care:

#### **Routine Offer of Screening**

All women who do not already have a diagnosis of diabetes should be offered screening for GDM by their LMC. This offer of screening should take place after the woman has been given full information as described in Section 3.0. If she makes an informed decision to participate, the timing of the screening test should be such that the result will be available at the time of her 28 week antenatal visit (or as soon as possible after this gestation if, for example, the diagnosis is made after this visit).

Women who may have already been screened due to risk factors present in early pregnancy and were found to have a negative result should also have a further discussion and be retested at this time. Indications for this early screening are discussed in Section 5.0.

Screening for GDM would involve ordering a polycose screening test (Glucose Challenge Test - GCT)

- If the screening test is abnormal the woman should be contacted within 48-72 hours with arrangements for a formal oral glucose tolerance test (OGTT) to be performed within one week
- For those women with a negative GCT or OGTT, but where concern continues that GDM may develop or have been missed, the following criteria determine which women will require retesting in 4 weeks.
  - ongoing glycosuria
  - onset of symptoms such as polyuria and excessive thirst,
  - where macrosomia or polyhydramnios are developing,

- high prior risk and a positive glucose challenge test but negative OGTT (repeat OGTT at one month after previous negative test – or earlier if risk factors have already emerged)
- high prior risk and a glucose challenge test of 7.2-7.7 mmol/l (repeat OGTT at one month after previous negative test – or earlier if other risk factors have already emerged)

### Diagnostic Results

Following the OGTT, the laboratory will supply the diagnostic test results to the LMC. The following describes the framework for what should occur should the result fall within the abnormal range.

### Diagnosis of GDM

- The LMC will inform the woman of her diagnosis of GDM and the implications this has on her pregnancy. Written information is also provided to the woman about GDM. The LMC will inform the women of the regional model of care available to her that has been developed by the Diabetes in Pregnancy Team, the LMCs and primary care providers. This model ideally is supported by multidisciplinary education so all health professionals who meet with the woman are consistent with information provided..
- The target time between abnormal screening result (polycose) and diagnosis (OGTT) should be up to 1 week.
- Education of the woman begins at the time of abnormal polycose result and continues with the diagnosis of GDM.
- The *initiation* of management should occur **within 24-48 hours** of diagnosis and should be the responsibility of the LMC, in conjunction with the woman's general practitioner, practice nurse, diabetes educator, dietitian and/or the specialist team. This is important in order to :
  - determine the level of risk of the GDM – this would include HbA1c estimation, initiation of glucose monitoring and ultrasound assessment of the baby
  - ensure the provision of dietary advice has commenced. Dietetic advice may be able to be provided by telephone in some cases
  - Ensure that the woman is fully informed about the potential impact of GDM and the rationale for management whilst reassuring her about concerns she may have for her pregnancy
  - Ensure that women's decisions about ongoing care are made with appropriate information available to herself and her LMC.
- Simultaneously a referral is sent by the LMC to the physician/obstetrician specialising in GDM who has been identified in that DHB
- An appointment with this service should occur between 1 day to 2 weeks of diagnosis depending on factors associated with the diagnosis of GDM and other care already being received. This would preferably be before 30 weeks gestation (if diagnosed before this time).

### **Dietitian/ Diabetes Nurse Educator Visit**

- At this appointment the woman will be informed again about the diagnosis and its potential implications
- Further written information is provided about GDM which builds on that provided by LMC and/ or the woman's GP/practice nurse
- The woman ideally receives dietary advice from a dietitian knowledgeable in the management of gestational diabetes so that dietary changes can be initiated prior to attending the specialist clinic
- The service should be able to provide the woman with, and teach her in the use of, a meter for capillary blood glucose measurements at home if this has not already happened. The women should be asked to ensure that results are available for visits to the specialist clinic
- There should be the capacity to down-load the meter results to a computer for analysis
- Dietary advice is provided and again this gives an opportunity for the woman to start to initiate these changes before attending the specialist clinic.

Ideally, every District Health Board should have a "**Diabetes in Pregnancy Team**". The members of this team will vary according to local resources, ethnic mix and geography. How the education and monitoring are delivered is also likely to vary. For example, in a major metropolitan area with many women with GDM some of the education aspects may be taught in a group setting; in some rural areas, local general practices may be more involved; the specialist dietitian may make use of telephone consultations in the education of the woman in some areas. The key issue is that the required level of education, dietetic advice as well as supervised self blood glucose monitoring is provided to all women as soon as possible after the diagnosis has been made and preferably before attendance at the specialist clinic.

### **The Specialist Clinic**

The following are key components of the **District Diabetes in Pregnancy** service:

- Co-location of obstetric and diabetes teams
  - Diabetes team to include diabetes physician with an interest in GDM, diabetes educator and dietitian
  - Obstetrician or team of obstetricians with a special interest in gestational diabetes
- Assessment of the clinical information, the self blood glucose monitoring readings, radiology and laboratory data to formulate a management plan appropriate to the level of risk including triaging to the required level of care.
- Ultrasound assessment of the fetus as required
- Measurement/ review of HbA1c result and glucose monitoring using direct downloadable glucose data from the woman's glucose meter as required
- Ability to educate the women in the use of insulin or other pharmacological treatment if this is required and supervise the treatment once initiated
- when there is a team approach all members of the team need to understand the importance of providing consistent advice to the woman

The specialist clinic visit should include a diabetes educator and dietitian review in the following instances:

- First visit for GDM following a diagnosis of GDM where such reviews have not yet occurred and insufficient information is available to assess maternal and fetal risk (eg no fingerprick glucose results)
- At first or subsequent visit where warranted by level of glycaemia achieved. (These will be locally agreed but may include HbA1c >5.6% and/or at least one before breakfast/meals fingerprick glucose  $\geq 5.0$  mmol/l and/or at least one fingerprick glucose  $\geq 6.0$  mmol/l two hours after a meal)
- Triaged to diabetes educator/dietitian review
- LMC/primary care concern

The specialist physician does not need to see all women. If any of the following occur there will need to be specialist physician review (with variations as decided by local specialist diabetes team):

- Glycaemia:  
At least two glucose levels:
  - before breakfast/meals fingerprick glucose  $\geq 5.0$  mmol/l
  - 2 hours after meal fingerprick glucose  $\geq 6.0$  mmol/l
- OR At least one glucose level:
  - before breakfast/meals fingerprick glucose  $\geq 5.5$  mmol/l
  - 2 hours after meal fingerprick glucose  $\geq 6.5$  mmol/l
- Evidence of macrosomia, polyhydramnios, multiple pregnancy
- Past stillbirth, macrosomia or shoulder dystocia
- LMC/primary care concern
- GDM diagnosed before 24 weeks or GDM triaged to physician care

#### 4.4 What does this mean for the woman?

All pregnancies complicated by GDM are considered at high risk of adverse outcomes which can be mitigated through careful management. Ultrasonographic evidence of accelerated growth<sup>1</sup> and hyperglycaemia<sup>2</sup> are both associated with worse outcomes, the latter ameliorated with insulin therapy (or other medication where appropriate). However, even those women on dietary therapy alone are at high risk (eg 29.3% of babies with neonatal hypoglycaemia in South Auckland were diet treated<sup>3</sup>). The ACHOIS study (Appendix 4 – Section 11.0), demonstrated significant improvements in outcome, even though only 20% of the intensively treated group received insulin therapy<sup>4</sup>. Therefore the evidence from ACHOIS is that even if the glucose control appears adequate and the ultrasound appears normal, careful monitoring and being prepared to intervene remain key aspects of management. The reasons for this continued risk are thought to include:

- Ultrasound scans can have poor predictability of shoulder dystocia and birth weight<sup>1</sup>. Paired growth scans give the best estimate of the likelihood of macrosomia, with its inherent risk of shoulder dystocia but have a wide margin of error<sup>18</sup>
- The effects of the period of time exposed to hyperglycaemia prior to therapy may have already had a significant impact on the health of the fetus and, for example, the risk of neonatal hypoglycaemia
- Only glucose levels are currently monitored although other body fuels may also be important. For example maternal hypertriglyceridaemia is also associated with adverse outcomes<sup>5</sup> and greater adiposity as a toddler<sup>6</sup>.

- Glucose monitoring itself is prone to errors (e.g. faulty meter, user errors) and HbA1c has a significant lag phase and interpretation can be difficult in the setting of the altered turnover of haemoglobin in pregnancy
- Other co-morbidities such as obesity

In spite of the continued high risk in all pregnancies complicated by GDM, it is felt that some pregnancies, with apparently adequate glucose control and appropriate fetal growth with no other complications, may be able to be managed with a lesser role by the specialist team. The Technical Working Party defined two groups of women:

- Those requiring specialist care
- Those requiring specialist oversight

These are defined below.

### **Specialist Care**

There will be a group of women where exclusive specialist management and intervention is required for the remainder of their pregnancy. These include:

- Women requiring insulin or other medication to maintain glycaemic control
- Women receiving dietary therapy with evidence of fetal macrosomia, asymmetrical growth, polyhydramnios or other diabetes/obstetric complications

A minority of these women will require one or more periods of inpatient care either for fetal or maternal monitoring and/or management

Whether the LMC remains involved with women requiring exclusive specialist care or whether a DHB sets up a secondary midwifery service that provides midwifery continuity for these women is for each DHB to determine. In doing so they will need to consider workforce availability and whether local LMCs can remain involved. Notwithstanding workforce issues, LMC midwives must be under no pressure to continue providing midwifery care for women with GDM if they do not feel confident about this aspect of the care.

### **Specialist Oversight**

There is a group of women who require an initial specialist review but whose day to day care is more appropriately managed by the LMC and local community based services (general practice teams). Ideally, the community health professionals involved are already known to the woman and/or and geographically convenient for the woman.

Most of these women are able to manage their blood glucose with dietary change and a minimum of other intervention other than review of blood glucose meter readings and ultrasonography (including paired growth scans which may be at an interval of up to four weeks but with a minimum of two scans occurring before the end of their pregnancy). Ongoing support in relation to dietary advice may also be needed. This group of women would have an initial consultation and then one more at 36 weeks gestation but the remainder of their care is managed within community settings by an LMC with additional input from, for example, a diabetes nurse specialist and/or dietitian. Such an approach has operated in the United States<sup>7</sup>.

The Diabetes in Pregnancy Team may oversee these women remotely with the following criteria for re-referral back to a specialist clinic:

- Women with worsening glycaemia who may require insulin or drug treatment to maintain glycaemic control
- Women with evidence of fetal macrosomia, asymmetrical growth, polyhydramnios and other diabetes/obstetric complications

The consultation at 36 weeks needs to include care planning for birth. In some cases there may also be a need at this stage to commence monitoring the baby. For some women this could include maternal fetal movement monitoring only, others may require regular cardiotocographs/ ultrasound assessment depending on the clinical scenario.

Those women under specialist oversight require a further scan closer to term to confirm there is no macrosomia or growth restriction and/or oligohydramnios and thereby inform the birthing plan and review fetal wellbeing.

For those women with GDM but who have no obstetric or diabetes concerns, induction may be able to be avoided and would be considered only when post due date (i.e. after 40 weeks).

### **Intra partum**

In view of the ongoing higher risk of all pregnancies complicated by GDM, there is evidence that intra-partum care at a secondary service facility is part of efficacious management. This is true even in women who are not receiving insulin therapy as outlined above. All women who have a diagnosis of GDM need to receive information that outlines for them the need to consider birthing at a facility where there is an obstetrician and neonatal paediatric service available.

All decisions about intrapartum care will necessitate a three way discussion between the woman, her LMC and the specialist service in order that the woman is fully informed.

### **Post- partum**

The following are components of post-partum care:

- The LMC providing postnatal care provides written referral to the woman's general practitioner prior to six weeks postpartum informing them of the diagnosis of GDM. It is recommended that the woman's general practitioner then discusses with the woman the need to arrange a post-partum oral glucose tolerance test and assessment of risk factors for cardiovascular disease (e.g. lipids, blood pressure) at approximately six-eight weeks post partum. Testing earlier than 6 weeks can miss undiagnosed permanent diabetes The LMC providing postnatal care needs to ensure the woman has been referred for a post-partum oral glucose tolerance test and assessment of risk factors for cardiovascular disease (eg lipids, blood pressure) at approximately six-eight weeks post partum. The general practitioner must be informed by the LMC whether he/she is completely responsible for organizing this follow up or whether the diabetes team will arrange the initial laboratory tests, with a copy or the results sent to the GP. It is important that the responsibility for arranging these tests is clearly communicated, as well as responsibility for conveying the results to the woman. Continued follow-up should be transferred to the primary provider to arrange. Testing

earlier than 6 weeks can miss undiagnosed permanent diabetes and should only be carried out where there is evidence that diabetes is present.

- The diabetes in pregnancy team or LMC need to also inform the woman and those in primary care about the importance of diagnosing GDM as early as possible in future pregnancies, the need for ongoing monitoring for the development of diabetes and health education for the prevention/delay of diabetes and cardiovascular disease for the woman, her baby and her family. Women should be offered routine recall for screening for the development of diabetes long term at least every 2 years and possibly annually.
- The diabetes in pregnancy team, primary care or LMC should ensure that the woman understands the long term implications of having experienced GDM and has had suitable dietary and lifestyle advice to ameliorate the risks of recurrence of GDM and long term occurrence of Type 2 diabetes and cardiovascular disease. The woman should also understand the need for routine recall for screening for diabetes into the future
- The involvement of the general practitioner is a critical part of providing long term health care for these women

#### **4.5 Care policy for babies born to women with GDM**

The aim is to monitor for and prevent complications in the neonate, particularly jaundice, respiratory distress syndrome, and hypoglycaemia. Such complications can occur even if the woman did not require insulin therapy and is not macrosomic.

Breastfeeding must be encouraged. If the mother and baby are separated due to the need for neonatal intensive care, expressing breast milk is recommended. Women remaining hyperglycaemic on diet therapy may require treatment. This is often with insulin. Recent studies suggest that the amount of Metformin that crosses into breast milk is considered to be below the level that is associated with risk to the baby<sup>8,9</sup>. Some sulphonylureas may be safe<sup>10</sup>, although the World Health Organisation still recommends monitoring for neonatal hypoglycaemia if used<sup>11</sup>. The decision to use oral agents currently requires discussion between the woman and a specialist. Where hyperglycaemia is not controlled using oral agents, insulin therapy is required.

The baby should breastfeed as early as possible following birth. Ideally the feed should be completed before the baby leaves the birthing area. Regular breastfeeding, at least every 2-3 hours, should be encouraged in the first 24-48 hours of life. The same guidelines apply for those babies who are artificially fed.

The baby must be kept warm and have immediate access to neonatal and intensive care unit facilities, but need not be admitted to the Neonatal Baby Care Unit, unless complications have occurred or if there are clinical concerns arising.

An initial blood glucose sample should be taken at one-hour from birth, or sooner if there are signs of hypoglycaemia. Blood glucose samples should subsequently then be taken prior to each feed, until there are three consecutive results  $\geq 2.6$  mmol/l in the first 24 hours. Blood glucose should be measured using laboratory level analytical machines, with prompt access to results. It is important to note that current by-the-bedside glucose meters do not have the required precision for detecting hypoglycaemia.



In view of the monitoring and potential treatment needs, it is recommended that women are informed of these and advised that all babies should be cared for in a secondary facility until 3 heel prick glucose results are  $\geq 2.6$  mmol/l and there is no evidence that complications have or are likely to occur.

#### **4.6 Quality and Audit**

The standard for quality assurance in New Zealand has already been set “*Today quality assurance and audit and evaluation are so much a part of health delivery that it could be said that it is no more one of the components of the original treatment, which happens to be carried out later on. On this view, treatment which does not include a subsequent audit could be seen as incomplete treatment*”<sup>12</sup>. Local audit of identifiable data is expected as part of this standard.

Diabetes in pregnancy, as a condition associated with significant levels of morbidity and mortality remains an area where audit is of the highest importance to maintain and enhance standards and the quality of care. In recognition of this, the Australasian Diabetes in Pregnancy Society (ADIPS), a multidisciplinary society including all of those involved in diabetes in pregnancy care has published guidelines for Australia and New Zealand in relation to the management of GDM<sup>13</sup>, Type 1 and Type 2 diabetes in pregnancy<sup>14</sup> and the use of Metformin in pregnancy<sup>15</sup>. ADIPS has also now piloted an audit and benchmarking programme in sites across Australia and New Zealand<sup>16</sup>. This included the piloting of paper, stand alone electronic and networked methods for collecting clinical information and addressing the privacy, security and organisational issues. ADIPS has now received initial funding for the pilot to be extended across all diabetes in pregnancy clinics, presenting an opportunity for those in New Zealand to access the audit and benchmarking tools and functions.

It is anticipated that all women with a diagnosis of GDM may have their first visit data entered onto a central local database after diagnosis, and processes of care, treatment and outcome data entered following birth. Local oversight of such data is crucial to allow the refining of processes of care including identification of any systematic barriers to optimal outcomes (this includes those related to socioeconomic status, as well as those around health services). Women must be informed who will hold and have access to this data, whether it will be identifiable or not and why this data is being collected. Use of identifiable data outside of local audit also requires consent of the woman.

#### **4.7 Model of Care Policy**

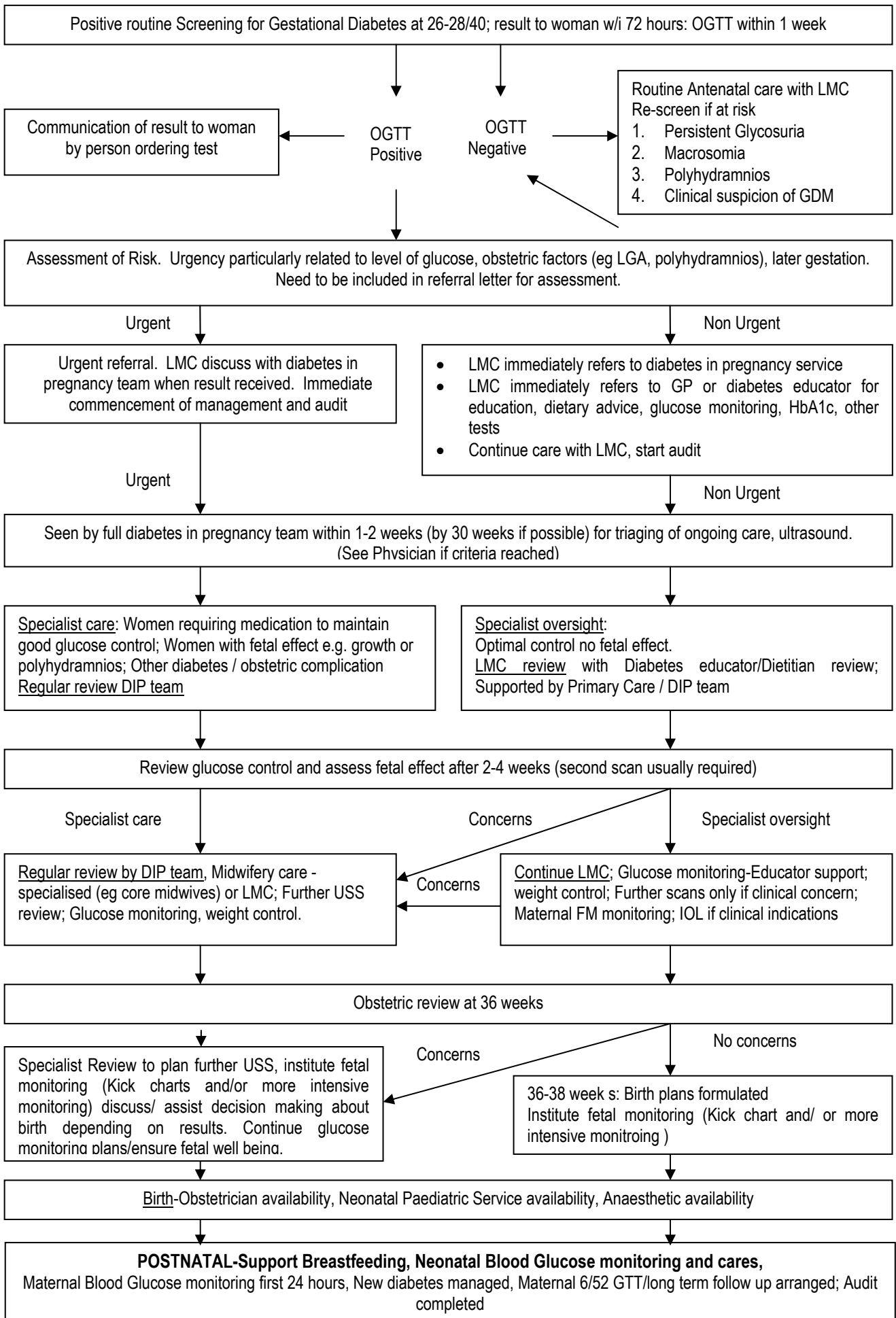
It is recommended by the Technical Working Party that all DHBs develop a model of care that best suits their region for GDM. They almost all have diabetes as a health priority and GDM is one of the areas they need to consider in relation to what is currently done, availability of personnel and the expected workload, educational activities required, quality improvement policies and how the DHB intends to audit the service.

#### **4.8 Recommendations for provision of care for women with GDM**

1. All District Health Boards require a defined Diabetes in Pregnancy Team.
2. The process for screening for GDM should include:
  - The development and establishment of a programme to increase awareness of GDM in the population

- Information about screening for GDM that is given to women before 24 weeks gestation so they have some background prior to the discussion about screening
  - Access to a diabetes in pregnancy team for all LMCs, with an agreed process for referral
  - The development of a specific information sheet, written with extensive consumer consultation, containing balanced information, in the appropriate languages and at the appropriate educational level. This should be given to, and discussed with, each woman. Information relating to healthy eating and physical activity must be included. Ideally this should be available for women during early pregnancy, as it may guide their diet and activity and reduce later risk of GDM. It can be formally discussed at the time of the offer for a glucose challenge test. The sheet could include a graph of the optimal gestation to screen.
  - Screening being offered at the 24 weeks visit (unless earlier-see below), and if agreed, to be completed between 26 and 28 weeks but before the 28 week visit. Offers of screening should incorporate use of the information sheet and it should be documented that informed consent to screen was given by the woman.
  - If the screening result is positive, the woman should be contacted by the person ordering the test to explain the result and refer for an oral glucose tolerance test (OGTT). This diagnostic test should be undertaken within one week. The OGTT should include the fasting and 2 hour glucose as a minimum. The 1 hour result within the OGTT is found to be helpful by many clinicians<sup>17</sup>
  - If the test results indicate GDM, the results will be explained by the person ordering the test, initial action should be initiated (see Model of Care section) and the woman should be referred to the diabetes in pregnancy team
  - An ongoing continuing professional education programme to support primary care services and facilitate primary care and specialist service integration. Lab staff could be included in this in relation to screening
3. A national ongoing monitoring system that monitors, at the DHB level, the proportion of women being screened, gestation at screening, gestation at OGTT, gestation at referral and gestation at first visit, linking with outcome data, should be in place.
  4. All District Health Boards should facilitate the local development and definition of a model of care that best suits their region that address the issues/ principles raised in this report particularly:
    - All diabetes in pregnancy, including GDM, is high risk and needs careful monitoring (ultrasound, glucose, clinical)
    - All LMCs should have access to a Diabetes in Pregnancy Team and ultrasound scanning facilities
    - A close relationship, particularly good communication, is needed between the woman's primary healthcare team, the diabetes educator and LMC
    - LMCs, primary healthcare and the Diabetes in Pregnancy Team in each District should develop agreed standards of care and referral pathways based upon Australasian Guidelines
    - The ability of midwives to provide dietary advice, glucose monitoring teaching and management and advice on diabetes in pregnancy is not a core competency for midwifery. This does not preclude that women need midwifery care and that some midwives have an interest in this area and will have additional education to provide care for women with GDM in conjunction with the diabetes in pregnancy service in that region.

- The management of diabetes in pregnancy should be integrated with the woman's primary healthcare team. This is essential to provide follow up for e.g. annual/biannual OGTTs for women with past GDM and they may be involved in initiation and community based aspects of management of GDM.
  - Those caring for women with diabetes in pregnancy need to be alert as the woman's clinical condition can change rapidly
  - Those in primary care will need updating and ongoing education about GDM management including pregnancy specific dietary, glucose monitoring and overall information advice.
5. Each district should consider participating in the ADIPS audit and benchmarking programme. All pregnancies complicated by GDM would be part of the audit programme as a result.



#### **4.9 How should the national development of services and resources for women with gestational diabetes be overseen?**

While services in Districts Health Board geographical areas and District Health Boards will need to define and ensure that district-wide diabetes in pregnancy services are in place, there is a requirement for a national view of quality and resources, and to support continuous improvements in quality before, during and after pregnancies.

Australia has had a National Diabetes in Pregnancy Advisory Committee for many years and this has helped to address a range of systematic obstacles to quality diabetes in pregnancy care.

#### **4.10 The way forward: Recommendations include:**

1. Local groups on a DHB basis to discuss the results of audits (although these may be difficult to establish in some areas)
2. A national working group may need to be created, comparable with the National Diabetes in Pregnancy Advisory Committee in Australia

## 5.0 Which women should be screened early and how?

### 5.1 Background:

It is appropriate to routinely offer screening for gestational diabetes (GDM) at 24-28 weeks gestation, but for women who may have undiagnosed Type 2 diabetes, it is preferable for them to be recognised as early as possible. Women with Type 2 diabetes, like women with type 1 diabetes, have additional risks of an adverse pregnancy outcome<sup>1,2</sup> and early recognition and treatment may modify these risks. Elevated glucose levels during organogenesis lead to an increased risk of congenital malformations, and although most women will book at a gestation that is too late to change this, making the diagnosis will alert the maternity provider to carefully discuss the issue with a woman and offer the opportunity to screen the baby for anomalies. Other pregnancy risks may be reduced with improved diabetes control early in pregnancy<sup>3</sup>.

This section discusses the issues associated with the detection of undiagnosed Type 2 diabetes in woman at booking.

Two key discussion points are

1. Who should we offer screening to, recognising the prevalence of unrecognised Type 2 diabetes is low?
2. What screening test should be performed once we have identified those women who potentially have undiagnosed Type 2 diabetes?

### 5.2 Who should be offered early screening?

As there is no ideal simple, sensitive and specific screening test (as discussed below), it is essential that well women are not exposed to additional investigations that have a significant false positive rate, as this may lead to increased anxiety. It is, however reasonable to offer a screening test at booking to women who are more likely to have unrecognised Type 2 diabetes. This would be based on risk factors that can be identified when a woman presents for her first antenatal visit. A key aspect of this part of the report is to reinforce the importance of early recognition of undiagnosed diabetes (at booking) so that treatment can be initiated to reduce the impact of this on pregnancy outcomes. The following characteristics have been identified as those to be alert to<sup>4</sup>:

- Having a diagnosis of impaired fasting glucose or impaired glucose tolerance prior to pregnancy
- Women with previous GDM
- Risk factors for Type 2 diabetes:
  - Polycystic ovarian syndrome (PCOS)
  - Glycosuria
  - Morbid obesity: (Ethnic specific<sup>5</sup>: European = BMI  $\geq 35$  kg/m<sup>2</sup>, Polynesian = BMI  $\geq 37$  kg/m<sup>2</sup>, Indian and Asian = BMI  $\geq 32$  kg/m<sup>2</sup>)
  - Two first degree relatives with diabetes
  - Previous unexplained stillbirth
  - Previous shoulder dystocia
  - Previous macrosomic baby:
    - $\geq 97^{\text{th}}$  percentile based on customised birth weight chart<sup>6</sup>

If no access to customised birth weight,  $\geq 4700\text{g}$  Polynesian,  $\geq 4,400\text{ g}$  European,  $\geq 4000\text{ g}$  Asians including South Asians (recognising this is less accurate than customised assessment)

### 5.3 What screening test?

In early pregnancy, a simple test that can be done with the booking bloods would be preferred as long as the test does not have too many false positives that lead to unnecessary additional tests, or too many false negatives, which means that women with Type 2 diabetes are missed. There are, however, no good pregnancy data to address this issue. While there are some data from non-pregnant subjects that are applicable in general terms, the World Health Organisation (WHO) and International Diabetes Federation (IDF) do not recommend any particular method<sup>9</sup>.

- Fasting Glucose (recommended outside of pregnancy in the UK and USA with a cut off either  $\geq 6.1\text{ mmol/L}$  or  $\geq 5.6\text{ mmol/L}$ <sup>7,8,10</sup>) is not a simple add-on test as it requires fasting and can be difficult if women have morning sickness and have been advised to eat frequently to avoid nausea. Test characteristics outside of pregnancy are available and suggest that quite a low fasting glucose would need to be used to pick up pregnant women with significant glucose intolerance. It would also lead to quite a high rate of subsequent OGTTs that would be normal.<sup>11, 12</sup>
- Random blood glucose: This has too many difficulties in defining an appropriate cut-off<sup>13</sup>
- Glycosuria: This is too insensitive<sup>13</sup>
- Glycosylated haemoglobin (HbA1c): Using an HbA1c and taking a cut-off of  $>5.6\%$  to request an OGTT had the highest cost effectiveness in detecting previously undiagnosed diabetes<sup>14</sup> and was associated with a sensitivity of 75.1% and specificity 56.6%. Combining an HbA1c of  $\geq 5.3\%$  in the subjects with one risk factor for diabetes in AusDiab<sup>12</sup>, gave a sensitivity of 78.7% and specificity of 82.8% for diabetes and 42.0% and 88.2% for IGT or IFG. The PPV was 15.5% and 43.2% respectively. The effect of using HbA1c gave similar results to using the FPG alone (but in the non-fasting state). A South Auckland study among European, Māori and Pacific people aged 40-79 years<sup>15</sup> showed that an HbA1c of  $\geq 5.3\%$  was the optimal screening cut-off with a sensitivity, specificity and PPV for undiagnosed diabetes those with at least 1 risk factor of 76.3%, 67.7% and 22.9% respectively.

The AusDiab and South Auckland studies<sup>12,15</sup> provide the best data about using a glycated haemoglobin strategy. Their strategy of requesting an OGTT in subjects with one risk factor and an HbA1c  $\geq 5.3\%$  led to a need for OGTT in 19.5% and 37.2% of patients respectively. In a population of women during childbearing years, using more restricted criteria, the need to proceed to an OGTT would be much less frequent (as fewer women will have risk factors or elevated HbA1c). It is noted that HbA1c in pregnancy is lower than outside pregnancy, so using this threshold in pregnancy will also lead to fewer diagnostic OGTTs<sup>16</sup>.

### 5.4 Outcome of review

An HbA1c screening strategy seems the most feasible to look at, but it cannot be recommended until more relevant data are collected. Most laboratories in New Zealand use 6.0% as upper limit of the reference range. While assessing the accuracy of using this as a screen in early pregnancy, it seems logical to use the upper limit as a cut off for further action. Currently midwives are unable to order this test. This will need to be addressed within the laboratory schedule and midwives informed that they can now do this.

## 5.5 Recommendations

1. Women with known IGT/IFG are considered to have at least a degree of hyperglycaemia that should be managed as GDM (and they may have progressed to Type 2 diabetes). They should have an HbA1c requested at booking and be directly referred to the diabetes in pregnancy team for management.
2. Women with previous GDM with “probable undiagnosed Type 2 diabetes” (eg had this “diagnosis” during pregnancy but never had a postpartum GTT or women with symptoms of diabetes or random finger-prick glucose >11.1 mmol/l), should be directly referred to the diabetes in pregnancy team for management and have an HbA1c requested at booking.
3. Other women with past GDM should have an HbA1c requested at booking (even if the previous non-pregnant OGTT was normal) and the reasons for this explained. If elevated ( $\geq 6.0\%$ ), the woman should be referred immediately to the diabetes in pregnancy team. If the HbA1c is  $<6.0\%$ , an OGTT should be undertaken at the earliest opportunity, typically 14-16 weeks. If OGTT normal, repeat OGTT at 24-28 weeks (or earlier if clinical suspicion occurs)
4. Other high risk women:
  - **Pilot area strategy** - a strategy for screening other high risk women (listed above) for underlying Type 2 diabetes using an HbA1c measurement at booking should be initiated as a pilot. Within this group women should be informed that we are still assessing the accuracy of using an HbA1c  $\geq 5.3\%$  as a threshold for further action. If HbA1c  $\geq 6.0\%$ , the woman should be referred directly to the diabetes in pregnancy team. If the HbA1c is 5.3- 5.9%, a 75g OGTT should be arranged for as soon as possible. If the HbA1c is  $<5.3\%$ , or the subsequent OGTT is normal, the OGTT should be repeated at 26-28 weeks The pilot would need to collect details on frequency of referral for OGTT, its sensitivity and specificity for detecting early abnormal glucose tolerance and its acceptability to women.
  - **Areas outside of the pilot area** to continue current practice of offering an OGTT to women considered at risk of undiagnosed Type 2 diabetes using the listed factors.



## 6.0 What 2 hour cut-off should New Zealand use for diagnosis of GDM?

GDM is not diagnosed on the non-fasting 50g screening test. The screening test identifies women who should be asked to undertake a fasting 2-hour OGTT to see if they have GDM.

In New Zealand, the current criteria for diagnosis of GDM are:

- 75g OGTT
- Fasting glucose  $\geq 5.5$  mmol/l and/or 2-hour  $\geq 9.0$  mmol/l

In New Zealand the cut off levels for diagnosis are different from most other countries. During 2005, the ACHOIS study (Appendix 4 – Section 11.0) was published. In this study a 75g OGTT was used and women with a 2-hour result between 7.8 – 11.0mmol/l were randomised to intervention for GDM or routine pregnancy care<sup>1</sup>. Women treated for GDM had significantly fewer serious adverse perinatal outcomes, less pre-eclampsia and fewer macrosomic babies. This study supported other evidence showing that treatment of GDM is important<sup>2</sup>. For New Zealand, it also reignited the issue of whether we should reset our diagnostic criteria to a different 2 hour cut-off, such as 7.8 mmol/l, as used in the ACHOIS study.

The answer to this issue is not clear. It has been recognised by the international community for many years that we do not “know” what glucose levels define GDM. There are few data looking at how glucose levels relate to specific pregnancy (and long term) risks.

The HAPO study (27) conducted in 17 countries has recently been completed to address this issue but results are not available at the time of writing this report. This study has recruited 25,000 women who have had 75g OGTTs at 24 – 32 weeks of pregnancy and not been treated for GDM unless the fasting glucose is  $>5.8$  mmol/l or 2 hr level  $>11.1$  mmol/l. A random plasma glucose is performed at 34 – 37 weeks or if symptoms suggest hyperglycaemia and results are unblinded and the woman treated if the glucose value is  $\geq 8.9$ mmol/L. The primary outcomes are caesarean delivery, increased fetal size, increased fetal adiposity, neonatal morbidity (e.g. hypoglycaemia) and fetal hyperinsulinaemia. The rates of complications can be looked at in relation to different OGTT cut offs. When these results are available during 2007, it is likely there will be recommended cut offs for the diagnosis of GDM and each country will need to decide whether to adopt this. How the findings and associated recommendations apply to New Zealand will need further discussion.

**This section provides a preliminary discussion about different criteria for diagnosing GDM. The Technical Working Party agreed that whilst it recognises the debate about which cut off to use is occurring, there is currently insufficient evidence to change the 2-hr cut off level. The Technical Working Party recommends reviewing the evidence and how it may apply to the New Zealand population. It makes recommendations about what action should be taken, if any within NZ, taking cognisance of the NZ population, once the outcomes of the HAPO study are published.**

**There was considerable debate regarding the 2 hour cut-off recommendation by the Technical Working Party. As such the evidence that has informed this discussion and final decision is contained as Appendix 6(Section 13.0)**

## 6.1 Recommendations based on current evidence

1. Whilst there is evidence that treatment of women identified by a lower 2 hour glucose level during the 75g OGTT is associated with a reduction of maternal and neonatal morbidity, there are no clear data demonstrating an optimal level. The Technical Working Party recommend that the status quo should be retained and data reviewed again when the results of HAPO are known
2. Further New Zealand information should be collated over 2006/2007:
  - a. To see if potentially different recommendations from HAPO are relevant to our population
  - b. To see what the impact of any change would be on the number of women diagnosed with GDM and resource implications.
  - c. To ensure that there are robust models of care that could be expanded to deal with the increase in numbers if any change to criteria was decided.
3. Currently, where NZ criteria for a diagnosis of GDM are not reached, but the 2 hour glucose is 8.0-8.9 mmol/l (the ADIPS-Australia criterion), and the clinician and woman have concerns, it would be reasonable to manage the pregnancy as for GDM.

## 7.0 References

### 7.1 Section 3.0

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## 9.0 APPENDIX 1 Working Party Members

<u>Representative</u>	<u>Organisation</u>
David Simmons	Co-Chair- Australasian Diabetes in Pregnancy Society
Norma Campbell	Co-Chair- New Zealand College of Midwives
Janet Rowan	Australasian Diabetes in Pregnancy Society
Margret Norris	DHB Maternity Managers Network
Pat Bent	Diabetes New Zealand
Barbara Beckford	Federation of Womens Health Councils
Lynda Williams	Maternity Services Consumer Council
Sandy Dawson	Ministry of Health
Peter Moore	New Zealand Society for the Study of Diabetes/Physician
Cate Wilson	New Zealand Society for the Study of Diabetes/Diabetes Nurse Specialist
Carol Perwick	New Zealand Society for the Study of Diabetes/New Zealand Dietetic Association
Estelle Mulligan	Ngā Maia o Aotearoa me Te Waipounamu
Nimisha Waller	NZ College of Midwives
Isabelle White	Pacifica Inc.
Jenny Valgre	Parents Centre New Zealand Ltd.
Rose Elder	Perinatal Society
Rosemary Reid	Royal Australian College of Obstetricians and Gynaecologists
Don Simmers	Royal New Zealand College of General Practitioners
Kristen Berger	Women's Health Action

**Members of the Working Party worked collaboratively to produce the Technical Report. It must be noted that consensus on issues was not reached on all aspects of this report.**

## 10.0 APPENDIX 2 The Australian Carbohydrate Intolerance Study In Pregnant Women

The findings of the Australian Carbohydrate Intolerance Study in Pregnant Women (ACHOIS)<sup>1</sup> demonstrated the benefits of treating women with GDM according to the 1998 Australasian Diabetes in Pregnancy Society (ADIPS) consensus guidelines on the management of gestational diabetes mellitus (GDM)<sup>2</sup>. Earlier studies had shown benefits of more intensive forms of treating GDM (e.g. targeting post- vs. pre-prandial glycaemia, 4 times vs. twice a day insulin), but none had an untreated control group<sup>3,4</sup>.

ACHOIS randomised 1000 women with GDM to either routine antenatal care or to an intervention including home glucose monitoring, review by a diabetes educator, dietitian and physician and insulin therapy if glycaemic targets were not met. Serious adverse perinatal outcomes affected 4% of the routine care group and 1% of the intervention group (Adjusted relative risk 0.33 (95% CI 0.14 – 0.75). Large for gestational age (LGA) babies were reduced from 22% to 13% without an increase in small for gestational age (SGA) infants. Induction of labour was more common in the intervention group (39% vs. 29%), but the rates of Caesarean delivery were similar at around 31%. Assessment of neonatal hypoglycaemia and respiratory distress syndrome was not systematic and prone to under-identification, particularly in the control group. Measures of maternal quality of life were also more favourable in the intervention group. Only 34 women required treatment to prevent one serious perinatal outcome.

ACHOIS was not a trial of screening for GDM, it did however, provide high level evidence that GDM once diagnosed could be effectively managed and provided estimates of the magnitude of benefits from such management. ACHOIS also did not provide a glucose level at which the benefits of screening for GDM were maximised. The current New Zealand guidelines<sup>2</sup> suggest fasting and 2 hour cutoffs of  $\geq 5.5$  mmol/l and/or  $\geq 9.0$  mmol/L respectively for the diagnosis of GDM. ACHOIS used a much lower criterion for the 2 hour venous plasma glucose on OGTT of  $\geq 7.8$  and  $< 11.0$  mmol/L as its inclusion criterion and women had a median fasting glucose of 4.8 mmol/l and 2 hour glucose of 8.6 mmol/l. A blinded prospective epidemiological study HAPO (Hyperglycaemia and Adverse Pregnancy Outcomes) is expected to report by mid 2007<sup>5</sup> and is likely to provide evidence to assist with identifying the optimal cut-off levels fasting, at 1 hour and 2 hours after a 75g glucose load.

### 10.1 References

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2. Hoffman L, Nolan C, Wilson JD, Oats JJN, Simmons D. Gestational diabetes mellitus-management guidelines. The Australasian Diabetes in Pregnancy Society. *Med J Aust.* 1998;169: 93-7.
3. De Veciana M, Major CA, Morgan MA, Asrat T, Toohey J, Lien J, et al. Postprandial versus preprandial blood glucose monitoring in women with gestational diabetes mellitus requiring insulin therapy versus preprandial blood glucose monitoring in women with gestational diabetes mellitus requiring insulin therapy. *New Engl J Med.* 1995;333:1237-1241.
4. Nachum Z, Ben-shlomo I, Weiner E, Shalev E. Twice daily versus four times daily insulin dose regimens for diabetes in pregnancy: randomised controlled trial. *BMJ* 1999;319:1223-7
5. HAPO Study Cooperative Research Group. The Hyperglycemia and Adverse Pregnancy Outcome (HAPO) Study. *Int J Gynaecol Obstet.* 2002;78:69-77.

## 11.0 APPENDIX 3

### Definitions

#### Macrosomia

This has multiple definitions in the literature. In this document, macrosomia is defined as

- $\geq 97^{\text{th}}$  percentile based on customised birth weight chart (McCowan, L Stewart, A. Term birthweight centiles for babies from New Zealand's main ethnic groups. AustNZ J Obstet Gynecol 2004;44:432-435)
- If no access to customised birth weight,  $\geq 4700\text{g}$  Polynesian,  $\geq 4,400\text{ g}$  European,  $\geq 4000\text{ g}$  Asians including South Asians (recognising this is less accurate than customised assessment)

#### Offspring

This term has been used for the babies and children of women with GDM who may develop diabetes and obesity up to and through adult life.

## 12.0 APPENDIX 4 The HDC Code of Health and Disability Services Consumers' Rights Regulation 1996

Available at: <http://www.hdc.org.nz/theact/theact-thecodedetail>

### 1. Consumers have Rights and Providers have Duties:

- 1) Every consumer has the rights in this Code.
- 2) Every provider is subject to the duties in this Code.
- 3) Every provider must take action to -
  - a) Inform consumers of their rights; and
  - b) Enable consumers to exercise their rights.

### 2. Rights of Consumers and Duties of Providers:

The rights of consumers and the duties of providers under this Code are as follows:

#### *RIGHT 1 Right to be Treated with Respect*

- 1) Every consumer has the right to be treated with respect.
- 2) Every consumer has the right to have his or her privacy respected.
- 3) Every consumer has the right to be provided with services that take into account the needs, values, and beliefs of different cultural, religious, social, and ethnic groups, including the needs, values, and beliefs of Maori.

#### *RIGHT 2 Right to Freedom from Discrimination, Coercion, Harassment, and Exploitation*

Every consumer has the right to be free from discrimination, coercion, harassment, and sexual, financial or other exploitation.

#### *RIGHT 3 Right to Dignity and Independence*

Every consumer has the right to have services provided in a manner that respects the dignity and independence of the individual.

#### *RIGHT 4 Right to Services of an Appropriate Standard*

- 1) Every consumer has the right to have services provided with reasonable care and skill.
- 2) Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards.
- 3) Every consumer has the right to have services provided in a manner consistent with his or her needs.
- 4) Every consumer has the right to have services provided in a manner that minimises the potential harm to, and optimises the quality of life of, that consumer.
- 5) Every consumer has the right to co-operation among providers to ensure quality and continuity of services.

#### *RIGHT 5 Right to Effective Communication*

- 1) Every consumer has the right to effective communication in a form, language, and manner that enables the consumer to understand the information

provided. Where necessary and reasonably practicable, this includes the right to a competent interpreter.

- 2) Every consumer has the right to an environment that enables both consumer and provider to communicate openly, honestly, and effectively.

#### *RIGHT 6*

##### *Right to be Fully Informed*

- 1) Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including -
  - a) An explanation of his or her condition; and
  - b) An explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option; and
  - c) Advice of the estimated time within which the services will be provided; and
  - d) Notification of any proposed participation in teaching or research, including whether the research requires and has received ethical approval; and
  - e) Any other information required by legal, professional, ethical, and other relevant standards; and
  - f) The results of tests; and
  - g) The results of procedures.
- 2) Before making a choice or giving consent, every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, needs to make an informed choice or give informed consent.
- 3) Every consumer has the right to honest and accurate answers to questions relating to services, including questions about -
  - a) The identity and qualifications of the provider; and
  - b) The recommendation of the provider; and
  - c) How to obtain an opinion from another provider; and
  - d) The results of research.
- 4) Every consumer has the right to receive, on request, a written summary of information provided.

#### *RIGHT 7*

##### *Right to Make an Informed Choice and Give Informed Consent*

- 1) Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent, except where any enactment, or the common law, or any other provision of this Code provides otherwise.
- 2) Every consumer must be presumed competent to make an informed choice and give informed consent, unless there are reasonable grounds for believing that the consumer is not competent.
- 3) Where a consumer has diminished competence, that consumer retains the right to make informed choices and give informed consent, to the extent appropriate to his or her level of competence.

- 4) Where a consumer is not competent to make an informed choice and give informed consent, and no person entitled to consent on behalf of the consumer is available, the provider may provide services where -
  - a) It is in the best interests of the consumer; and
  - b) Reasonable steps have been taken to ascertain the views of the consumer; and
  - c) Either, -
    - i. If the consumer's views have been ascertained, and having regard to those views, the provider believes, on reasonable grounds, that the provision of the services is consistent with the informed choice the consumer would make if he or she were competent; or
    - ii. If the consumer's views have not been ascertained, the provider takes into account the views of other suitable persons who are interested in the welfare of the consumer and available to advise the provider.
- 5) Every consumer may use an advance directive in accordance with the common law.
- 6) Where informed consent to a health care procedure is required, it must be in writing if -
  - a) The consumer is to participate in any research; or
  - b) The procedure is experimental; or
  - c) The consumer will be under general anaesthetic; or
  - d) There is a significant risk of adverse effects on the consumer.
- 7) Every consumer has the right to refuse services and to withdraw consent to services.
- 8) Every consumer has the right to express a preference as to who will provide services and have that preference met where practicable.
- 9) Every consumer has the right to make a decision about the return or disposal of any body parts or bodily substances removed or obtained in the course of a health care procedure.
- 10) No body part or bodily substance removed or obtained in the course of a health care procedure may be stored, preserved, or used otherwise than
  - a) with the informed consent of the consumer; or
  - b) For the purposes of research that has received the approval of an ethics committee; or
  - c) For the purposes of 1 or more of the following activities, being activities that are each undertaken to assure or improve the quality of services:
    - i. a professionally recognised quality assurance programme;
    - ii. an external audit of services;
    - iii. an external evaluation of services.

*RIGHT 8 Right to Support*

Every consumer has the right to have one or more support persons of his or her choice present, except where safety may be compromised or another consumer's rights may be unreasonably infringed.

*RIGHT 9 Rights in Respect of Teaching or Research*

The rights in this Code extend to those occasions when a consumer is participating in, or it is proposed that a consumer participate in, teaching or research.

*RIGHT 10 Right to Complain*

- 1) Every consumer has the right to complain about a provider in any form appropriate to the consumer.
- 2) Every consumer may make a complaint to -
  - a) The individual or individuals who provided the services complained of; and
  - b) Any person authorised to receive complaints about that provider; and
  - c) Any other appropriate person, including -
    - i. An independent advocate provided under the Health and Disability Commissioner Act 1994; and
    - ii. The Health and Disability Commissioner.
- 3) Every provider must facilitate the fair, simple, speedy, and efficient resolution of complaints.
- 4) Every provider must inform a consumer about progress on the consumer's complaint at intervals of not more than 1 month.
- 5) Every provider must comply with all the other relevant rights in this Code when dealing with complaints.
- 6) Every provider, unless an employee of a provider, must have a complaints procedure that ensures that -
  - a) The complaint is acknowledged in writing within 5 working days of receipt, unless it has been resolved to the satisfaction of the consumer within that period; and
  - b) The consumer is informed of any relevant internal and external complaints procedures, including the availability of -
    - i. Independent advocates provided under the Health and Disability Commissioner Act 1994; and
    - ii. The Health and Disability Commissioner; and
  - c) The consumer's complaint and the actions of the provider regarding that complaint are documented; and
  - d) The consumer receives all information held by the provider that is or may be relevant to the complaint.
- 7) Within 10 working days of giving written acknowledgement of a complaint, the provider must, -
  - a) Decide whether the provider -
    - i. Accepts that the complaint is justified; or

- ii. Does not accept that the complaint is justified; or
  - b) If it decides that more time is needed to investigate the complaint, -
    - i. Determine how much additional time is needed; and
    - ii. If that additional time is more than 20 working days, inform the consumer of that determination and of the reasons for it.
- 8) As soon as practicable after a provider decides whether or not it accepts that a complaint is justified, the provider must inform the consumer of -
  - a) The reasons for the decision; and
  - b) Any actions the provider proposes to take; and
  - c) Any appeal procedure the provider has in place.

### 3. Provider Compliance

- A provider is not in breach of this Code if the provider has taken reasonable actions in the circumstances to give effect to the rights, and comply with the duties, in this Code.
- The onus is on the provider to prove it took reasonable actions.
- For the purposes of this clause, "the circumstances" means all the relevant circumstances, including the consumer's clinical circumstances and the provider's resource constraints.

### 4. Definitions

In this Code,

- **"Advance directive"** means a written or oral directive-
  - (a) By which a consumer makes a choice about a possible future health care procedure; and
  - (b) That is intended to be effective only when he or she is not competent:
- **"Choice"** means a decision-
  - (a) To receive services:
  - (b) To refuse services:
  - (c) To withdraw consent to services:
- **"Consumer"** means a health consumer or a disability services consumer; and, for the purposes of rights 5, 6, 7(1), 7(7) to 7(10), and 10, includes a person entitled to give consent on behalf of that consumer:
- **"Discrimination"** means discrimination that is unlawful by virtue of Part II of the Human Rights Act 1993:
- **"Duties"** includes duties and obligations corresponding to the rights in this Code
- **"Ethics Committee"** means an ethics committee -
  - (a) established by, or appointed under, an enactment; or
  - (b) approved by the Director-General of Health.



- **"Exploitation"** includes any abuse of a position of trust, breach of a fiduciary duty, or exercise of undue influence:
- **"Optimise the quality of life"** means to take a holistic view of the needs of the consumer in order to achieve the best possible outcome in the circumstances:
- **"Privacy"** means all matters of privacy in respect of the consumer, other than matters of privacy that may be the subject of a complaint under Part VII or Part VIII of the Privacy Act 1993 or matters to which Part X of that Act relates:
- **"Provider"** means a health care provider or disability services provider:
- **"Research"** means health research or disability research:
- **"Rights"** includes rights corresponding to the duties in this Code:
- **"Services"** means health services, or disability services, or both; and includes health care procedures:
- **"Teaching"** includes training of providers.

**5. Other Enactment's**

Nothing in this Code shall require a provider to act in breach of any duty or obligation imposed by any enactment or prevents a provider doing an act authorised by any enactment.

**6. Other Rights**

An existing right is not overridden or restricted simply because the right is not included in this Code or is included only in part.

## 13.0 APPENDIX 5 What 2 hour cut-off should be used in the 2 hour glucose tolerance test

### 13.1 **Background**

Before discussing what glucose threshold should define GDM, it is important to know what normal glucose levels are during pregnancy. Studies in women without GDM, using continuous interstitial glucose monitoring (adjusted to equate with venous plasma) reported a mean (SD) fasting glucose of 4.2 mmol/l and after eating a 1-hr glucose of 6.1 (0.89) and 2-hr glucose of 5.4 (0.55) mmol/l<sup>20</sup>. Post meal levels were higher in obese women (1-hr glucose 6.2 (0.73) mmol/l and 2-hr 6.0 (0.78) mmol/l). It is recognised that obese women have increased adverse perinatal outcomes and it is possible that higher glucose levels are a contributing factor.

In a recent population study from Denmark, women without recognised risk factors for GDM were administered a 75g OGTT at 32 weeks'. The reference range for a normal OGTT result was a fasting plasma glucose of 4.01-5.26 (95<sup>th</sup> CI 3.96-5.34) mmol/l and 2-hr glucose of 2.8-7.58 (95<sup>th</sup> CI 2.56 – 7.82) mmol/l<sup>21</sup>.

### 13.2 **Why do we use a 2-hr diagnostic cut off of 9.0 mmol/l in New Zealand?**

The present NZ criteria for the diagnosis of GDM are based on data from a European study<sup>3</sup>. Eleven centres provided results of a 75g oral glucose tolerance test (OGTT) performed on 1009 women at different stages of pregnancy. However, the screening population was not clearly defined and women with significantly abnormal glucose tolerance were included (e.g. 95<sup>th</sup> percentile for fasting glucose in the 200 women who were tested in 2<sup>nd</sup> trimester was 6.9 mmol/l, quite different from population studies of normal glucose levels above). In this study, when they used a 2-hour cut-off of 8.0 mmol/l to diagnose GDM, the prevalence of GDM in the study population was 7.8% and when they used a 2-hour cut-off of 9.0 mmol/l the prevalence of GDM in the study was 3.2%. New Zealand adopted the higher 2-hr cut off criteria in 1991, with the rationale that we would be able to cope with the number of women diagnosed with GDM and offer treatment to those that may benefit most.

### 13.3 **What do other cutoffs tell us?**

The following will outline the development of diagnostic tests for GDM, summarise what the data tell us from other countries and how they relate to the current New Zealand diagnostic criteria. The evidence is difficult to compare directly, as there are many different criteria used. Some countries use a 100g glucose load instead of 75g; some include information from testing the glucose levels at one hour and three hours after the glucose load in addition to the fasting and 2 hour result; some countries just rely on a 1 hour result after a fasting woman is given a 75g glucose load.

### 13.4 **The history of diagnosing GDM and development of the test in the USA**

O'Sullivan, from the United States derived the original data for the diagnosis of GDM and published his findings in 1964<sup>4</sup>. He noted that women who developed Type 2 diabetes in later life had an obstetric history suggesting they had developed temporary glucose intolerance during pregnancy. He reported normal whole blood glucose levels in 752 unselected pregnant women who were administered a 3 hour 100g OGTT. He looked at the cut-off levels in the population that predicted later Type 2 diabetes in the mother. The mean+ 2SD or 97<sup>th</sup> percentile glucose level predicted an 8 year risk of Type 2 diabetes of

30%. He applied these criteria during pregnancy to diagnose GDM and subsequently reported prospectively that this group of women had increased perinatal losses<sup>5</sup>.

As plasma glucose is now measured, other researchers have converted O'Sullivan's whole blood measurements into plasma glucose measurements by various assays. In the United States, two different criteria were developed using a 100g load, one with a 2-hour cut-off of 9.2 mmol/l<sup>6</sup> and one with a 2-hour cut-off of 8.6 mmol/l<sup>7</sup>. Among others, hospitals in Toronto that used the higher 2-hour cut-off compared pregnancy outcomes in treated women, with those who would have been treated if the lower diagnostic cut-off was used. They reported increased pregnancy morbidity in the untreated group<sup>8</sup>. The American Diabetes Association (ADA) subsequently moved to endorse the lower cut-off for diagnosis of GDM<sup>9</sup>.

What does this mean for New Zealand? It tells us the American criteria have been lowered, after looking at their data, but the exact levels are hard to compare with NZ criteria. There are data comparing 75g with 100g OGTT results showing that, at 2-hours, the 75g load leads to a plasma glucose approximately 0.5 mmol/l lower than the 100g load<sup>10</sup>. This means a 2-hour result of 8.6 mmol/l by the American criteria would be similar to a 2-hour result of approximately 8.1 mmol/l by a 75g OGTT. We should not change our criteria based solely on this evidence however, as the comparison is more complex, in that the American 100g test is a 3 hour test, and 2 results have to be abnormal to diagnose GDM, although some centres use just one abnormal result, as risks have been shown to be increased with one elevated test<sup>11,12</sup>.

### 13.5 Other Criteria

The WHO endorses a 75g OGTT during pregnancy and 2-hour diagnostic cut-off of 7.8 mmol/l<sup>13</sup>. This level diagnoses impaired glucose tolerance outside pregnancy, and the logic is that we should use the same criteria in pregnancy unless there are good data to show differently. They do not focus on the fasting level, as most women develop intolerance to a glucose load before developing fasting hyperglycaemia. The International Diabetes Federation has also recently endorsed a 2 hour cut-off of 7.8 mmol/l using a 75g load<sup>14</sup>. The ACHOIS study used these criteria to show that treatment of GDM is associated with benefit.

Many countries use the WHO 2-hour criteria, some round the 2-hr level to 8.0 mmol/l, including Australia. Pregnancy outcomes using this cut-off have been compared to outcomes in women with a higher cut off level (9.0 mmol/l that is used in New Zealand)<sup>15-18</sup>. These studies show that pregnancy risks are increased with a 2-hour level above 7.8 or 8.0 mmol/l. No increase in adverse outcomes were reported using the lower cut-off level. Again, the data are not definitive enough to recommend a change in NZ criteria prior to the report from HAPO.

One problem with the diagnostic criteria throughout the world is that it was originally derived by looking at maternal risk of later diabetes rather than at fetal risk. The only data so far to address what maternal glucose level in a 75g OGTT is associated with fetal hyperinsulinaemia, (which is a key measure related to what we are trying to prevent in the fetus) is from Austria<sup>19</sup>. They identified fetal hyperinsulinaemia in pregnancies by performing amniocenteses. They then looked at what maternal 75g OGTT results identified the fetuses with hyperinsulinaemia. The best fasting cut-off was 5.0 mmol/l, but it only detected 60% of fetuses with hyperinsulinaemia. In other words, the mothers of the other 40% of fetuses with hyperinsulinaemia had a fasting glucose < 5.0 mmol/l. The best two hour cut-off was 7.8

mmol/l which also detected less than 60% of fetuses with hyperinsulinaemia. A one hour test of 8.9 mmol/l or above was the best predictor of fetal hyperinsulinaemia with 97% sensitivity and 99% specificity. We do not include a 1-hour test in the current criteria in New Zealand, but the point of raising these data here is that if a **one** hour result of 8.9 mmol/l identifies a fetus at risk, it suggests a 2-hour test of 9.0 mmol/l is missing a significant proportion of these.

The countries that adopt this criterion do not perform a preliminary screening test. Women are sent to the laboratory fasting, given a 75g OGTT and a plasma glucose is measured one hour later. The argument for this diagnostic test includes the simplicity and reduced cost of testing the women. Although this sounds attractive, more information is required to assess whether this would be an appropriate test for New Zealand. Using this approach may also identify large numbers of women who may not have a fetus with hyperinsulinaemia as well as the ones that do. There are errors with a single glucose estimation. HAPO will be able to look at this criterion as part of its analysis.

### **13.6 Other evidence that supports reviewing the 2-hour cut off criterion**

- Women with an elevated screening test (non-fasting 50g polycose and 1 hour glucose  $\geq 7.8$  mmol/l) but subsequent normal GTT may have worse outcomes than women who have elevated GTT result and are treated for GDM (suggesting cut-off may be too high even where lower levels are used)<sup>22,23</sup>. Treating all women with an elevated screening test has been shown to be cost-effective in one centre<sup>24</sup>.
- There are data showing that the 2-hour maternal glucose level following OGTT during pregnancy correlates with childhood obesity<sup>25</sup>. By the age of 25 years, offspring of women with a 2 hour glucose of 7.8-11.0 mmol/l have significantly higher risks of obesity than those with 2 hour glucose concentrations  $<7.8$  mmol/l. Rates of obesity increase even within the "normal" range of glucose levels (6.7-7.7 mmol/l). Maternal glucose levels may therefore be a convenient marker of over-nutrition to the fetus and with the current epidemic of obesity, they may identify which women would benefit from more intensive dietary counselling during pregnancy.
- Within the same organisation (ADIPS) there are different criteria, as New Zealand uses a 2 hour of 9.0 mmol/l and the Australians use a 2-hour or 8.0 mmol/l with some centres moving to a 2 hour of 7.8 mmol/l since ACHOIS has been published<sup>26</sup>. It seems sensible for an Australasian organisation to adopt agreed criteria across both New Zealand and Australia.

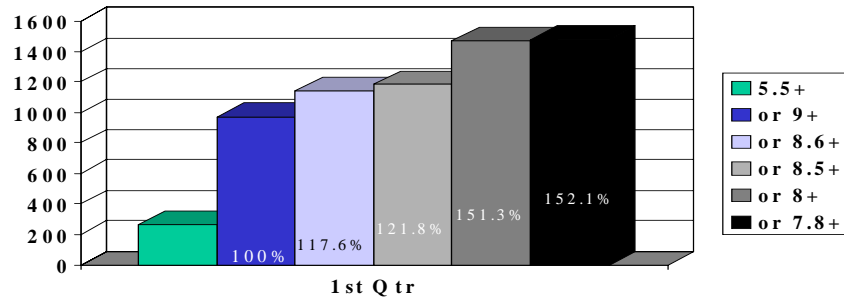
### **13.7 If we need to change the diagnostic criteria to a lower cut off, what are the implications of this for NZ?**

There are some data to assist with early predictions of the impact of any lowering of the 2 hour criteria on numbers diagnosed with GDM. These come from:

1. Published papers included in the reference list<sup>15-17</sup>, whereby numbers of women with GDM approximately doubled when looking at a cut-off of 7.8 mmol/l compared with 9.0 mmol/l.
2. Auckland: it was estimated, through talks with Diagnostic Medlab during 2005 and on previous occasions (personal communication, Tim Cundy) that the numbers of women diagnosed with GDM would increase by 50-100% if the 2-hour cut-off reduced from 9.0 mmol/l to 8.0 mmol/l (the additional impact from increased numbers of women with a GDM diagnosis would also need to be taken into consideration)
3. Christchurch: Numbers would increase by approximately 100% if cut-off decreased from 9.0 mmol/l to 8.0 mmol/l

4. Sydney: Jeff Flack has provided data allowing the graph below to be created showing numbers of women who meet different cut-off criteria. This shows numbers would increase by 52% if changed from 9.0 mmol/l to 7.8 mmol/l.

Numbers with GDM criteria using different criteria in an area of Sydney (1996-2006) (Courtesy J Flack)



This significant increase in numbers would have resource implications for caring for the women, but there may be cost-benefits relating to improved pregnancy outcomes (and potentially long term outcomes) It is hoped that HAPO would also be able to guide analysis of secondary reductions in workload due particularly to reduced morbidity (e.g. macrosomia, neonatal hypoglycaemia).