# Gestational Diabetes Mellitus:

## Current practices, screening and diagnosis in the South Eastern Sydney Illawarra Area Health Service

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# CERTIFICATE OF AUTHORSHIP/ORIGINALITY

I certify that the work in this thesis has not previously been submitted for a degree nor has it been submitted as part of requirements for a degree except as fully acknowledged within the text.

I also certify that the thesis has been written by me. Any help that I have received in my research work and the preparation of the thesis itself has been acknowledged. In addition, I certify that all information sources and literature used are indicated in the thesis.

Signature of Candidate

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## Prologue

This study examines the current practices within South Eastern Sydney Illawarra Area Health Service (SESIAHS) in relation to the screening of pregnant women for gestational diabetes mellitus (GDM). It is hoped that by examining the current practices and determining what would be considered best practice for screening for GDM, the research will form the platform for the development of Area wide practice guidelines.

Why study GDM? In 2004 in my workplace, which is a rural maternity unit in New South Wales (NSW), two near term stillbirths occurred in quick succession. Both were babies born to women who had poorly controlled GDM. A period of reflection ensued which prompted me to undertake this research. The starting point of this quest was a review of local practices relating to the screening, diagnosis and management of GDM. Following this, a review of the literature revealed a lack of consensus, not just on a local level, but on a global scale.

The questions generated by the clinical events and initial investigations required refinement to a focussed researchable question, which could impact on clinical practice to improve outcomes for mothers and babies. These questions led to this Master of Midwifery project.

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## Abstract

Aim: The aim was to examine the current practices related to the screening and diagnosis of Gestational Diabetes Mellitus (GDM) in the South Eastern Sydney Illawarra Area Health Service (SESIAHS), and to provide evidence to form the basis for the development of appropriate evidence-based guidelines for screening for GDM in this Area Health Service.

The objectives of the study were to:

1) Identify the range of practices employed for the screening and diagnosis for GDM across the SESIAHS;

2) Assess the level of screening by oral glucose challenge test (OGCT) and adherence to site policies regarding this test; and,

3) Establish the incidence of GDM in women giving birth at the three sites within the SESIAHS.

Study Design: A retrospective, quantitative, descriptive study, with comparative analysis of data between sites was undertaken. The aims and objectives of the study were addressed through examination of the policies and guidelines at the three sites and an assessment of the level of screening by oral glucose challenge test (OGCT). This was achieved through a medical record audit which also identified adherence to site policies regarding screening. The incidence of GDM in women giving birth at the three locations was ascertained via the Midwives Data Collection. Comparison of site and population characteristics was undertaken to explore any differences between the facilities.

Sample: Three components formed the sample for the study. These included the policies and guidelines from the three sites to identify the

range of practices employed to screen for GDM. The second sample component was 90 to 100 medical records per site for audit purposes to assess the level of screening by OGCT and adherence to site policies. The final component of the sample consisted of all women who gave birth at three sites in the SESIAHS from 2001 to 2005.

Results: There was a lack of consensus surrounding GDM apparent within the South Eastern Sydney Illawarra Area Health Service. Three differing approaches to screening for GDM were identified on examination of site policies and guidelines. Screening of women for GDM by OGCT or the one step diagnostic OGTT ranged from 76 – 88% at the three sites. Non-adherence to site policies was present in 11 – 14% of records examined. Risk factors for GDM were readily identified in 61 – 91% of the women whose medical records were reviewed. Over the five year study period, the incidence of GDM at Site 1 was 3.0 – 5.1%; at Site 2 it was 4.1 – 5.9%, and at Site 3 it was 5.5 – 7.1%. The incidence of GDM in the entire SESIAHS was 3.7 – 4.3% and in NSW 3.8 – 4.7% during the study period.

Conclusions: A universal screening strategy which offers the OGCT to all women is recommended. This conclusion has been reached after consideration of the findings of the literature review, the upward trend of GDM, and the high rate of GDM risk factors identified in the women at the three sites within the SESIAHS. Added to these features, the omission of screening for GDM in 11 – 14% of women with risk factors further supports a universal screening strategy. This strategy would serve to remove confusion around whether or not to offer a screening test to pregnant women. A uniform approach, based on the best available evidence, should be developed to guide screening, diagnosis and treatment practices for GDM within the SESIAHS.

## Abbreviations

| | |
|---|---|
| ACHOIS | Australian Carbohydrate Intolerance Study |
| ACOG | American College of Obstetricians and Gynecologists |
| ADA | American Diabetes Association |
| ADIPS | Australian Diabetes in Pregnancy Society |
| AIHW | Australian Institute of Health and Welfare |
| BMI | Body Mass Index |
| CDA | Canadian Diabetes Association |
| CINAHL | Cumulative Index to Nursing and Allied Health Literature |
| EASD | European Association for the Study of Diabetes |
| GDM | Gestational Diabetes Mellitus |
| GP | General Practitioner |
| HAPO | Hyperglycaemia and Adverse Pregnancy Outcomes |
| HREC | Human Research Ethics Committee |
| IFG | Impaired Fasting Glucose |
| IGT | Impaired Glucose Tolerance |
| MDC | Midwives Data Collection |
| NDDG | National Diabetes Data Group |
| NICE | National Institute for Health and Clinical Excellence |
| NZSSD | New Zealand Society for the Study of Diabetes |
| OGCT | Oral Glucose Challenge Test |
| OGTT | Oral Glucose Tolerance Test |
| RANZCOG | Royal Australian and New Zealand College of Obstetricians and Gynaecologists |
| SESIAHS | South Eastern Sydney Illawarra Area Health Service |
| WHO | World Health Organisation |

# CHAPTER 1: Introduction

## 1.1 Introduction

Gestational diabetes mellitus (GDM) is defined as glucose intolerance that is first recognised or diagnosed in pregnancy (Setji, Brown & Feinglos, 2005). Ancient Egyptian, Greek and Hindu documents dating back to 1400 – 1500 BC portray the symptoms of diabetes mellitus. The earliest known description of GDM was written in 1824 by Heinrich Bennewitz for his doctoral thesis (Hadden, 1998). Since this time, the concept of GDM has kindled keen interest amongst researchers and clinicians alike. Debate over the significance of GDM, the efficacy and usefulness of screening for the condition and the impact of treatment on maternal and neonatal outcomes is clearly evident in the literature. As a consequence of this debate, no uniform guidelines for the management of GDM exist on a local, national or global level. Providing women with information to afford them the opportunity to make an informed decision about GDM also presents a challenge. As a midwife working in the South Eastern Sydney Illawarra Area Health Service (SESIAHS), this same lack of consensus surrounding the management of GDM became apparent to me. In response to the debate introduced above, and the situation in my workplace, the research question for this study is; what are the current practices and levels of screening and diagnosis of Gestational Diabetes Mellitus (GDM) at three sites across the SESIAHS?

The overall aim of the study is to form the basis for the development of appropriate evidence based guidelines for the screening and diagnosis of GDM across the Area Health Service.

The objectives of the research are to:

1) Examine the local policies and guidelines to identify the range of practices employed for the screening and diagnosis of GDM across three sites in the SESIAHS;

2) Assess the level of screening by oral glucose challenge test (OGCT) and adherence to local guidelines; and,

3) Establish the incidence of GDM at the three sites.

## 1.2 Organisation of Thesis

This thesis is set out in five chapters. Chapter 1 introduces the subject of GDM, providing a background for the research and identifying the controversy surrounding GDM internationally. Chapter 2 reviews the literature on a number of aspects of GDM from a global perspective, including the historical context, pathophysiology, prevalence of GDM, screening and diagnostic practices, treatment of GDM and maternal and neonatal outcomes associated with GDM. Chapter 3 describes the methodology undertaken for the study. The results of the research are presented in Chapter 4 and include a detailed description of site policies and guidelines, the findings of the medical record audits and the analysis of the data provided by the Midwives Data Collection. Discussion and recommendations generated by the research are presented in Chapter 5, with particular emphasis on the application to clinical practice. Also considered in this chapter are the issues of working in partnership with women to facilitate informed decision making, what constitutes evidence and the impact of these issues on practice. Limitations of the research and opportunities for future research are also considered in this chapter.

## 1.3 Gestational Diabetes Mellitus Overview

Gestational diabetes mellitus is defined as carbohydrate intolerance that is first recognised or diagnosed during pregnancy (Russell, Carpenter & Coustan, 2007). Gestational diabetes mellitus represents an insulin resistant state, possibly due to the placental production of progesterone, cortisol, prolactin and other hormones which interfere with normal glucose metabolism (Buchanan & Xiang, 2005). Insulin resistance usually appears in the second trimester of pregnancy and increases as the pregnancy advances. Thus, as the pregnancy progresses, more insulin is required to maintain normal blood glucose levels. Most women are able to meet the increased demand for insulin. Women with GDM are unable to produce sufficient insulin to cope with the increased demand. As insulin resistance mounts, women with GDM become hyperglycaemic. The higher level of blood glucose crosses from the mother to the fetus via the placenta, in turn stimulating fetal insulin secretion and fetal growth (Ben-Haroush, Yogev & Hod, 2003; Jansson, Cetin, Powell, Desoye, Radaelli, Ericsson & Sibley, 2006). The pathophysiology of GDM is further explored in the literature review in Chapter 2.

Globally, the quoted prevalence of GDM ranges from 1 - 16% (Agarwal, Dhatt, Punnose & Koster, 2005). This may be in part due to the different screening and diagnostic strategies employed to identify the condition and the particular population studied. The Australian Carbohydrate Intolerance Study (ACHOIS) undertaken in 14 centres in Australia and 4 centres in the United Kingdom reported that GDM affected 2 - 9% of all pregnancies (Crowther, Hiller, Moss, McPhee, Jeffries & Robinson, 2005). Whilst, Tuffnell, West and Walkinshaw (2003) in their systematic review of treatments for GDM and impaired glucose tolerance (IGT), for the

Cochrane Database state that 3 - 6% of all pregnancies are affected by GDM and IGT.

Gestational Diabetes Mellitus is associated with an increase in perinatal morbidity (Crowther et al, 2005), is one of the commonest complications of pregnancy and is predicted to increase over time. The New South Wales Mothers and Babies Report, (2005), stratifies the occurrence of GDM according to maternal country of birth, with incidence ranging from 2.6% in women born in western and northern Europe to 12.4% in women born in southern Asia. The overall incidence of GDM was recorded as 4.7% in NSW in 2005. This is second only to pre eclampsia, which had an incidence of 5.1% as a major complication of pregnancy. Globally, the incidence of GDM has increased in line with the escalating rate of Type 2 diabetes in the general population (Dabelea, Bischoff, Snell-Bergeon, Hamman, Hartsfield & McDuffie, 2005; Vidaeff, Yeomans & Ramin, 2003).

The prevalence of GDM is also markedly higher in particular ethnic communities. King (1998), in her international, epidemiological summary of GDM cites a prevalence range of 0.6% - 15% dependent on ethnicity and country of birth or residence. The prevalence in Zuni Indian women in America was 14.3%, whilst an overall rate of 4% GDM was reported for all ethnic groups in America and is therefore similar to the rates in NSW quoted above. Other ethnic groups who displayed an elevated prevalence of GDM in King's report (1998) were American Chinese (7.3%), Mexican (6.0%), Indian born women living in Australia (15.0%), Asian women in Australia (11.9%) and African born women living in Australia (9.4%). The lowest prevalence of GDM tabled in King's report (1998) was 0.6% in Southern Indian women and Chinese women in Taiwan.

A number of risk factors for the development of GDM, other than ethnicity, are well documented in the literature and will be explored in greater depth in Chapter 2 of this thesis. Recognised risk factors include increasing maternal age and parity, obesity or a Body Mass Index (BMI) greater than 27, maternal low birth weight, a family history of Type 2 diabetes or GDM, polycystic ovary syndrome and a previous macrosomic infant or stillbirth (Ben-Haroush et al, 2003; Pettit & Jovanovic, 2007).

Although once deemed 'a diagnosis still looking for a disease' (Hunter & Milner, 1985), mounting evidence supports the association of GDM with a rise in perinatal morbidity for both mother and baby (Langer, Yogev, Xenakis & Brustman, 2005: Crowther et al, 2005; Magee, Walden, Benedetti, Thomas & Knopp, 1993; Vidaeff et al, 2003). Maternal morbidities include pregnancy induced hypertension, pre eclampsia, polyhydramnios, caesarean section, birth trauma and the subsequent development of Type 2 diabetes ( Crowther et al, 2005; Setji, Brown, & Feinglos, 2005).

The range of fetal/neonatal consequences for babies born to mothers with GDM include – macrosomia, birth injury, hypoglycaemia/hyperglycaemia, hypocalcaemia, polycythaemia, impaired glucose tolerance, obesity and childhood diabetes (Vidaeff et al, 2003; Crowther et al, 2005). This range of consequences indicates the significance of GDM on fetal/neonatal well being and the potential long term consequences for children born to mothers who are diagnosed with GDM.

Screening methods, diagnostic criteria and the significance of GDM have long been issues of contention (Vidaeff et al, 2003). Expert committees worldwide have advocated a diverse range of strategies for the screening, diagnosis and management of GDM based on opinion and consensus rather

than evidence (Hoffman, Nolan, Wilson, Oats & Simmons, 2002; Dabelea et al, 2005). The dilemma for clinicians, up until now, has been the absence of well constructed clinical trials with sufficient participant numbers to determine the efficacy of screening, diagnosis and treatment of GDM.

The landmark study of Crowther et al (2005), known as, the Australian Carbohydrate Intolerance Study (ACHOIS), has to some degree, answered the call by many researchers and clinicians for a well designed clinical trial. This study, along with other research evidence (Langer et al, 2005; Crowther et al, 2005; Magee et al, 1993; Vidaeff et al, 2003) confirmed the clinical grounds for screening and treatment of GDM. This trial will be discussed in greater depth in the literature review.

Clinical practice, as guided by policies and guidelines should reflect research evidence. There is no uniform guideline or strategy for the screening and diagnosis of GDM in the SESIAHS. The proposed research, with its stated aim and objectives, will determine the current practices in relation to screening the population of pregnant women attending three hospitals in the SESIAHS. Knowledge gained from the study will form the first step in the development of evidence -based guidelines for these aspects of the management of GDM, which could be applied across the Area Health Service and perhaps throughout NSW.

In this chapter, an overall review of GDM reveals a lengthy history, clouded by controversy. GDM is a common complication of pregnancy, associated with an increased perinatal morbidity and the incidence is expected to rise over time in line with escalating rates of Type 2 diabetes in the general population.

# CHAPTER 2: Literature Review

## 2.1 Introduction

The literature review was conducted by searching for journal articles on the Cumulative Index to Nursing and Allied Health Literature database (CINAHL), Pubmed, Medline, Old Medline (1950 – 1965), the Cochrane Database of Systematic Reviews, the World Health Organization (WHO) and the NSW Department of Health websites. The search terms used included GDM, diabetes/gestational, pregnancy and diabetes, prediabetes and pregnancy, gestational diabetes and screening, gestational diabetes and diagnosis and impaired glucose tolerance with sub headings related to the screening, diagnosis, epidemiology, classification, treatment and history of GDM. The initial search was limited to the years from 1995 to the present; however, as important pioneering work was identified in the literature this limitation was expanded to capture the earlier research. Reference and bibliographical lists in the articles retrieved in searches were scanned for additional research papers which could contribute to the literature review and these papers were actively sought. Searches by author and particular journals were also conducted to identify relevant studies and reports. Assistance was given by the SESIAHS librarian in the retrieval of several articles that were difficult to access. *A Guide to Effective Care in Pregnancy and Childbirth* (Enkin, Keirse, Neilson, Crowther, Duley, Hodnett & Hofmeyr, 2000), 3rd edition was accessed via the hospital library, as was *Clinical Epidemiology, the Essentials* (Fletcher, Fletcher & Wagner, 1996).

The literature review explores the historical context of GDM, the physiology/pathophysiology, incidence, screening and diagnostic practices, treatment and outcomes. The broad scope of the literature review provides

a comprehensive examination of the current evidence around all aspects of GDM.

## 2.2 History

Descriptions of diabetes mellitus are found in ancient Egyptian, Greek and Hindu writings, dating back to 1500 BC, with evidence suggesting that some of these writings may have been copied from centuries earlier documents (3400 BC). The term diabetes, from the Greek meaning siphon, was first used by Aretaeus a disciple of Hippocrates. The Latin word for honey, 'mellitus' was added by William Cullen in 1769, although, the ancient Hindus coined the phrase 'honey urine', noting that the urine attracted bees and flies (Sanders, 2002).

The first known case study of GDM was reported by Bennewitz in 1824, for his doctoral presentation, in which he described the case of a young woman in her fifth pregnancy, which was complicated by newly diagnosed diabetes. The symptoms of the young woman's diabetes – an unquenchable thirst, polyuria and glycosuria, appeared during the pregnancy. These resolved spontaneously after the birth, despite treatment with sweating, purging and the application of leeches. The pregnancy resulted in the birth of a 12 pound stillborn male infant (Hadden, 1998). The next known description was in 1882 when Matthews Duncan of Aberdeen presented a review of 22 pregnancies complicated by diabetes to a meeting of the Obstetrical Society of London and made reference to Bennewitz's earlier work (Hadden, 1998).

The term, GDM, was first used by Pedersen in 1951 (Vidaeff et al, 2003). Despite extensive investigation into the condition since this time, GDM remains an area of controversy and debate (Brody, Harris & Lohr, 2003; Langer et al, 2005; Vidaeff et al, 2003). The most recent research relating

to GDM, endeavours to address aspects of the debate by determining the association of maternal hyperglycaemia with an increased risk of adverse pregnancy outcome (Hyperglycaemia and Adverse Pregnancy Outcome (HAPO) study cooperative group, 2008) and ascertaining whether treatment of the condition can decrease perinatal morbidity (Crowther et al, 2005).

Early researchers into the phenomenon of GDM were interested in the predictive value of identifying women who may subsequently develop Type 2 diabetes rather than the impact of the condition on the pregnancy and birth (O'Sullivan & Mahan, 1964). However, the evidence demonstrating the increased maternal and neonatal morbidities associated with GDM is mounting and the consequences of a diagnosis of GDM for pregnancy and birth have become equal to, if not more important, than its predictive value. These consequences will be addressed in turn in the literature review.

Terminology in the literature, relating to disturbances of carbohydrate metabolism in pregnancy can be confusing. In 1985, the World Health Organization (WHO) classification subdivided abnormal glucose tolerance in pregnancy into three categories defined by fasting venous glucose levels and venous plasma glucose values two hours after a 75gram oral glucose load (Nordin, Wei, Naing and Symonds, 2006). The three classifications were impaired fasting glucose (IFG), impaired glucose tolerance (IGT) and GDM. The revised WHO classification (1999) now defines GDM as any abnormal carbohydrate metabolism first recognized, or diagnosed in pregnancy, regardless of severity. Remnants of the earlier classification are still encountered in the literature. Table 1 describes the three categories.

**Table 1: Abnormal glucose tolerance in pregnancy – the WHO classification 1985**

| WHO Classification | Fasting glucose level (mmol/L) | Glucose level 2hrs post load (mmol/L) |
|---|---|---|
| Impaired fasting glucose (IFG) | ≥6.1 <7.0 | < 7.8 |
| Impaired Glucose Tolerance (IGT) | <7.0 | ≥7.8 |
| Gestational diabetes Mellitus (GDM) | ≥7.0 | ≥11.1 |

## 2.3 Physiology/pathophysiology

A number of complex changes in maternal metabolism accompany pregnancy. Normal and progressive features of pregnancy in relation to glucose metabolism include pancreatic islet hypertrophy, hyperinsulinaemia and insulin resistance (Lain & Catalino, 2007). The endocrine and metabolic adaptation seen in pregnancy is thought to be necessary to meet the nutritional needs of the fetus and to prepare the mother for birth and lactation (Di Cianni, Miccoli, Volpe, Lencioni & Del Prato, 2003).

Insulin is produced by the beta cells of the pancreatic islets of Langerhans and is the major regulator of organic metabolism in the body. It acts directly or indirectly on most tissues of the body. Insulin has two broad categories of action – metabolic effects on carbohydrate, lipid and protein synthesis, and secondly, growth promoting effects on DNA synthesis, mitosis and cell differentiation. Insulin release is influenced by both neural

and hormonal factors; however, the key regulator is the blood glucose level. A rise in blood glucose level will trigger an increase in insulin secretion, whereas a low blood glucose level will produce a decrease in insulin secretion. Other factors which influence insulin secretion include an increase in amino acid concentration, gastro intestinal hormones released in response to a meal and parasympathetic neuron activation of beta cells during ingestion of a meal – all of which increase insulin secretion. Activation of sympathetic neurons or an increase in catecholamines, as occurs during stress or exercise, will inhibit insulin release. (Molina, 2006)

The underlying pathophysiology of GDM is due to decreased maternal insulin sensitivity and abnormal pancreatic beta cell response (Catalino, 2003). As in Type 2 diabetes mellitus, the combination of resistance to insulin action and an inadequate secretory response by the beta pancreatic cells results in a relative insulin deficiency.

Whilst various theories have been proposed to account for the relative insulin deficiency encountered in pregnancy and GDM, the exact mechanisms are not known for certain. (Tomazic, Janez, Sketelj, Kocijancic, Eckel & Sharma, 2002). Placental hormones are implicated in the development of insulin resistance in pregnancy including human placental lactogen, human placental growth hormone and progesterone (Barbour, McCurdy, Hernandez, Kirwan, Catalano & Friedman, 2007; Branisteanu & Mathieu, 2003). The return to normal or near normal glucose metabolism after the birth further supports the impact of placental hormones on glucose metabolism. There is an expectation that most women will have a normal oral glucose tolerance test (OGTT) by 6 weeks post partum and follow up testing is generally recommended at this time (Metzger, 2007). A study by Tomazic et al (2002) cites defects in the insulin signaling pathway as a possible factor in the development of insulin

resistance in GDM. In a study by Retnakaran, Hanley, Sermer & Zinman, (2005) adinopectin concentrations were shown to have a positive correlation with GDM in 180 women. This led the researchers to conclude that adinopectin may perform an important role in limiting insulin resistance and beta cell dysfunction in GDM. Impairment of glucose transport in skeletal muscle has also been demonstrated in pregnancy and to a greater degree in women with GDM ((Barbour et al, 2007). Other substances known as adipokines – protein messengers produced by adipocytes, are suspected of contributing to insulin resistance in pregnancy and GDM. They include tumour necrosis factor α, leptin, interleukin-6 and resistin (Barbour et al, 2007; Lain & Catalano, 2007; Desoye & Hauguel-de Mouzon, 2007).

Obesity and genetics appear to influence the degree of insulin resistance in pregnancy (Di Cianni et al, 2003). Inflammation and elevated serum ferritin levels in early pregnancy have also been cited as possible contributors to the development of insulin resistance in GDM (Chen, Scholl & Stein, 2006; Wolf, Sauk, Shah, Jimenez-Kimble, Ecker & Thadhani, 2004).

In summary, pregnancy is normally accompanied by hyperinsulinaemia and increasing insulin resistance. The insulin resistance and inadequate beta cell response of GDM are well recognised, however, the exact mechanism is likely to be multifaceted and as yet, not clearly understood.

## 2.4 Incidence of GDM

The rates of diagnosis of GDM vary according to the population studied and the method utilised for screening. However, an increased incidence of GDM, which mirrors the increasing incidence of Type 2 diabetes in the

general population is well documented in the literature (Vidaeff et al, 2003; Langer et al, 2005; Dabelea et al, 2005; HAPO Study Cooperative Research Group, 2002; Anna, van der Ploeg, Cheung, Huxley & Bauman, 2008)).

The increased prevalence of GDM in certain ethnic groups is apparent in the literature (King, 1998; Centre for Epidemiology and Research, NSW Department of Health, 2005; Dabelea et al, 2005). In the Dabelea et al (2005) study, described above, the latter three groups of women, (Hispanic, African American & Asian women) were considered to be at high risk of developing GDM. The proportion of women in high risk ethnic groups increased during the study period from 28% of all eligible pregnancies in 1994 to 33% in 2002. A significant increase in GDM persisted following adjustment for ethnicity and other confounding variables such as maternal age, GDM in a previous pregnancy and parity. High levels of screening were a strength of the Dabelea et al (2005) study with a random sample of 2328 women in 1996 revealing a 98% screening rate and in 2001 to 2002, 96% of eligible women were screened. Body mass index (BMI) information was not available for the participants and therefore, whilst the authors postulated a link between GDM and rising obesity levels in the general population, no conclusion in relation to this risk factor can be verified. The authors' judge, on the evidence presented, that GDM may be increasing in prevalence amongst American women from a variety of ethnic backgrounds, independent of age, parity or history of previous GDM.

A report examining trends on the incidence of GDM (Dabelea et al, 2005) in the Denver (USA) metropolitan area demonstrated a twofold increase between 1994 and 2002. The study included a total of 36,403 women from varying ethnic backgrounds who were routinely screened for GDM using a

50 gram oral glucose challenge test (OGCT). Since the late 1980s, all pregnant women in the study area have been offered an OGCT to screen for GDM between 24 – 28 weeks gestation. Women with a positive OGCT result (threshold value of $\geq$ 7.8mmol/L) undergo an OGTT to confirm a diagnosis of GDM. These well established screening and diagnostic procedures, as well as computerised data collection in place at the study site for over twenty years, were strengths of the study and enabled the researchers to track the incidence of GDM over time. The women were divided into four race/ethnic groups for the purposes of data analysis and to gauge the effect of ethnicity on the prevalence of GDM. Group one consisted of non-Hispanic white women, group two were Hispanic women, group three were African American women and group four were Asian women. Increasing prevalence of GDM was noted in all of the four groups whether deemed at high or low risk for GDM.

The 2007 Report on Adult Health (Centre for Epidemiology and Research, NSW Department of Health, 2008) indicates rising levels of overweight and obesity in the SESIAHS and NSW – a well recognised risk factor for GDM and other pregnancy complications. This same document, whilst not collecting specific data in relation to GDM, reports an increasing prevalence of Type 2 diabetes. These results from the NSW Population Survey, 2007, emulate the findings of other studies which observe an increase in Type 2diabetes and therefore, GDM over time.

Callaway, Prins, Chang and McIntyre (2006) assessed the prevalence of overweight and obesity in an Australian population and its impact on maternal and neonatal outcomes. In their review, 35% of Australian women aged 25 to 35 years were considered to be overweight or obese. The association of GDM with an increased body mass index is confirmed in this study. Similar concerns of the increased risks for overweight and obese

pregnant women in the United Kingdom are raised by Richens in her report (2008).

A recent study conducted in NSW, examined the data from over 95,000 births in an 11 year period, from 1995 to 2005 (Anna et al, 2008). Over the study period, an increase of 45% in the incidence of GDM in NSW was demonstrated. A strong inverse correlation between socioeconomic status and GDM was observed, with women from low socioeconomic groups across all ethnic backgrounds, at greater risk of GDM. Increasing maternal age and rising obesity levels are cited as possible contributors to the growing incidence of GDM. The authors of this study presume a practice of 'almost universal screening for gestational diabetes', across NSW, however the results of this research and other studies (Moses, Webb & Comber, 2003) do not support this assumption. The varying practices identified in this research and the suspected under reporting of GDM in the Midwives Data Collection (MDC), (Moses, Webb & Comber, 2003) would imply that a 45% increase in the prevalence of GDM over the 11 year study period is likely to be an underestimate.

A GDM rate of 4.7% is reported, in the NSW Mothers and Babies Report, 2005which is an increase from the 2001 level of 3.8%. An incidence of GDM of 3.3% is reported for Aboriginal and Torres Strait Islander women and it is speculated that under-detection and/or under reporting may account for this low rate, given that the rate of Type 2 diabetes in the Indigenous population is three times greater than that of non-Indigenous people. Overall, Indigenous mothers and babies experience poorer perinatal outcomes than other Australians (Australian Institute of Health & Welfare, 2008), are less likely to access mainstream health services (Stamp, et al, 2008) and are identified as more likely to enter antenatal care at later gestations (Thuy Thi Trinh & Rubin; 2006). Fear of hospitalisation,

feelings of vulnerability, miscommunication, loneliness and isolation are cited by Simmons, Khan and Teale (2005) as issues which impact on Aboriginal communities' utilisation of health services. The custodians of the MDC also conclude under-reporting of Aboriginality when their data are compared with maternal Aboriginality on birth registrations (MDC, 2005). These factors may account for the suspected under- detection and/or reporting of GDM amongst Aboriginal women.

In the 2005 NSW Mothers and Babies report, as in the 2004 document (previously cited), the prevalence of GDM differs markedly between ethnic groups. The highest rate of GDM was detected in women born in Southern Asia (12.4%) and the lowest rate was reported in women born in Western and Northern Europe (2.6%).

The incidence of GDM in the SESIAHS at the three individual study sites for the years 2001 to 2005, are described in detail in Chapter 4. Factors which may influence the incidence of GDM, such as parity, maternal age and ethnicity are also presented for the three sites in Chapter 4.

## 2.5 Screening for GDM

In this section, the literature relating to screening tests in general and those specifically offered in pregnancy are discussed. Gestational diabetes mellitus screening strategies and practices are examined in depth.

### *2.5.1 Screening tests*

Screening is the process by which asymptomatic disease or risk factors for disease may be identified (Fletcher, Fletcher & Wagner, 1996). Screening tests or procedures take the form of history taking (e.g. family history of certain conditions), physical examination (e.g. breast examination), laboratory investigations (e.g. Newborn Screening test) or other procedures

such as a Pap smear or colonoscopy. Screening tests are not intended to be diagnostic but pinpoint those people who are at risk or require further investigation to determine if they do indeed have the screened for condition (Fletcher, Fletcher & Wagner, 1996). Wilson and Jungner, in 1968, (cited National Institute for Health and Clinical Excellence (NICE) Antenatal Care Guideline, 2008) developed a set of principles to appraise the suitability of a condition for screening and the validity of screening tests. It included the following attributes – screened for disorders should be clinically well defined, have a known incidence, be associated with significant morbidity or mortality, effective treatment for the condition should be available and there should be a period before emergence of symptoms which allows intervention or informed choice to occur. The screening tool should be safe, ethical, simple and robust, as well as cost effective. Russell, Carpenter and Coustan (2007) agree with these criteria in assessing the suitability of a condition and a screening test. They also cite a high sensitivity and specificity, simple administration and acceptability to the target population and clinician alike as valuable characteristics of a screening tool. The sensitivity of a screening tool refers to the proportion of people with the target disorder in whom a screening test result is positive. The specificity of a screening tool refers to the proportion of people without the target disorder in whom a screening test result is negative. A screening tool is only useful if it assists in identifying those conditions in which early treatment or intervention is beneficial.

### *2.5.2 Screening tests in pregnancy*

Women are offered a number of screening tests during pregnancy with the aim of identifying, treating or preventing conditions which may adversely affect the mother or baby (Dodd, Crowther & Robinson, 2002). An analysis of 107 antenatal protocols from across Australia revealed a wide variation

in screening recommendations and inconsistent compliance with national policies and research evidence (Hunt & Lumley, 2002). Screening tests offered may include a nuchal translucency ultrasound scan to identify the risk of Down syndrome in the fetus, a fetal anomaly ultrasound scan for structural abnormalities, screening for infections such as Human Immunodeficiency Virus (HIV), hepatitis B and C, syphilis and group B streptococcus, asymptomatic bacteruria and haematological screening for rubella immunity, anaemia and presence of antibodies. Before a screening test is offered in pregnancy, the National Institute for Health and Clinical Excellence (NICE) Antenatal Care Guidelines (2008) advocate the consideration of the potential reduction in perinatal morbidity and mortality versus the risks associated with a diagnosis. The long term health benefits need to be weighed against the possible increase in obstetric intervention and the associated risk and an increase in health expenditure.

The decision to accept a screening test in pregnancy should be an informed one. Appropriate information needs to be communicated to women, which includes the risks, benefits and implications of any offered screening test to allow an informed decision to be made. Two recent studies, one in the Netherlands and a second in Australia, concluded that women's prenatal screening choices are often not well informed (37% & 51% informed choice, respectively) ( van den Berg, Timmermans, ten Kate, van Vugt, & van der Wal, 2006; Rowe, Fisher & Quinlivan, 2006).

### *2.5.3 GDM screening*

Gestational diabetes mellitus meets many of the features which make it suitable for screening. That is, it is a clinically well defined condition (although thresholds for diagnosis vary), with a known incidence, associated with an increased perinatal morbidity, has a period before

emergence of symptoms and treatment is known to improve outcomes (Crowther et al, 2005; HAPO Study cooperative research group, 2008). However, Russell, Carpenter and Coustan (2007), in their review of the literature from 1950 to 2006, found no well designed studies which focused on screening strategies for GDM.

Screening for GDM by a 50gram OGCT was first used in 1954 in a prospective study of abnormal glucose tolerance in pregnancy that was conducted in Boston (Hadden, 1998; Vidaeff et al, 2003) and was said to have a sensitivity of 79% and specificity of 87% for identification of GDM. The primary purpose of diagnosing women with GDM in the early screening programs was to identify future or latent diabetics rather than attempting to mitigate the effect on the current pregnancy (O'Sullivan & Mahan, 1964; O'Sullivan, Gellis, Dandrow, & Tenney, 1966). O'Sullivan and Mahan (1964) established a graded test criteria for the diagnosis of GDM and demonstrated a strong correlation between the severity of glucose intolerance and subsequent development of Type 2 diabetes after pregnancy. Widespread OGCT screening for GDM was in practice by the 1980's based on the glucose thresholds developed by the pioneering work of O'Sullivan and Mahan (1964).

The debate over screening divides the proponents into two groups – those advocating universal screening of all women for GDM and those in favour of a risk-based screening approach. Variations on these two practices have been proposed with Naylor , Sermer, Chen and Farine (1997) suggesting a method of identifying women who should be screened by OGCT and those who did not require screening. The women were divided into three groups based on a score which took into account physical and clinical attributes such as age, race and BMI. Low risk women would not be offered OGCT screening, the intermediate risk group would be offered OGCT screening

and the high risk women would be screened by OGCT with lower plasma glucose thresholds (7.2mmol/L v 7.8mmol/L for routine screening). Although the proposed method would reduce the number of women undergoing OGCT and would not significantly decrease the number of GDM cases identified, this strategy has not been embraced, perhaps due to the complexities of application of such a method in clinical practice. A number of alternatives to the OGCT have been proposed including fasting plasma glucose (Agarwal, Dhatt, Punnose & Zayed, 2007), random glucose levels, blood glucose measurement two hours post prandial and glycosylated haemoglobin levels (Agarwal, Dhatt, Punnose & Koster, 2005), none of which have proven to have the sensitivity of the OGCT as a screening tool (Vidaeff et al, 2003).

Hunt and Lumley (2002) discovered a variety of screening tests recommended for GDM in their assessment of 107 Australian antenatal protocols, including the OGCT, OGTT, random blood sugar levels and HbA1c. They also found discrepancies in terminology in naming these tests and expressed doubt over the value of screening for GDM.

The recommendations of the Fifth International Workshop-conference on Gestational Diabetes Mellitus (Metzger et al, 2007) outline a risk screening strategy for the detection of GDM. Screening tests are offered on the basis of whether women are deemed at low, average or high risk of developing GDM. Table 2 summarises the levels of risk and the associated strategy when screening for GDM.

**Table 2: Fifth International Workshop-conference on GDM recommendations for screening**

| Risk category | Risk assessment |
|---|---|
| Low risk: no OGCT/OGTT required | Low prevalence ethnic group, no family history, age<25 years, normal weight pre pregnancy and at birth, no previous poor obstetric outcome, no prior abnormal glucose metabolism |
| Average risk: OGCT &/or OGTT, 24-28 weeks gestation | If does not fulfill all of the above characteristics |
| High risk: OGCT &/or OGTT as soon as possible, repeat 24-28weeks if negative | One or more of the characteristics above are not present, plus severe obesity, strong family history, previous GDM or glucose impairment, glycosuria |

A comparison of guidelines for screening for GDM (Vogel, Burnand, Vial, Ruiz, Paccaud and Hohlfeld, 2000) showed a diverse range of practices and threshold values for a positive result. A total of ten published guidelines were examined which fell into three categories. Five guidelines advocated universal screening by OGCT, three guidelines supported selective screening and two guidelines did not recommend either method. The risk factors applied to determine if an OGCT was required varied between guidelines. Whilst maternal age was a common risk factor, the age limits for screening by OGCT varied from greater than 25 years to greater than 40 years of age. Ethnic groups at high risk of GDM also differed between guidelines. Weight or BMI thresholds, above which women were considered to be at high risk of GDM were not specified in several of the guidelines. An adverse outcome in a previous pregnancy was also listed as a risk factor, although explicit outcomes were not necessarily stated.

In an Australian study, a 2.8% GDM rate was identified in a low risk pregnant cohort by Moses, Moses and Davis (1998). No difference in pregnancy outcomes between low and high risk groups, as measured by maternal and neonatal morbidities was found. The proportion of large or small for gestational age infants, as well as birthweight, neonatal admissions to special care nursery, emergency caesarean section rates and the number of women requiring insulin were compared between the low and high risk groups. Women less than 25 years of age, of Caucasian ethnic origin and with a BMI of less than 25kg/$m^2$ formed the low risk group. Their findings led the authors to conclude that almost 10% of all women with GDM would be missed if selective risk based screening alone was used (Moses et al, 1998).

A prospective observational study in a Malaysian university hospital (Tan, Ling, Zawiah, 2007) which enrolled 1600 women at the antenatal booking visit, identified an 11.4% incidence of GDM. Universal screening by OGCT, with a positive test threshold of 7.2 mmol/L was applied during the study. The sensitivity of the OGCT at this threshold is 90%. Women with a history of GDM were excluded from the study and thus the incidence of GDM is probably an underestimate. In the women diagnosed with GDM, 58 of 183 (31%) reported no risk factors and therefore would have been overlooked had selective risk based screening been used.

Other studies have also supported the view that selective risk based screening for GDM fails to identify a significant number of women with the condition. In their study of 532 women, conducted in Helsinki, Polyhonen-Alho, Teramo, Kaaje and Hiilesmaa, (2005), found 47% of women with GDM would have been missed using risk based screening. All women in the study had an OGCT at 26 to 28 weeks gestation. A venous plasma glucose level of > 7.3mmol/L at one hour after a 50gram

oral glucose load was considered positive. An OGTT was performed for all women with a positive result. Women with known risk factors also underwent OGTT regardless of the result of the OGCT. A BMI greater than 27kg/$m^2$, maternal age greater than 40 years, previous GDM or previous macrosomic infant with a birthweight of greater than 4500grams were considered risk factors. A major weakness of this study is the omission of a familial history of Type 2 diabetes and particular ethnic groups as risk factors for the development of GDM. Other studies differ in risk categories, most including family history, maternal age greater than 30 years and high risk ethnic groups. Risk based screening may have identified GDM with greater accuracy had these categories been included. The study population in the Helsinki group was comprised of predominately Caucasian women.

An observational study in France which compared the outcomes of pregnant women who had either universal or selective screening for GDM (Cosson, Benchimol, Carbillon, Pharisieu, Paries, Valensi, Lormeau, Bolie, Uzan & Ahali, 2006) concluded that at least 30% of women with GDM were missed using the selective screening strategy. Significantly improved outcomes were observed in the universal screening group.

In contrast to the conclusions reached by Polyhonen-Alho et al (2005) and Cosson et al (2006), the United Kingdom's NICE guidelines recommend screening for GDM using risk factors at the booking in appointment and do not support routine screening by OGCT (2008). Their position is also directly opposed to that of the Australian Diabetes in Pregnancy Society (ADIPS) who recommend universal screening by OGCT for GDM of all pregnant women.

In accordance with the finding that a significant number of women with GDM would be missed if a selective risk based screening model was used,

the Australasian Diabetes in Pregnancy Society (ADIPS), recommend universal screening by 50gram OGCT for GDM (Hoffman, Nolan, Wilson, Oats & Simmons, 2002). In contrast, the Summary of Evidence for the US Preventive Task Force (Brody, Harris & Lohr, 2003) was equivocal in its findings in relation to the impact of screening on maternal and neonatal outcomes, concluding there was insufficient evidence to recommend universal screening by OGCT. In 2008, an update by the U.S. Preventive Services Taskforce on GDM maintained their previous stance.

The more recent systematic review on screening for GDM for the U.S. Preventive Services Task Force (Hillier, Vesco, Pedula, Beil, Whitlock & Pettit, 2008) sought to address five key questions. Question one related to a reduction in perinatal morbidity and mortality for mother or infant associated with screening. No trials were identified which examined screening and subsequent treatment. The second key question considered the sensitivity, specificity and reliability of GDM screening tests. Again, no articles met the criteria for inclusion in the review. The third question asked if treatment of GDM resulted in a reduction in maternal and infant morbidity and mortality. The Australian Carbohydrate Study (ACHOIS) was cited as a good quality study which demonstrated improved outcomes in women with mild gestational diabetes who received treatment. The final two questions examined evidence of adverse effects associated with screening and treatment of GDM. Whilst evidence was limited, the reviewers concluded that screening and treatment of GDM had no long term adverse impact.

There is some evidence to suggest screening for and diagnosing GDM increases intervention rates in the form of increased fetal surveillance, induction of labour, caesarean section and neonatal admission to a special care nursery (Crowther et al, 2005; HAPO, 2008; NICE, 2008; Russell,

Carpenter & Coustan, 2007). Adverse psychosocial impacts may also accompany the diagnosis of GDM with increasing maternal anxiety, fear, depression and a loss of control reported as possible sequelae (Evans & O'Brien, 2005), however the ACHOIS did not support these psychosocial effects.

A survey of 214 obstetric units in the United Kingdom (Mires, Williams & Harper, 1999) established that selective screening based on risk factors was used by 81% of study participants. However, lack of consensus on screening and diagnostic methods existed between units and obstetric consultants. Maternal risk factors are not specified in the Mires et al survey, hence uniformity or inclusiveness cannot be ascertained.

The sensitivity of OGCT varies with the method and criteria used for a positive result. Keshavarz, Cheung and Babaee, (2006) found an 88% sensitivity using a 50gram glucose load and threshold value of 140mg/dl (7.8 mmol/L) or 96% sensitivity with a 130mg/dl (7.2mmol/L) threshold value. Specificity was 88% and 81% respectively.

Examples of screening strategies are outlined below in table format. The screening tools used include risk based screening, the OGCT and the OGTT or a combination of these. Recommended timing of testing and thresholds for a positive result vary between the organizations. The sample in Table 3 is by no means an exhaustive list.

**Table 3: Examples of screening strategies**

| Organisation | Screening strategy | Screening tool | Timing | Threshold value |
|---|---|---|---|---|
| ADIPS<br><br>RANZCOG | Universal | OGCT<br><br>50gm glucose load | 26 – 28 weeks gestation | Fasting:<br><br>≥5.5mmol/L<br><br>At 1 hr<br>≥7.8mmol/L |
| NICE | Selective | Risk based +/- 75gm OGTT | Initial visit risk assess – high risk 16-18 weeks, medium risk 24-28weeks | Fasting:<br>≥6.1mmol/L<br><br>At 2hr:<br>≥7.8mmol/L |
| WHO | Universal | OGCT 50gm glucose load | 24 – 28 weeks gestation | At 2hr:<br>≥7.8mmol/L |
| 5TH INTERNATIONAL WORKSHOP | Selective | Risk based +/- 50gm OGCT or 75/100gm OGTT | 24 – 28 weeks gestation | At 1hr after OGCT:<br>≥7.8mmol/L |

### *2.5.4 Cost effectiveness of GDM screening*

There are also questions raised about the cost effectiveness of GDM screening. The cost effectiveness of four screening strategies was analysed by Nicholson, Fleisher, Fox and Powe (2005). The study identified three main GDM screening strategies used globally and these were compared with a 'no screening approach' to assess cost effectiveness. The three main

strategies employed were the sequential screening strategy using a 50gram OGCT, followed by 100gram OGTT if the 50gram OGCT was positive, the 75gram OGTT and the 100gram OGTT. A threshold value described as 'the standard cut off value of 7.8mmol/L' was used to interpret the results of OGCT, although the origin of this threshold is not stated. The WHO two hour threshold of 7.8mmol/L was used to interpret the 75gram OGTT and modified threshold levels developed by Carpenter and Coustan, were used on the 100gram OGTT results. Whilst the authors concede that the efficacy of these screening strategies has not been established, most obstetricians in the USA offer universal screening for GDM in some form. The universal application of the sequential strategy of OGCT then OGTT was found to be the most cost effective approach after analysis of maternal and neonatal outcomes. Maternal outcomes included hypertensive disease, polyhydramnios, caesarean or vaginal birth and the potential complications of the two modes of birth. Neonatal outcomes encompassed hypoglycaemia requiring intravenous therapy and observation, macrosomia (birth weight $\geq$ 4500g), respiratory distress and shoulder dystocia. No long term outcomes were included in the cost analysis despite the known association of GDM with the later development of Type 2 diabetes in both mothers with GDM and their babies.

Enkin et al in *'A Guide to Effective Care in Pregnancy and Childbirth'*, (2000) concluded from their review of clinical trials that there was no evidence to support the practice of universal screening of all pregnant women for GDM. At this time, they were also unconvinced by the available evidence that treatment improved perinatal outcomes.

*2.5.5 Summary*

Discussion continues as to the best practice for screening and management of GDM (Cutchie, Cheung & Simmons, 2006; Walters, 2006; Lao, Ho, Chan & Leung, 2006; Elchalal & Brzezinski, 2006; Richard, Vanhaeverbeek & Amaryllis, 2006). The ACHOIS results may resolve the debate in favour of the universal screening strategy as it demonstrated significant improvements in perinatal morbidity in a low risk population who may not have been diagnosed with GDM had a selective risk based screening approach been employed (Crowther et al, 2005). It should be noted that the aim of the ACHOIS was to determine if treatment of women with mild GDM reduced complications and did not set out to ascertain if universal screening was justified.

## 2.6 Diagnosis of GDM

Similar issues encountered in the debate on whether or not to routinely offer screening tests for GDM are also evident when reviewing recommendations for the diagnosis of GDM. An array of diagnostic methods and criteria is in current use (Agarwal, Dhatt, Punnose and Koster, 2005; Magee et al, 1993).

The diagnostic test for GDM is the oral glucose tolerance test, which requires the woman to fast overnight and two to four blood samples to be taken over a two to three hour period. The oral glucose load differs (75gm or 100gm) according to which organisations' criteria are utilised to perform and interpret the test results.

As previously discussed, a diagnosis of GDM may be accompanied by an increased level of fetal surveillance, higher intervention rates in the form of induction of labour and caesarean section birth, increased neonatal

admissions to a special care nursery, as well as possible psychosocial impacts on the mother, when the pregnancy is labeled as 'at risk' (Evans & O'Brien, 2005).

Table 4, represents a sample of the diagnostic criteria recommended by 'expert bodies' however, it is not a comprehensive list of all the criteria in use. These criteria and thresholds are applied to test results following a 75gram or 100gram oral glucose load and the number of abnormal results required for a positive diagnosis is listed in Column 2.

**Table 4: Sample of Expert Bodies diagnostic criteria for GDM**

| Expert Group | No. abnormal values | 0 hr value (mmol/L) | 1 hr value (mmol/L) | 2 hr value (mmol/L) | 3hr value (mmol/L) |
|---|---|---|---|---|---|
| WHO | ≥1 | 7.0 | - | 7.8 | - |
| ADA | ≥2 | 5.3 | 10.0 | 8.6 | 7.8 |
| ADIPS | ≥1 | 5.5 | - | 8.0 | - |
| NDDG | ≥2 | 5.9 | 10.6 | 9.2 | 8.0 |
| CDA | ≥2 | 5.3 | 10.6 | 8.9 | |
| EASD | ≥1 | 6.0 | - | 9.0 | - |
| NZSSD[2] | ≥1 | 5.5 | - | 9.0 | - |

[2] World Health Organization (WHO), American Diabetes Association (ADA), Australasian Diabetes in Pregnancy Society (ADIPS), National Diabetes Data Group (NDDG), Canadian Diabetes Association (CDA), European Association for the Study of Diabetes (EASD) and the New Zealand Society for the Study of Diabetes (NZSSD).

Agarwal et al, (2005) in their study in the United Arab Emirates, employed the different diagnostic criteria of six international expert panels on the test results of 2554 women who underwent a 75 gram oral glucose tolerance test (OGTT ) at 24 to 28 weeks gestation. The diagnostic criteria used were those recommended by ADA, ADIPS, NZSSD, WHO, CDA, EASD (see table footnote for abbreviations). The rate of GDM diagnosed ranged from 7.9% to 24.9% and was dependent on the diagnostic criteria applied. Two aspects of pregnancy outcome, caesarean section and macrosomia (birth weight $\geq$ 4000grams), were examined to determine if different criteria were able to predict an adverse outcome. None of the six criteria could reliably do this, although ADIPS criteria came close. The ADIPS criteria represent the broadest guidelines which identified the highest rate of GDM. Whilst the six expert panels agreed that the OGTT was the best method to diagnose GDM, this is where consensus ended.

In the USA and Canada, the 100 gram, three hour OGTT is recommended as the definitive diagnostic test for GDM. At least two abnormal values out of four venous blood samples are required for a positive result and diagnosis of GDM, although the thresholds differ between the two countries (Vidaeff et al, 2003) as listed in Table 4. The European Association for the Study of Diabetes, the New Zealand Society for the Study of Diabetes, the World Health Organization and Australian Diabetes in Pregnancy Society recommend a 75gram oral glucose load. One or more abnormal results are considered diagnostic for GDM, however, the plasma glucose values for a diagnosis of GDM vary amongst the countries (Agarwal et al, 2005). Table 4 displays the varying diagnostic criteria across countries.

## 2.7 Treatment and Outcomes

Treatment and management of GDM is aimed at maintaining glucose levels within a normal range and incorporates dietary modification with carbohydrate restriction, exercise regimes and insulin therapy if required. Although insulin has been the drug of choice if dietary and exercise measures are insufficient to maintain normal glucose levels, a recent randomised controlled trial has been conducted to establish the safety and effectiveness of the oral hypoglycaemic agent, metformin, in pregnancy (Rowan, Hague, Gao, Battin & Moore, 2008). Metformin improves insulin sensitivity without causing hypoglycaemia or weight gain. This study found no difference in adverse outcomes, measured as a composite of neonatal complications, however, despite these findings, the use of metformin in pregnancy remains contentious. The contention arises from the fact that metformin crosses the placenta and could influence fetal physiology, whereas insulin does not cross the placenta under normal circumstances.

The focus of GDM treatment is to limit fetal exposure to hyperglycaemia and the subsequent increase in insulin production by the fetus which accelerates growth. A number of fetal/neonatal morbidities, such as shoulder dystocia, nerve palsies and other birth injuries, are directly related to macrosomia which may result from fetal exposure to maternal hyperglycaemia. Pedersen, in 1952, first proposed the mechanism of macrosomia when a fetus is exposed to maternal hyperglycaemia and this theory has remained fundamental to our current understanding of the fetal effects of GDM today (HAPO, 2008).

The measurement of perinatal outcome is used in a number of studies to determine effectiveness and benefits of treatment of GDM (Langer et al,

2003; Crowther et al, 2005; Johns, Olynik, Mase, Kreisman & Tildesley, 2006; Nordin et al, 2006; Magee et al, 1993; Moses et al, 1998). The method of measuring neonatal perinatal outcome varied to some extent between studies, however, often included macrosomia or large for gestational age infants, shoulder dystocia, hypoglycaemia, hyperbilirubinaemia, admission to neonatal nursery, bone fracture resulting from the difficult birth of large infants, nerve palsy or death. Maternal perinatal outcomes measured included induction of labour, caesarean section, polyhydramnios, hypertension and general health status.

Tuffnell, West and Walkinshaw (2005), in their systematic review of treatment of GDM and impaired glucose tolerance in pregnancy (IGT), found only three studies eligible for inclusion, with a total of just 223 participants. The distinction between IGT and GDM is imprecise due to the variation in diagnostic criteria across the globe. Lesser degrees of glucose intolerance may be classified as IGT. The original WHO classification defined IGT as a blood glucose value of 7.8 - 11mmol/L at two hours after a 75gram oral glucose load, however, from 1998 the WHO classification of GDM changed to include all women with an abnormal OGTT. The WHO threshold blood glucose level was set at 7.8mmol/L. All three studies, admitted to the review, addressed IGT according to the reviewers classification, (blood glucose 7.8 - 11.0mmol/L). No trials examining GDM met the standard for inclusion in the review. Tuffnell, West and Walkinshaw (2005) concluded that insufficient data were available to determine the effect of treatment of IGT on perinatal outcomes. The classification of IGT, in this review, is now classed as GDM according to the WHO and other expert groups' diagnostic criteria. The review highlights the inconsistencies and confusion in the area of GDM and cites the need for large well constructed trials to establish benefits of treatment.

In a letter in the British Journal of Obstetrics and Gynaecology, commenting on the results of the ACHOIS, these same reviewers concluded that 'for the first time there is demonstrable clinical validity to screening for gestational diabetes on the basis of improved obstetric outcomes' (Tuffnell et al 2005).

The ACHOIS (Crowther, Hiller, Moss. McPhee, Jeffries & Robinson, 2005) demonstrated significantly lower serious perinatal outcomes in a treated GDM group when compared with an untreated group (1% v 4%, p= 0.01). In this study it was estimated that 1000 women would need to be enrolled to give a statistical power of 80%, to expose a risk reduction from 5.2% to 2.0% in relation to a serious perinatal outcome. A P value of 0.05 was deemed statistically significant. The study was conducted as a multi-centre, cross-country, randomised control trial, enrolling 1000 women over an almost 10 year period. Study participants were recruited from fourteen hospitals in Australia and four in the United Kingdom. An important aspect of the Crowther et al (2005) study was the profile of the participants. Initially, the women recruited to the trial were classified as having glucose intolerance of pregnancy (IGT) according to the 1985 WHO criteria. In 1998, during the course of the trial, the WHO classification was altered to encompass all women with an abnormal oral glucose tolerance test as having gestational diabetes. The study population, therefore, was at the lower spectrum of glucose intolerance. The mean age of participants was less than 30 years. The women were of predominantly European background and with a mean BMI of 26kg/$m^2$. These characteristics confirmed the women as low risk for developing GDM. Despite the relatively low risk profile of ACHOIS participants, benefits of treatment were convincing. This finding impacts on the argument for universal

OGCT screening of all pregnant women, although this was not the aim of the study.

Eligible women in the ACHOIS (Crowther et al, 2005) were those with a single or twin pregnancy, who were 16 to 30 weeks gestation and attending for antenatal care at one of the eighteen collaborating centres and with a venous plasma glucose reading of 7.8 to 11.0mmol/L following a 75gram OGTT. These thresholds originally placed them in the IGT classification according to WHO guidelines, however as stated earlier, during the course of the study the WHO classification was altered, which then situated the study participants in the GDM group. Women with a blood glucose level of greater than 11.0mmol/L were excluded from the sample, as were those with pre existing active chronic systemic disease or those who had previously been treated for GDM. Women were assigned to one of two groups – the intervention group (n=490) and the routine care group (n=510). The intervention group received dietary advice, self monitored their blood glucose levels and received insulin therapy according to predetermined capillary blood glucose levels. The routine care group received care from clinicians unaware of the diagnosis of GDM. If symptoms or risk factors for GDM arose in this group, screening and treatment were initiated as indicated. Serious perinatal outcomes were measured using a composite tool which included death, shoulder dystocia and fractures and nerve palsy in the infants. Primary maternal outcomes were induction of labour, caesarean section, maternal health status and psychological well being. Secondary outcomes were also measured and included individual components of the composite tool as well as gestational age at birth, birth weight and other health measures for the neonates. Maternal secondary outcomes included the number of antenatal visits,

mode of birth, weight gain during pregnancy, antenatal admissions, pre eclampsia and other complications.

The rate of serious perinatal outcomes, as defined by the primary outcome measures, was significantly lower in the intervention group than the routine care group (1% v 4%, $p < 0.01$). Infants born to women in the intervention group were more likely to be admitted to a neonatal nursery (71% v 61%, $p < 0.01$) despite there being no significant difference in the five minute Apgar score or neonatal jaundice requiring phototherapy or hypoglycaemia requiring intravenous therapy. The increase in neonatal nursery admission may be due to the infants being labeled as 'high risk' or different criteria for admission to the neonatal nursery at the various centres, rather than actual clinical indications. The rate of induction of labour was higher in the intervention group (39% v 29%, $p<0.001$), although the rate of caesarean section births did not differ between the two groups. Maternal health status was measured by self administered questionnaires and results revealed a similar level of anxiety between the two groups. Scores on the Edinburgh Postnatal Depression Scale suggestive of depression were higher in the routine care group (17% v 8%) and more favourable trends for the intervention group on the Short Form General Health Survey at three months postpartum were evident, although not all of statistical significance.

In the ACHOIS there were no perinatal deaths in the intervention group, whilst five were recorded for the routine care group. No significant difference was found between the two groups for shoulder dystocia (1% v 3%), bone fractures (0% v <1%), nerve palsy (0% v 1%) , small for gestational age (7% v 7%), five minute Apgar score less than 7 (1% v 2%) or hypoglycaemia requiring intravenous therapy (7% v 5%). Infants in the intervention group had a significantly lower mean birthweight than those in the routine care group ($p<0.001$). Macrosomia, defined as birthweight

higher than the 90th percentile on standard weight chart, was evident in 10% of the intervention group and 21% of the routine care group. Secondary maternal outcomes revealed women in the intervention group had more visits to the physician, dietitian and diabetic educator, received increased rates of insulin therapy (20% v 3%) and gained less weight. Pre eclampsia was diagnosed less in the intervention group (12% v 18%, p=0.02) when compared with the routine care group. No significant difference was identified between the groups for antenatal admissions, perineal trauma, length of hospital stay, pyrexia, gestational age at birth, postpartum haemorrhage greater than 600mls and breastfeeding at discharge.

An ethical question arises over the design of the study related to the fact that women were assigned to the routine care group but were not informed of their diagnosis. However, the authors argue that no conclusive evidence of the benefits of treatment for GDM existed and there was wide disparity in clinical practice for screening and treatment during the period of the study. This disparity, they claimed, justified their methods. Research directed towards identifying gaps in screening and management of GDM, gauging women's understanding of GDM and its long term implications and comparison of outcomes in different models of care could assist in developing 'best practice' guidelines for GDM.

A case control study by Langer, Yogev, Most and Xenakis (2005), also examined the hypothesis that treatment would improve outcomes with a reduction in perinatal morbidity. Three different groups were compared: Group 1 consisted of 555 women diagnosed with GDM at 37 weeks gestation or later; Group 2 was made up of 1110 women diagnosed and treated for GDM; and, Group 3 comprised 1110 non-diabetic pregnant women. Universal screening by OGCT, followed by OGTT was adopted to

confirm a diagnosis of GDM as defined by ADA criteria. The women in Group 1 did not present for care until late in their pregnancies and therefore were not diagnosed with GDM until greater than 37 weeks gestation. As a consequence, clinicians and women were unaware of the diagnosis as treatment at this late stage of pregnancy was deemed not to affect neonatal outcome. Women in Group 2 were cared for by a multidisciplinary team, taught self monitoring of blood glucose levels, advised about diet and commenced on insulin if glycaemic control (according to pre established levels) was not achieved with two weeks of diet therapy. Group 3 received routine care. Eligibility criteria were women with singleton pregnancies and a fasting plasma glucose less than 7.8mmol/L on OGTT. Excluded from the study were those women who had a multiple pregnancy, were substance users, who had fetal anomalies and women with diabetes which predated the pregnancy. The population samples were drawn over a nine and a half year period from maternal health clinics in a metropolitan, economically disadvantaged area in America. The researchers attempted to eliminate shortcomings of previous studies by increasing the sample size, as well as by matching the women across the groups for age obesity, ethnicity, parity and gestational age at birth. The sample was further stratified according to BMI to assess the confounding factor of obesity on GDM outcomes. The primary neonatal outcome was measured as a composite variable, as in the ACHOIS. The composite variable was composed of stillbirth, macrosomia, large for gestational age infant, hypoglycaemia, erythrocytosis and hyperbilirubinaemia. The separate components of the composite variable were also compared across the three groups, as well as, birth weight, ponderal index, arterial cord blood pH, metabolic complications, respiratory distress, shoulder dystocia and caesarean section rates.

The results showed a significantly higher rate of adverse outcome (again measured by a composite variable) for Group 1 (59%), when compared with Group 2 (18%) and Group 3 (11%). Further stratification according to maternal BMI and disease severity (based on fasting plasma glucose) revealed significantly higher rates of adverse outcomes for the untreated women in Group 1 when compared with the treatment Group 2 in all severity categories. In the lowest severity category, the untreated Group 1, significantly lower rates of adverse outcomes were identified, suggesting a link between disease severity and adverse outcome. Following logistic regression analysis, the authors concluded, that in the untreated Group 1, previous macrosomia, degree of weight gain in pregnancy, obesity, parity and fasting plasma glucose levels were significant contributors to the adverse neonatal outcome score. Maternal age, ethnicity, family history, gestational age at birth, pre eclampsia and chronic hypertension did not impact significantly on outcomes. The question arises as to whether the overall poorer antenatal care of Group 1, who presented very late in their pregnancies, with fewer antenatal visits recorded than the other two groups, contributed to the higher rate of adverse outcomes for the group. The authors concluded that timely and effective treatment of GDM may improve outcomes.

The hyperglycaemia and adverse pregnancy outcome (HAPO) study (HAPO Study Cooperative Research Group, 2008) was conducted with the aim of determining the risk of adverse outcomes associated with different levels of maternal glucose intolerance, specifically maternal glucose levels below those diagnostic of GDM. The study was conducted as a prospective, observational epidemiological study which enrolled 25,505 women at 15 centres across 9 countries. These women underwent a 75gm OGTT and results were blinded if the fasting plasma glucose level was $\leq$ 5.8mmol/L or

≤ 11.1mmol/L at 2hours post glucose load. Data for 23,316 participants were blinded and analysed. Primary outcome measures were birth weight above the 90$^{th}$ percentile for gestational age, primary caesarean section, clinical neonatal hypoglycaemia and cord blood serum c-peptide level above the 90$^{th}$ percentile. Serum c-peptide measurement was used as an alternative to cord insulin levels. Cord blood samples may be haemolysed in approximately 15% of cases which affects the insulin level. C-peptide is co secreted with insulin in equal amounts but is unaffected by haemolysis and is therefore a more reliable measure of insulin levels in cord blood samples and thus indicates fetal beta cell function. Secondary outcomes were premature birth (<37 weeks gestation), shoulder dystocia or birth injury, admission to neonatal intensive care, hyperbilirubinaemia and pre eclampsia. There was a strong association with rising maternal glucose levels (as determined by OGTT) and adverse outcome measures as described above. This association was particularly evident in relation to birthweight above the 90$^{th}$ percentile for gestational age and cord blood serum c-peptide measures above the 90$^{th}$ percentile. No obvious thresholds for increased risk of adverse outcome were identified by the HAPO study.

The strengths of the HAPO study include its size and the diversity of study participants across 9 countries. Standardised data collection and the analysis of samples at a centralised laboratory ensured consistency and quality of results. Blinded data minimised caregiver bias. However, several limitations exist in the conduct of the study which include the definition of GDM – the plasma glucose thresholds used to classify women with maternal glucose levels below that of GDM are those proposed by the WHO prior to 1998. The changes to the WHO thresholds in 1998 mean that a number of the women included in the blinded data population would now be classified as having GDM. The knowledge of caregivers of other factors

such as previous GDM, macrosomia and maternal BMI may have prompted some clinical decisions like the mode of birth, which may have influenced pregnancy outcomes. Pregnancy weight gain data were not collected in the study and this may have had an impact on perinatal outcomes. Possible variation in 'usual practice' in regard to antenatal care, timing of birth, induction of labour and neonatal care at the participating centres may also have had an influence on results.

Whilst determining the efficacy and benefit of screening for GDM were not the primary aims of this study, the results along with the outcomes of the ACHOIS contribute significantly to the debate in favour of screening for and treating women with GDM to improve perinatal outcomes. The long term consequences for the babies of mothers' with GDM are also of concern. The development of obesity in childhood, through to adulthood, abnormal glucose metabolism, Type 2 diabetes and metabolic syndrome have all been implicated as a result of fetal exposure to a hyperglycaemic intrauterine environment, as may be seen in GDM (Vohr & Boney, 2008; Metzger, 2007).

## 2.8 Summary

In summary, the literature reveals a lack of consensus on screening, diagnosis and the impact of treatment of GDM, with a wide variation in strategies recommended by the expert bodies globally and largely based on consensus. The most recent research supports the hypothesis that identification and treatment of GDM does improve outcomes for mothers and babies (Crowther et al, 2005; Langer et al, 2005; Leipold, Worda, Gruber, Kautzky-Willer, Husslein & Bancher-Todesca, 2004, HAPO Study Cooperative Research Group, 2008).

It is envisaged that the research in this thesis will reveal similar differences in approach to the screening, diagnosis and management of GDM within the SESIAHS. Identifying the current practices will provide the opportunity for review and development of guidelines based on the most recent available evidence area wide. The next chapter describes the research undertaken, including the design, method, sample, data sources, analysis, ethical considerations and approval process.

# CHAPTER 3: The Research

## 3.1 Introduction

The research question for this thesis is, what are the current practices and levels of screening and diagnosis of GDM at three sites across the SESIAHS? The question was formulated to determine the practices related to screening for GDM in the SESIAHS, with the aim of developing a uniform, evidence based guideline for the entire area health service.

The first objective of the study was to identify the range of practices employed for screening and diagnosis of GDM across the SESIAHS. This was addressed by the examination of policies and guidelines at the three selected sites. The second objective of the study was to assess the level of screening by OGCT and adherence to site policies regarding screening. This was ascertained through medical record audit of 90 to 100 records at each of the three sites. The intention was to examine 100 medical records at each site, however, at one site only 90 records were available for audit. The third and final objective of the study was to establish the incidence of GDM in women giving birth at the three sites. Data from the Midwives Data Collection (MDC) for births at the three sites for the years 2002 to 2005 provided this information.

## 3.2 Research Design and Method

A retrospective, quantitative descriptive study design was used to address the research question, with comparisons between sites. This approach was used to provide an account of the GDM screening practices at three sites within the SESIAHS, to examine the characteristics of the women giving birth at these sites and to establish the level of diagnosis of GDM. The differing demographic composition of the three populations was compared

alongside the rates of GDM to reveal any variation between sites. An extensive literature review was conducted to construct a picture of the history of GDM, the debate over screening and the current recommendations based on evidence for the antenatal management of GDM. A summary of the literature review is found in Chapter 2.

Policy and guideline documents were examined at the three sites to identify the range of practices used for the screening and diagnosis of GDM across the SESIAHS. An audit of medical records was conducted at each site to assess the level of screening by OGCT and to assess adherence to site policies. Time and resource limitations determined the number of records examined per site with the aim of creating a snapshot of practices and adherence to policy across the sites. Data for all births at three sites across the SESIAHS were collected for the years 2001 to 2005 inclusive, to determine the incidence of GDM at the three sites. These aspects of the study are described in more detail in this chapter

## 3.3 Sample

There were three components to the study sample. The first component of the sample was the policies and guidelines from the three sites, related to screening for GDM. The second component of the sample was the 90 to 100 medical records examined from each site. One hundred medical records were selected for audit at each site; however, at Site 3 only 90 records were available. The final component of the sample consisted of all women who gave birth at three sites in the SESIAHS from 2001 to 2005 inclusive. Demographic data accessible via the MDC were used to generate a profile of the women who gave birth at the three sites. A table comparing the age, ethnicity, Aboriginality and parity of the three sub samples was then produced, along with the rates of GDM diagnosed. For the women at

these 3 sites, English speaking born denotes born in Australia, New Zealand, United Kingdom and Ireland. Middle East and Africa signifies women born in Iraq, Lebanon and Egypt. Melanesia, Micronesia and Polynesia represents women born in Fiji and Tonga. South East Asian women were born in Indonesia, Malaysia, the Philippines and Vietnam. North East Asian women were born in China, Hong Kong and Japan. Bangladesh, India, Nepal and Pakistan are grouped as Southern Asia and Macedonia, Serbia and Montenegro as Southern Europe. These groupings of country of maternal birth are in accordance with those used by the MDC and the NSW Mothers and Babies Reports.

The three study sites were purposefully selected to incorporate the different role delineations[3] (Appendix A) and models of antenatal care available within the Area Health Service. The three sites are: 1) a rural or regional site, where antenatal care is fragmented and delivered by general practitioners (GP) and obstetricians in the community, 2) a metropolitan site, where GP shared care, midwives clinics and team midwifery are antenatal care options and 3) a referral institution, where women with higher risk pregnancies may receive antenatal care. Antenatal care options at this site include caseload and team midwifery models, GP shared care, midwives clinics and private obstetric care.

The total number of births at the three hospitals during the five year period was: site 1) 3,894; site 2) 10,008; site 3) 11,233, giving an overall total of 25,135 births. The selection of these three sites represents a cross-section of the differing role delineations of hospitals in the SESIAHS and the various antenatal models of care available. The age, parity and ethnicity of the women giving birth at the three study sites were also compared.

[3] NSW Health designates role delineations of health services according to the level of care available at the health facility.

Table 5: Summary of site characteristics

| | Site 1 | Site 2 | Site 3 |
|---|---|---|---|
| **Description** | Rural/regional | Metropolitan | Referral |
| **Antenatal care options** | GP &/ or obstetrician in the community | GP shared care, midwives clinics, Team midwifery, private Obstetrician | Caseload, team midwifery, GP shared care, midwives clinic, private Obstetrician |
| **Role delineation** | Low to moderate risk pregnancies & births ≥ 34 weeks, level 4 role delineation | Low, mod & high risk pregnancies births ≥ 32 weeks, level 5 role delineation | Low, mod & high risk pregnancies & births ≥ 32 weeks, level 5 role delineation |
| **Total births 2001-2005** | 3,894 | 10,008 | 11,233 |

## 3.4 Variables

The primary variables of interest for the three sites included:

- the different policies and guidelines for each site;
- the number of women screened by OGCT;
- the number of women diagnosed with GDM by site; and,
- the number of births at each site and the role delineations of the three sites.

Additional variables of interest include those factors that are known to influence the incidence of GDM – age, parity and ethnicity. These were considered for each site to assess factors which may influence the rate of

GDM diagnosed at each site. It was not possible to collect from the study population a number of other variables, such as BMI, previous GDM and/or previous macrosomic infant, which are known to impact upon the incidence of GDM.

### 3.5 Data Sources

The institutional policies and guidelines relating to screening practices for GDM were examined to determine stated practices for each site. A checklist to assist in the examination of the site documents related to screening practices for GDM was formulated to ensure consistency in the review of the documents. The checklist (Appendix B) asked a series of questions which focussed on whether a guiding document for the screening of GDM existed at each site, if the document advocated universal screening for GDM or selective screening based on the presence of risk factors, or another strategy for screening for GDM. Additional information, such as the method of universal screening (OGCT or OGTT) and what was considered to be risk factors, was also sought from the document. A detailed description of the documents is given in the results chapter.

A sub sample of women's medical records was examined at each site to ascertain the practices employed to screen for GDM and the percentage of women screened by OGCT or an alternative method. The records of 100 women, who gave birth at the different facilities during 2005, were selected for this purpose. The medical records for review were selected at the three sites by dividing the number of site births for 2005 by 100. This equated to every 8th record at Site 1, every 23$^{rd}$ record at Site 2 and every 22$^{nd}$ record at Site 3. If the selected medical record was unavailable the record immediately preceding or following was selected for audit. At two of the three sites medical record staff located the selected records and made them

available for audit. At Site 3 this task was performed by the researcher and an assistant. A new appreciation of the time and effort involved to undertake medical record audits developed during this phase of data collection.

A template audit tool (Appendix C) was generated to ensure uniformity in the review of the medical records. A list was also formulated for the purposes of identifying women with risk factors for GDM via the medical record audit. Factors included were age $\geq$ 30 years, weight $\geq$ 70kgs on booking, high risk ethnic groups, Aboriginality, multiparity $\geq$ 4, family history of diabetes, previous GDM, previous baby $\geq$ 4kgs and previous stillbirth.

The audit tool was piloted on 20 medical records at Site 1 to ascertain its suitability, and with minor changes was used for the complete medical record audit. Records from 2005 were examined to establish the most recent practices at the three study sites. Adherence to site policy and guidelines was gauged from the medical record audit.

The NSW Mothers and Babies Reports[4] for the years 2001 to 2005, inclusive, collected partially via the NSW Midwives Data Collection (MDC), provided data for the majority of the variables of interest and were accessed via the Population Health Division of the NSW Department of Health. Data were available at the individual hospital level. The NSW MDC is reliant on information submitted in either written or electronic form by midwives and doctors attending births in NSW. In 2004, 66% of MDC information was electronically submitted by email or disk. All NSW births in public and private hospitals, as well as homebirths are included in

[4] The NSW Mothers and Babies Report is generated annually by NSW Department of Health from data received from the NSW Midwives Data Collection, the NSW Birth Defects Register, the Neonatal Intensive Care Units Data Collection, Maternal and Perinatal Death Reviews and NSW Inpatient Statistics Collection.

the MDC, regardless of the usual place of maternal residence. A study conducted to assess the accuracy and reliability of NSW Inpatients Statistics Collection and perinatal data collection (including MDC) showed a high level of overall agreement (Taylor, Travis, Pym, Olive & Henderson-Smart, 2005). GDM was found to be well reported, although Moses, Webb and Comber (2003) maintain that the condition is under reported following a comparison between the MDC and a medical record audit at three hospitals in the Illawarra region[5]. The overall incidence of GDM in NSW, according to the NSW Mothers and Babies Report, 2005, was 4.7% (Centre for Epidemiology and Research, 2005). This would equate to approximately 1181 cases of GDM across the three sites in the study period and provide opportunities for comparison between the samples.

In summary, examination of policies and guidelines established the current stated practices related to screening for GDM at the three sites. The medical record audit answered the question about the number of women screened by OGCT or any other method and whether policy and practice concurred. Standard forms were developed and used to assess these documents to ensure uniformity of data collection. Data from NSW Mothers and Babies Reports provided information on the number of births at each site, the number diagnosed with GDM and the demographic data (age, parity, Aboriginality and ethnicity) for comparison between sites.

### 3.6 Analysis

A detailed account of the three sites is given, including role delineations and the antenatal care options available to women. The policy and guideline documents are described to draw attention to the inconsistency of

[5] The Illawarra region forms part of the SESIAHS

antenatal GDM screening practices between sites within the one area health service.

The findings of the medical record audit are described and also displayed in table format to allow for comparison of results. Included in the table are the proportion of women with an identified risk factor for GDM, those women with a risk factor who have no evidence in the medical record of screening, the percentage of medical records with evidence of screening for GDM by OGCT or OGTT and the level of adherence to site policies.

The data acquired from the MDC was tabulated and compared between sites to establish any differences in the maternal characteristics and the incidence of GDM. The incidence of GDM in NSW as a whole was also included for evaluation purposes. Likely reasons for variations in the incidence of GDM between sites, based on the demographic data, are discussed.

### 3.7 Ethical implications and approval process

Ethics approval for the research was sought and gained from the University of Technology Sydney Human Research Ethics Committee (HREC) and the lead Ethics Committee of the SESIAHS. Ethics approval reference numbers are 2007-127A and HEO7/235 respectively (Appendix D). The University of Technology Sydney criteria for the levels of risk in research deem this form of study low risk.

Initially applications for ethics approval were prepared for two committees within the SESIAHS, however, in 2007 the NSW Health Department issued a policy directive which outlined the process for a single ethical and scientific review of multi-centre research (PD2007_044, NSW Health, 2007). Designated lead human research ethics committees (HREC) were

authorised to review and approve ethics applications for research at multiple sites within the NSW public health system. This single review system improved the efficiency of the ethics approval process enormously. In addition to the application to undertake research involving human participants, a privacy form and written evidence of approval from each site was required by the lead HREC of the SESIAHS.

Applications to access medical records at the three sites were submitted to the department managers. Evidence of ethics approval and site management approval accompanied these applications.

The Health Records and Information Privacy Act, 2002 (2004), Statutory Guidelines, outline 4 criteria under which health information may be used without the consent of the person. By permanently removing all identifiers at the time of data collection, all four criteria were met.

Discussions with the custodians of the MDC confirmed there was no requirement for ethics approval to access de-identified data. A request for further data to the MDC custodians, at a later stage of the research required an undertaking by a responsible person to sign a confidentiality agreement to ensure security of the data. The research supervisor agreed to be the person accountable for the security of the data.

As all data from the NSW Mothers and Babies Reports[6] are de-identified, the privacy of individuals is assured and no harm or risk to participants is anticipated. Information obtained via the medical record audit was also de-identified at the point of collection, with a number assigned to each record, thus ensuring the privacy of individuals. The size of both the overall

[6] The NSW Mothers and Babies Report is generated annually by NSW Department of Health from data received from the NSW Midwives Data Collection, the NSW Birth Defects Register, the Neonatal Intensive Care Units Data Collection, Maternal and Perinatal Death Reviews and NSW Inpatient Statistics Collection.

sample and the sub-sample of medical records precluded any inadvertent identification of study participants. Minority groups, such as Aboriginal and Torres Strait Islander women, members of other ethnic groups and young mothers are quantified as a percentage of the overall sample, however, as for all other study participants, individuals are not identifiable.

The National Statement on Ethical Conduct in Research Involving Humans (National Health & Medical Research Council,1999) states in Clause 1.11, "it is ethically acceptable to conduct certain types of research without obtaining consent from participants" – this research is one of these categories, that is, de-identified data in epidemiological research. Therefore, no consent was required from individual study participants.

De-identified data was stored electronically with disk back up and located in a locked filing cabinet and office. Access to the data is limited to the student and supervisor/chief investigator. Data will be archived electronically in the described manner for a period of at least five years as per the Australian Code for the Responsible Conduct of Research (2007).

# CHAPTER 4: Results

## 4.1 Introduction

This chapter details the results of the research undertaken and includes a description of the policy and guideline documents, highlighting the disparity between sites and the findings of the medical record audit. The site and population characteristics and the incidence of GDM across the sites also form part of this chapter and are described in detail. The disparity of opinion and practice around screening and diagnosis of GDM evident in the review of the literature was also apparent on examination of the guideline documents at the study sites with no uniform approach identified even within the one area health service.

## 4.2 Policies and guidelines related to screening for GDM

Utilising the checklist developed for the purpose, policy and guideline documents from the three sites were examined. The findings of this examination are set out below under site headings.

### *4.2.1 Site 1(A Rural/regional public hospital)*

During the study period, Site 1 had no policy or guideline in relation to the antenatal screening for GDM. The absence of such documents was due to the unavailability of a public antenatal care option for women at this site. Consequently all antenatal care was delivered by General Practitioners (GP) or obstetricians within a private practice setting.

The local Division of General Practice[7] has developed and distributed a document which outlines normal pregnancy care and recommended tests to be offered in pregnancy. Included in the document is the recommendation

[7] Local incorporated association of GPs providing education and resources for GPs.

to offer all women an OGCT at 24 – 28 weeks gestation to screen for GDM.

There is no process for ensuring any standard of antenatal care is met and no obligation to follow the suggested guidelines within the document. Thus, antenatal care is at the discretion of the practitioner. No accreditation process for antenatal care givers exists in this area. The role delineation for Site 1 is level 4.

*4.2.2 Site 2 (A Metropolitan public hospital)*

During the study period, Site 2 had a policy of offering an OGTT to all women at 28 weeks gestation. This is a one step process to screen for, and diagnose, GDM. No description of the process of OGTT is given. The document was last reviewed and approved in 2007. Despite the policy for universal screening by OGTT, an educational note within the document states that the current literature does not support routine testing for GDM in women without risk markers. An antenatal care document guides GPs and midwives with a schedule of visits and tests and investigations to be offered to pregnant women.

Women at Site 2 are able to access a variety of antenatal care options including GP/midwife shared care, GP care only, private obstetrician and team midwifery care. An accreditation program is in place for GPs who wish to participate in the shared care of antenatal women. The role delineation for Site 2 is level 5.

*4.2.3 Site 3 (A Referral hospital)*

During the study period Site 3 had a guideline which advocated screening for GDM by exception. That is, all women are offered an OGCT at 26 to 28 weeks gestation except those who meet all the following criteria – Anglo-

Celtic background, age ≤ 30 years, ≤ 70kg pre pregnant weight and no family history of diabetes. Women classified at high risk of GDM - previous GDM, strong family history and glycosuria at booking are offered screening by OGTT at the booking in appointment. If the initial OGTT in high risk women is performed earlier in the pregnancy and yields a negative result, it is repeated at 26 to 28 weeks gestation. A detailed explanation of the OGCT and the OGTT, including glucose thresholds for a positive result, is given in the document. The document was last reviewed and approved in 2007.

Antenatal care options available to women at Site 3 included caseload and team midwifery, GP shared care, public obstetric care, midwives clinics and private obstetric care. The role delineation for Site 3 is level 5. Descriptions of the role delineation levels are given in Appendix A.

### 4.3 Medical Record Audit

A sub-sample of women's medical records was examined at each site to ascertain the practices employed to screen for GDM and the percentage of women screened by OGCT or an alternative method. The medical record audit also gauged adherence to stated site policies. The sub-sample size of 100 medical records per site was chosen due to time and resource constraints and provided a snapshot of practices across the area. In the section on data sources a more comprehensive explanation of how the medical records were selected is presented.

At Site 3, only 90 medical records were examined as 10 of the requested records were unavailable on the day of audit. Due to limited resources there was no opportunity to return to Site 3 to access an alternative 10 medical records.

**Table 6: Summary of findings of Medical Record Audit**

| Site | 1 | 2 | 3 |
|---|---|---|---|
| Total records reviewed | 100 | 100 | 90 |
| Women with identified risk factors for GDM | 78 (78%) | 61 (61%) | 82 (91%) |
| Women Screened by OGCT or OGTT | 88 (88%) | 76 (76%) | 77 (85%) |
| Women who had a risk factor with no evidence of OGCT/OGTT[8] | 11 (11%) | 14 (14%) | 10 (11%) |
| Proportion of women who were not screened according to policy | No policy | 24% | 11% |

[8] Risk factors were identified according to a list developed for audit purposes. Risks included age ≥30 years, weight ≥70kgs on booking, high risk ethnic groups, Aboriginality, parity ≥4, family history of diabetes, previous GDM, previous baby ≥4kgs and previous stillbirth.

In summary, at Site 1 where there is no antenatal screening policy for GDM, 88% of sampled women were screened using an OGCT. At Site 2, with a stated policy of universal screening by OGTT, 76% of women were screened by this method or an OGCT. The screening 'by risk factor policy' at Site 3, resulted in 85% of sampled women being screened by OGCT. Across the sites, this audit showed that 11 – 14% of women with identifiable risk factors for GDM did not have evidence of an OGCT or OGTT in their medical record, regardless of the variation in policies.

The policy for universal screening at Site 2 could not be verified by documentation in 24% of the medical records, whilst the policy for screening by exception and risk factors, in use at Site 3, was not supported

by documentation in 11% of the medical records. Therefore, in these records adherence to site policies and guidelines was not demonstrated.

## 4.4 Site and Population Characteristics

### *4.4.1 Site 1(A Rural/regional public hospital)*

Site 1 had a total of 3,894 births in the five year study period. The number of births ranged from 695 – 885 births per annum.

The role delineation[9] (Appendix A) of Site 1 is to manage low to moderate risk pregnancies and births from 34 weeks gestation. As previously outlined this site did not offer any public antenatal care option for women and all antenatal care was provided by GPs and obstetricians in the private practice setting. Women are seen by the midwives at a booking visit and then may not present to the health facility again until admitted in labour.

The women who gave birth at Site 1 during the study period were more likely to be less than 20 years old, Aboriginal or of English speaking background and multiparous than at the other sites. Greater than 95% of women at Site 1 were born in Australia, New Zealand and the United Kingdom in the five year study period and 7.3% identified as Aboriginal. More women were 30 years old or greater than at Site 2 (42%, 2001-2005), but less than at Site 3 (see Table 8).

### *4.4.2 Site 2 (A Metropolitan public hospital)*

A total of 10,008 births occurred at Site 2 in the five year study period, ranging from 1,795 to 2,264 births per annum. The role delineation for Site 2 is to manage low, moderate and high risk pregnancies and births from 32 weeks gestation. Antenatal care options at Site 2 included GP/midwife

[9] Role delineations of NSW Public Health Institutions are designated according to the level of care and services available at the site. The higher the role delineation the higher the level of care available.

shared care, GP only care, private obstetric care and team midwifery.

Women at Site 2 were more ethnically diverse than at Site 1, but less so than at Site 3. They were more likely to be of Aboriginal background than women at Site 3. Greater than 87% of women were born in Australia, New Zealand and the United Kingdom during the 5 year study period and 2.9% identified as Aboriginal. More women at Site 2 were multiparous when compared with the Site 3 population. Site 2 recorded the least number of women 30 years of age or older (40%, 2001-2005).

*4.4.3 Site 3 (A Referral public hospital)*

Site 3 had a total of 11,233 birth in the 5 year study period from 2001 – 2005. The number of births ranged from 2,199 to 2,304 per annum. The role delineation for Site 3 is to manage low, moderate and high risk pregnancies and births from 32 weeks gestation. Antenatal care options for women at Site 3 included caseload and team midwifery, GP shared care, public obstetric care, midwives clinics and private obstetric care.

Women giving birth at Site 3 during the study period were a more ethnically diverse group than at the other 2 sites. Only 56% of women were recorded as born in an English speaking country at Site 3, compared with >95% at Site 1 and >87% at Site 2. At Site 3, more than 31 % of women were recorded as born in a country where the risk of GDM is high.

Women at Site 3 were more likely to be older (51% $\geq$30 years, 2001-2005), primiparous and born in a non English speaking country than at the other sites. They were also less likely to be Aboriginal than at the other sites. Data on Aboriginality for 2001 and 2002 were unavailable for Site 3, however data for the three years from 2003 to 2005 record less than 0.3% of women as Aboriginal.

## 4.5 Gestational Diabetes across the sites

**Table 7: Diagnosis of GDM by year & site**

| GDM by year | Site 1 | Site 2 | Site 3 | SESIAHS* | NSW# |
|---|---|---|---|---|---|
| **2001** | 21 (3.02) | 109 (5.68) | 125 (5.47) | 576 (3.66) | 3.8% |
| **2002** | 26 (3.28) | 105 (5.84) | 132 (6.00) | 638 (4.00) | 4.4% |
| **2003** | 22 (3.07) | 108 (5.57) | 123 (5.51) | 645 (4.07) | 4.5% |
| **2004** | 24 (2.71) | 86 (4.10) | 152 (6.85) | 605 (3.85) | 4.3% |
| **2005** | 41 (5.08) | 134 (5.91) | 163 (7.07) | 699 (4.31) | 4.7% |
| **Births for 5 years** | 3,894 | 10,008 | 11,233 | 79,363 | |

* The three study sites do not constitute all maternity services across the SESIAHS

# Data from Mothers and Babies Reports years 2001 to 2005

The table above summarises the incidence of GDM at the 3 sites. In the entire SESIAHS[10] the incidence of GDM was 3.7% in 2001, 4.0% in 2002, 4.1% in 2003, 3.9% in 2004 and 4.3% in 2005. Comparing these percentages with the ranges at the three sites, it can be seen that only Site 1 had a similar incidence of GDM from 2001 to 2004 and in all other years and sites the incidence of GDM was greater than that for the SESIAHS and the overall incidence for NSW. The diverse ethnic background of women at Site 2, and particularly at Site 3 may go some way to explaining the higher rate of GDM diagnosed. Women at Site 1 were more likely to be Aboriginal than the other 2 sites and this may have contributed to the increased incidence of GDM.

[10] The three study sites do not constitute all maternity services available across SESIAHS

**Table 8: Characteristics of the women from the three sites**

| 2005 | Site 1 | Site 2 | Site 3 |
|---|---|---|---|
| **Aboriginal and Torres Strait Islander women** | 60 (7.4%) | 63 (2.8%) | 6 (0.3%) |
| **Maternal Age** | | | |
| <30yrs | 449 (55.6%) | 1328 (58.6%) | 1074 (46.6%) |
| ≥30yrs | 358 (44.3%) | 934 (41.25%) | 1225 (53.2%) |
| Unknown | 0 | 2 (0.08%) | 5 (0.2%) |
| **Maternal Country of Birth** | | | |
| English speaking | 773 (95.8%) | 2006 (88.6%) | 1269 (55%) |
| Melanesia/Micronesia/Polynesia* | 0 | 0 | 40 (1.7%) |
| Middle East/Africa* | 0 | 28 (1.2%) | 201 (8.7%) |
| South East Asia* | 0 | 18 (0.8%) | 128 (5.5%) |
| North East Asia* | 0 | 16 (0.7%) | 291 (12.6%) |
| Southern Asia* | 0 | 0 | 98 (4.3%) |
| Southern Europe* | 0 | 24 (1.0%) | 31 (1.3%) |
| Unknown | 34 (4.2%) | 172 (7.6%) | 246 (10.7%) |
| **Number of previous pregnancies** | | | |
| < 2 | 719 (89%) | 2027 (89.5%) | 2114 (91.8%) |
| >3 | 88 (10.9%) | 237 (10.5%) | 190 (8.2%) |
| **Total births** | 807 | 2264 | 2304 |

* Indicates those women whose ethnic backgrounds put them at high risk of GDM.

English speaking women were those born in Australia, New Zealand, United Kingdom and Ireland. Middle East and Africa signifies women born in Iraq, Lebanon and Egypt. Melanesia, Micronesia and Polynesia represents women born in Fiji and Tonga. South East Asian women were born in Indonesia, Malaysia, the Philippines and Vietnam. North East Asian women were born in China, Hong Kong and Japan. Bangladesh, India, Nepal and Pakistan are grouped as Southern Asia and Macedonia, Serbia and Montenegro as Southern Europe. These groups correspond to the groupings used in the NSW Mothers and Babies Reports.

# CHAPTER 5: Discussion and Recommendations

## 5.1 Introduction

The research undertaken highlights the lack of consistency in the approach to antenatal screening for GDM in the SESIAHS. This disparity is a reflection of the national and global situation. Recent research supports a universal offer of screening for GDM to all women (Cosson et al, 2006; Moses et al, 1998; Polyhonen-Alho, 2005; Tan et al, 2007). Several known risk factors for GDM, including increasing maternal age and obesity levels, are rising, and with them the expectation that the incidence of GDM will also escalate.

The overall aim of this research was to form the basis for the development of evidence-based guidelines which could be applied across the Area Health Service. The objectives of the research were to identify what screening policies and guidelines were in current use, the number of women screened for GDM, the adherence to site policies and guidelines and the incidence of GDM across the SESIAHS. Screening strategies for women differed at the three sites, with no uniform policy or guideline identified. Screening for GDM by OGCT or OGTT occurred for 76 to 88% of the women. Adherence to site policies and guidelines was absent 11 to 24% of the time. The incidence of GDM at the three study sites was higher than for the SESIAHS (inclusive of all maternity services within SESIAHS) and NSW. The incidence of GDM at the three sites increased over the study period. A high level of risk factors for the development of GDM was apparent at all three study sites and ranged from 61 to 91% of women. The implications for clinical practice are discussed in detail in this chapter.

## 5.2 Implications for Clinical Practice

The aim of the research was to form the basis for the development of appropriate evidence based guidelines for screening for GDM in SESIAHS, by identifying the current range of practices, the number of women screened via OGCT and the incidence of GDM. Examination of past and current research was undertaken to ascertain what may be considered best practice for GDM screening.

The hyperglycaemia and adverse pregnancy outcomes study demonstrated a clear association of increasing blood glucose levels and adverse pregnancy outcomes (HAPO study Cooperative research group, 2008), whilst the ACHOIS in pregnant women (Crowther et al, 2005) showed a significant reduction in perinatal morbidity with treatment of GDM. These two large randomised controlled trials support the view that screening for and treating women with GDM would improve outcomes. Both these studies enrolled women who by earlier definitions would not have been classified as GDM. That is, women with less severe carbohydrate intolerance, and yet they demonstrated an increased risk of adverse outcomes and improvement with treatment.

Several studies (Cosson et al, 2006: Polyhonen-Alho et al, 2005: Tan et al, 2007; Moses et al, 1998) conclude that risk based screening of women overlook a significant number with GDM and therefore advocate universal screening by OGCT (2 step: screen then diagnostic test if positive) or OGTT (1 step diagnostic test).

Considering these findings, that is, a significant number of women with GDM overlooked by risk-based screening, the association of rising carbohydrate intolerance with adverse pregnancy outcomes and a demonstrated improvement in outcomes with treatment, it would seem

prudent to offer screening by OGCT or OGTT to all women. In addition to the potential for GDM to adversely affect the pregnancy and birth, evidence suggests that the onset of Type 2 diabetes can be delayed or even prevented by lifestyle changes and treatment with metformin. (Tuomilehto, Lindstrom, Eriksson & Valle, 2001; Ramachandran, Mary, Snehalatha, Ping & Yamuna, 2007; Diabetes Prevention Program Research group, 2002). Therefore, a diagnosis of GDM represents an opportunity for women to adopt lifestyle changes and/or commence treatment to delay or avert Type 2 diabetes, as was the original intention of GDM screening programs.

It is known that the intrauterine environment may have long term consequences on the children of women with GDM, in the form of childhood obesity, impaired glucose metabolism and the development of Type 2 diabetes. There is also evidence to suggest a link with an increased risk of metabolic syndrome in the children of women with a history of GDM. This association is increased with higher glycaemic levels in the third trimester of pregnancy (Vohr & Boney, 2008). These risks may be ameliorated by normalising blood glucose levels with treatment of GDM.

Another aspect of the research to consider is the level of risk factors identified in the women at all three sites during the medical record audit. At Site 1, 78% of women had at least one risk factor for GDM; at Site 2, 61% had at least one risk factor for GDM and at Site 3, 91% had at least one risk factor, on examination of the medical records. Given this high level of identified risk and the lack of evidence in the medical record of OGCT or OGTT screening in 11 – 14% of these women, a universal screening policy would eliminate any confusion over whether to screen or not. The inclusion of GDM screening and diagnostic testing on the newly developed Area Health Service antenatal clinic record document and educational checklist

may serve as a reminder to antenatal care providers to discuss and offer screening to all women. The Obstetrix database is now used by all maternity services across SESIAHS and GDM screening appears as a field within the database, providing another prompt to offer all women screening. This may assist in improving compliance in those women with identified risk factors for GDM. The new antenatal clinic record and educational checklist, as well as the use of the Obstetrix database on an area-wide basis may also enhance the documentation of the decision process when OGCT is offered to women. It could be argued that selective screening adds an unnecessary layer of complexity to the screening and diagnosis of GDM which could result in some women who would benefit from treatment being overlooked. In New Zealand a similar situation was apparent in a review of 4,953 medical records by Yappa and Simmons (2000). Universal screening by OGCT of all pregnant women is recommended in New Zealand, with consideration for selective screening if there are limited resources available. Their review found that 53% of Maori women and 31% of Pacific Islander women (both high risk ethnic groups) were not screened and hypothesised that the complexity of implementing a risk based selective screening approach resulted in women at high risk of GDM being omitted. The reviewers further suggest that since only a small number of women have no risk factors at all for GDM, debate over whether to screen or not may be undermining appropriate GDM screening and treatment for the majority. The medical record audit conducted during this study revealed a high level of risk factors for GDM at the three sites. It is likely that with rising levels of obesity in the general population, an even greater number of women will present for antenatal care who are overweight or obese and therefore fall into the 'at risk' group for GDM (Callaway, Prins, Chang & McIntyre, 2006).

A number of other screening tests are routinely offered to women in pregnancy. Not all of the conditions screened for, or the tests used, fulfil the attributes outlined by Wilson and Jungner in 1968 which make them suitable for screening (cited NICE Antenatal Care Guidelines, 2008). For example, the NICE Antenatal care Guidelines (2008) do not recommend offering women Hepatitis C screening, citing insufficient evidence to support this practice. However, the Royal Australian and New Zealand College of Obstetricians and Gynaecologists recommend universal screening for Hepatitis C (College Statement, C-Obs 3, RANZCOG, 2008). There are no interventions currently available for Hepatitis C which reduces the risk of vertical transmission of the disease. Hence, it could be argued that pregnancy is not the most appropriate time to make a diagnosis of Hepatitis C (Hunt & Lumley, 2002). Universal screening of pregnant women for syphilis is the usual practice in Australia and yet the prevalence of the disease is low and high risk groups are identifiable. Other screening tools with uncertain or insufficient evidence to support their use, yet widely applied in Australia, include screening for domestic violence, antenatal screening for postnatal depression and group B streptococcus screening (NICE, 2008). In the light of recent evidence, screening for GDM would appear to be a worthy inclusion in those tests universally offered to women during pregnancy.

The NICE Antenatal Care Guidelines (2008) assert that women should be afforded the opportunity to make informed decisions about the care and treatment they receive in pregnancy. These decisions should be made in partnership with their healthcare professionals. This relationship between the woman, her partner, other significant family members and the healthcare professional should be based on good communication which provides information and support appropriate to their needs. The Royal

Australian and New Zealand College of Obstetricians and Gynaecologists (2008) maintain that any test or procedure offered in pregnancy should only be performed once informed consent has been given. Implications, limitations and the possible consequences of any investigation should form part of the discussion prior to gaining consent. The Australian College of Midwives incorporate informed choice as a guiding principle in the National Midwifery Guidelines for Consultation and Referral (2008). It would appear that despite the rhetoric, antenatal choices are not always well informed with a study in the Netherlands (van den Berg et al, 2006) revealing 37% of women did not make an informed decision and in an Australian study, 51% of participants did not make informed decisions in relation to the antenatal tests offered (Rowe et al, 2006). Considering these findings, perhaps our focus should be on how we, as antenatal care providers in partnership with women, can improve this situation rather than whether to screen for GDM or not. Information about the risks and benefits of a diagnosis of GDM should be communicated to all women with the offer of a screening test, allowing them to make an informed choice. Documentation of the discussion and the subsequent decision to screen or not screen for GDM must be recorded in the antenatal record. This same process of information sharing, discussion and decision making should be a repetitive one throughout the pregnancy. Figure 1 depicts this cycle.

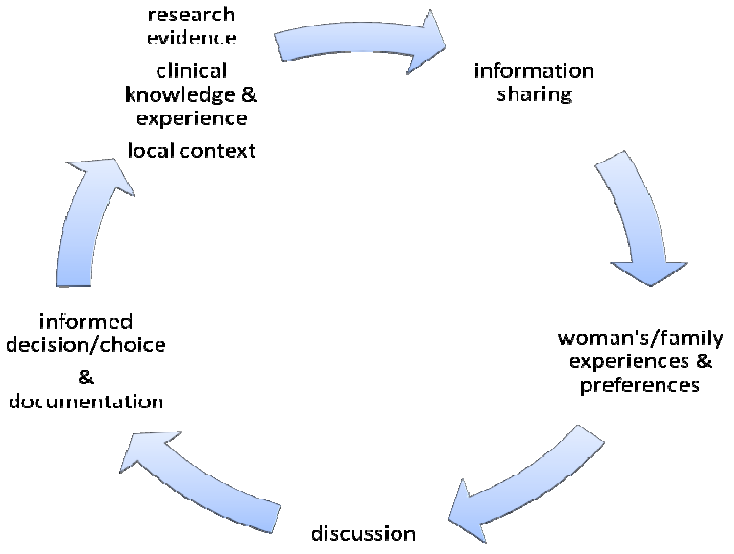



**Figure 1: The Informed Decision Cycle**

Nicholson, Fleisher, Fox and Powe (2005) in their comparison of the cost effectiveness of different strategies for screening for GDM concluded that the sequential method of OGCT followed by an OGTT if necessary was the most cost effective. The possibility of identifying a greater number of women with GDM and the subsequent cost of caring for these women needs to be considered. The increased costs associated with identifying more women with GDM may well be offset by the potential long term health benefits for both the women and their children.

Another aspect of the GDM debate which requires attention is the unwanted interventions and outcomes associated with a diagnosis of GDM. These include induction of labour, neonatal admission to a nursery and psychosocial impacts for women. Clinical decisions need to be made on the basis of clinical indications and not founded merely on a diagnosis of GDM. Whilst recognising these potentially negative consequences of a diagnosis of GDM, the exploration of strategies to change these practices are beyond the scope of this study.

### 5.3 Linking Evidence to Practice

Reflection on practice is always undertaken with the view to improving practice or enabling personal and professional growth (Ruth-Sahd, 2003). In accordance with the goals of reflection, the aim of this study, from its inception, has been to form the basis for the development of evidence based guidelines for screening for GDM which could impact on clinical practice to improve outcomes for mothers and babies. Varying practices for screening have been identified at each site and the current literature explored to determine what might be deemed 'best practice'. Whilst the most recent randomised controlled trials demonstrate an increasing risk of adverse perinatal outcomes with increasing blood glucose levels ( HAPO

Study Group, 2008) and a reduction in adverse outcomes with treatment of GDM (Crowther et al, 2005), much controversy on the subject of screening for GDM persists.

Evidence based practice is defined by Burns and Grove (2005, p736) as 'the conscientious integration of best research evidence with clinical expertise and patient values and needs in the delivery of quality, cost effective healthcare'. However, the very concept of evidence, is itself subject to divergent interpretations. The randomised controlled trial is seen by many espousing evidence based practice as the gold standard of research evidence, whilst others acknowledge the contribution of alternative forms of knowledge founded in clinical experience, the preferences and experiences of recipients of care and the context in which care is provided (Estabrooks, 1998; Rycroft-Malone et al, 2004; Taylor & Allen, 2007). The evidence, once assembled, may be used to develop clinical guidelines to assist both the healthcare provider and the recipient (the woman/partner and family) in the process of informed decision making with regard to diagnostic and therapeutic interventions. Clinical judgement is not negated by the existence of a clinical guideline, but supported.

The partnership model of care promotes the notion of relationship between women, families and midwives as equal partners built on trust and shared decision making. Information is shared in this partnership and decisions made with respect to the individuals particular needs and desires (Davis, 2005; Stewart, 2001; Australian College of Midwives, National Midwifery Guidelines for Consultation and Referral, 2008). In this partnership model the unique needs of women are to be recognised, though this should not be used by clinicians as a reason to ignore evidence (Stewart, 2001). If midwives and primary maternity carers genuinely seek to be in partnership with women it is their responsibility to make information available to

women to facilitate the informed decision making process. In reality this may be difficult to achieve within current resources.

The recommendation from this research is that information about GDM should be given to and discussed with all women, to allow an informed decision or choice to occur with regard to screening. A consistent guideline and policy document, applicable across the sites should be developed to facilitate this practice. In conjunction with the guideline an information brochure could be developed to make information about GDM available and accessible to women. Many such brochures are already in existence in relation to a number of tests or procedures offered as part of the antenatal care package. At different sites within SESIAHS an information brochure would need to be available in a variety of languages to be useful. Brochures would assist in the dissemination of information to women with minimal impact on the time resources of antenatal care providers. The same cycle of information sharing, discussion, alongside the offer of a screening test, followed by a decision or choice should be a repetitive one, considering the many investigations and screening tests offered 'routinely' throughout pregnancy (see Figure 1). Antenatal care providers must have a basic understanding of the tests offered to women in pregnancy and refer to more expert clinicians as appropriate. Staff education would be a component of the introduction of any new guideline.

Translating research evidence into practice is not always as simple as it appears and assorted barriers may be encountered. Barriers to the utilisation of research in clinical practice include time and workload pressures, a lack of support from colleagues or at an organisational level, a lack of confidence in research methods and in the interpretation of research (Taylor & Allen, 2007; Nagy, 2001). Professionals may view clinical guidelines developed from research evidence as prescriptive and

encroaching on their autonomous practice, whilst conversely, nurses and midwives may perhaps question research evidence informed solely by quantitative research methods which tend to be more highly valued (Rycroft-Malone, 2004; Taylor & Allen, 2007; Sackett et al, 1996). Cultural, spiritual and social aspects of care need to be considered as well.

A number of models have been proposed for translating research into practice. The basic steps of the models are similar and include the selection of a topic or research question, a search for and critique of the evidence, adaptation of the evidence for clinical application (clinical guideline development), an implementation phase and evaluation of the effect and outcomes (Titler, 2007).

The National Health and Medical Research Council (NHMRC) (1998) describe clinical practice guidelines as statements which assist clinicians and 'patients' to make decisions in specific clinical circumstances. The statements are systematically developed and take into account current evidence and opinion. The NHMRC suggests nine guiding principles underpin the guideline development process. These principles include a multidisciplinary approach which involves consumers, use of the best available evidence, flexibility to allow guidelines to be adapted to local conditions and resource constraints. Evaluation of clinical guidelines should be outcome focused and subject to regular review. Policies developed at the local level are informed by the clinical guideline to reflect best practice based on the evidence.

The current research project is the first step in the process of translating research into practice. Actions to follow on from this point include the convening of a multi disciplinary working party and an examination of the literature and the research by the broader group. The Area Midwifery

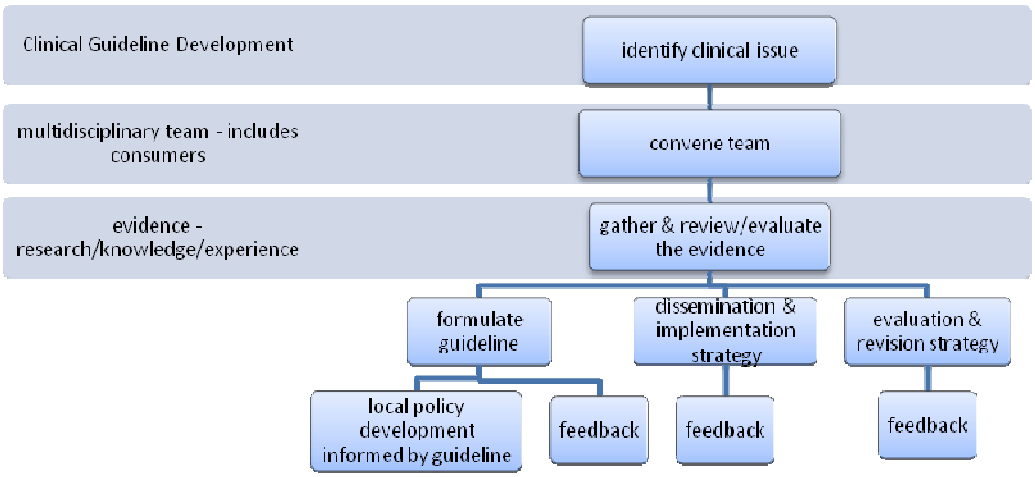
Practice Development Group (AMPDG) may be the appropriate forum in which to initially raise the issue of the need to align practice across sites, before establishing a multi disciplinary working party to examine the issue. The terms of reference for the AMPDG include the development of Area policies and to ensure a consistent approach in the implementation of Area and NSW Health policy initiatives related to midwifery. There is midwifery representation from all sites within the SESIAHS and members for a working party could be nominated from within this group. Clinicians from other relevant disciplines and consumer representatives would then be invited to form the membership of the working party to ensure a multidisciplinary approach to clinical guideline development. Since the inception of the AMPDG in early 2008, the group has tackled a range of issues, in consultation with other clinicians. Documents generated or revised by the AMPDG are then tabled at the Area Clinical Stream Women and Babies Health Governance meeting for comment, amendment and ratification. The clinical governance group is comprised of representatives from all SESIAHS sites and clinical disciplines involved in maternity care. Currently awaiting ratification by the clinical governance group is the cord pH sampling policy and the Anti D administration policy. Under review are the referral to coroner's department, group B streptococcus, separation of mother and baby and induction of labour policies – all documents generated by the AMPDG. The AMPDG have contributed to the development of clinical pathways and documents including the partogram, vaginal birth pathway, caesarean birth pathway, antenatal admission pathway and observation chart and the separation of mother and baby sticker in use throughout SEIAHS maternity services. The antenatal clinic record and educational checklist is close to completion. Another SESIAHS group who has achieved much in developing policies and resources for Area use is the Breastfeeding Working Party. They have produced

standardised, evidence based information handouts for parents on a range of breastfeeding topics. Policies and guidelines to inform staff practices around breastfeeding have also been produced by this group. The SESIAHS Breastfeeding Working Party convened in response to the NSW Health policy, *Breastfeeding in NSW: promotion, protection and support (2008).* This document is cited as "the first evidence based directive with specific actions to promote and support breastfeeding within a state health system in Australia (Hector, Hyde, Worgan & Macoun, 2008). The task to both develop and implement evidence based guidelines for practice in midwifery, applicable across the Area, is mammoth and time consuming. However, it is apparent from the preceding examples that the task is attainable and I believe a worthwhile exercise.

Alongside the process of guideline development, the dissemination and implementation phases of the process need to be considered. The NHMRC (1998) suggest a number of strategies to assist in the dissemination and implementation phases. These include involving in the development phase, those clinicians who would use the guideline. This strategy promotes ownership and acceptance of a new guideline. Engaging with clinical leaders or site 'champions' at all stages of the guideline and policy development process may be beneficial. Short summaries of drafts of the guideline can be circulated via various forums to encourage contribution and comment from a wide range of maternity care providers. Other suggested strategies are presentation at conferences or workshops, publication in professional journals and piloting draft guidelines to assess their relevance and appropriateness for practice. A combination of these strategies would be the most likely course of action to implement a clinical guideline on screening for GDM.

Figure 2 outlines the steps in the clinical guideline development process. Following the initial identification of a clinical issue a team to examine the issue is convened. A number of the stages of clinical guideline development take place concurrently as depicted in Figure 2.

**Figure 2: Clinical Guideline Development Process**




## 5.4 Limitations

The research is a descriptive, retrospective study and as such sets out to examine practice and outcomes without any intervention. The study's purpose is to form the platform for determining what is currently being done with the view to establishing what should be done in relation to screening for GDM in the SESIAHS.

The medical record audit found no evidence of OGCT or OGTT in 11 – 14% of notes, however, no further steps were taken to ascertain if these tests had actually been performed and then not documented in the notes, for example, telephoning doctor's surgeries, or following up results via laboratories may have found more screening results . The lack of resources to conduct a larger medical record audit was also a limitation of the

research.

Data on a number of possible contributing factors for the incidence of GDM at the three sites were unavailable. Maternal weight gain during pregnancy, ethnic background as opposed to maternal country of birth and BMI are examples of features which may contribute to the incidence of GDM and adverse outcomes and were not included in the study.

A further limitation to the research may prove to be the ability to develop and implement an Area wide guideline within the current resources, given the lengthy process to develop the guideline in the first place and that providing women with information about screening for GDM and any ensuing discussion will also impact on the time of antenatal care providers.

## 5.5 Future Research

Further research into how to support women to make informed choices and to participate fully as partners in their antenatal care is needed, along with an examination of the effects on women of screening for GDM and a diagnosis of GDM. Research into the interventions which may accompany a diagnosis of GDM, such as induction of labour, caesarean section and neonatal admission to a special care nursery would also be valuable, to determine if these interventions are justified. Further studies examining the outcomes for women with GDM and the model of care would be of interest as well.

Research into the progression of women with a history of GDM to Type 2 diabetes is another important area. Strategies to delay or avert the development of Type 2 diabetes warrant further investigation.

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## Appendices

Appendix (A): NSW Health Role Delineations

# NSW Health Role Delineations

**Maternity**

| Level / Delineation | Description of Service |
|---|---|
| 0 | Service not provided at this facility. |
| 1 | Postnatal(1) only. Normal post-partum mothers and babies delivered elsewhere returned for post-natal care provided there are no complications. Mothercraft nurses and RNs(2) with post-graduate qualifications and/or experience specific to the needs of the service. Access to midwives(2) with current clinical experience preferable. Nursing and midwifery education programs available, specific to the needs of the service. Has Level 1 Neonatal Service. Quality improvement activities(3). Interpreters as per Circular 94/10. |
| 2 | Normal risk(1) delivery only. As Level 1. Plus able to cope with sudden unexpected complications until transfer. Has 24 hour access to Medical Officers(2) on site or available within 10 minutes. NUM(2) is desirable for general ward. Midwives available. Continual education programs for all clinical staff in neonatal and adult resuscitation methods and the management of obstetric emergencies (as per Circular 99/86). Has Level 2 Neonatal Service. Links with units at higher levels of service, for referrals and transfers, consistent protocols and continuing education. Strategies in place to ensure ongoing competency of all providers of maternity care. Has more than 80 deliveries per year, or has Medical Practitioners complying with the RACGP/RACOG "Recommended Guidelines relating to Hospital Access and Delineation of Clinical Privileges In Obstetrics for GPs". (If minimum caseload cannot be achieved, considerations may be made for the degree of geographic isolation). Has Level 2 General Surgery. Formal quality improvement program(3). Formal protocols and referral links to allied health and psychiatry services. |
| 3 | As Level 2 plus may deliver selected moderate(1) risk pregnancies (>36 week gestation) in consultation. Access to obstetrician/s for consultation. Has Accredited Medical Practitioners(2) to provide simultaneous care of mother and neonate in theatre. Specialist anaesthetist (may be GP anaesthetist credentialled for obstetric anaesthesia) and an additional Accredited Medical Practitioner(2) in new born paediatrics. Sufficient Accredited Medical Practitioners(2) (may be GP anaesthetist credentialled for obstetric anaesthesia) and General Surgeon (may be accredited Medical Practitioner in obstetrics) credentialled for lower segment caesarean section (LSCS). Has NUM. Midwives on all shifts(2). Some RNs with experience in neonatal care and/or having or undertaking relevant post-basic studies. |
| 4 | As Level 3 plus care for mothers and babies (>34 weeks gestation) at moderate risk(1) and elective LSCS. Obstetricians, Paediatricians and Specialist Anaesthetists(2) on call 24 hours. Accredited(2) Medical Practitioners(2) on site 24 hours. Has NUM(2) and experienced RNs(2). Experienced midwives on all shifts. Established links with CNC and/or CNE(2) in midwifery and neonatal nursing. Has a minimum of Level 3 Neonatal Service. Allied health professionals and liaison psychiatry available. |
| 5 | As Level 4 plus may deliver selected high risk pregnancies. Has Level 4 Neonatal Service. CNCs and/or CNE(2) in midwifery on site. |
| 6 | Care of normal, moderate and high risk(1) deliveries. Obstetric Registrar(4) on site 24 hours. Anaesthetic Registrar(4) on site 24 hours and available exclusively for obstetrics for hospitals with more than 3000 births per year. Obstetricians may have specific subspecialties/skills/training. Access to feto-maternal specialist. May participate on High Risk Pregnancy and Feto-Maternal Advisory Line (PAL) roster. Experienced midwives(2) on all shifts. Capacity to provide high ratio of nurse/patient care for women with acute complications with pregnancy or birth. 24 hour access to ultrasound services and reporting. CTG monitoring available with capacity to carry out fetal scalp pH in labour ward. Operating suite staff on site. Capacity to carry out caesarean section within 30 minutes. Usually a specialist supra regional unit or statewide role. The lead hospital within a defined network, in which the combined total is at least 3000 births per year. Has Level 5 Neonatal Service. 24 hour access to liaison psychiatry and allied health services. Full-time CNC and/or CNE(2) in midwifery. |

## Appendix (B): Policy and Guideline Checklist

**Gestational Diabetes Mellitus: Screening**
**Policy and Guideline Checklist**

**Site:**

**Date:**

**Auditor:**

1. Does a site policy, protocol or guideline exist for screening for Gestational diabetes Mellitus?

Yes No

2. Does the document advocate screening for GDM by risk factors?

Yes No

3. What risk factors?

4. Does the document advocate universal screening for GDM using oral glucose challenge test (OGCT)?

Yes No

5. Any additional information?

Appendix (C): Medical Record Audit Tool

**Gestational Diabetes Mellitus Medical Record Audit**

**Site:**

**Date:**

**Auditor:**

**Outcome: the number of records showing adherence to policy for screening for GDM & number screened by OGCT**

*attach site policy*

| | **Risk factors GDM** | | **Screened byOGCT** | | **model of antenatal care** | | | |
|---|---|---|---|---|---|---|---|---|
| **MR no.** | **yes** | **no** | **yes** | **no** | **GP** | **Obst** | **Midwife** | **other** |
| | | | | | | | | |

## Appendix (D) (i): Ethics Approval SESIAHS

**APPROVAL – SES&IAHS AUTHORISATION**
**In reply please quote HE07/235**
Further Enquiries Ph: 4221 4457

**20 September 2007**

**A/Professor Linette Lock**
**PO Box 222, Lindfield**
**NSW 2070**

Dear A/Professor Lock,

Thank you for your response of 11 September 2007 to the HREC review letter dated 27 August 2007. I am pleased to advise that the application has been **approved.**

| | |
|---|---|
| Ethics Number: | HE07/235 |
| Project Title: | Gestational Diabetes Mellitus: current practices in screening and diagnosis. |
| Name of Researchers: | A/Professor Linette Lock, Professor Caroline Homer, Ms Lois Berry |
| Approval Date: | 13 September 2007 |
| Expiry Date: | 12 September 2008 |

The University of Wollongong/SESIAHS Health and Medical HREC is constituted and functions in accordance with the NHMRC *National Statement on the Ethical Conduct in Human Research.* The HREC has reviewed the research proposal for compliance with the *National Statement* and approval of this project is conditional upon your continuing compliance with this document. As evidence of continuing compliance, the Human Research Ethics Committee requires that researchers immediately report:

- proposed changes to the protocol including changes to investigators involved
- serious or unexpected adverse effects on participants
- unforseen events that might affect continued ethical acceptability of the project.

You are also required to complete monitoring reports annually and at the end of your project.

These reports are sent out approximately 6 weeks prior to the date your ethics approval

expires. The reports must be completed, signed by the appropriate Head of Department, and

returned to the Research Services Office prior to the expiry date.

**Before you can proceed with the project you must first have authorisation from the**

**SESIAHS. A copy of this advice has been forwarded to the AHS.**

Yours Sincerely,

A/Professor Arthur Jenkins
**Chairperson**
**Human Research Ethics Committee**

cc. Research Directorate, Illawarra Health

## Appendix (D) (ii): Ethics Approval UTS

***21 August 2007***

Associate Professor Lin Lock
KG05.02.03
Faculty of Nursing,Midwifery and Health
UNIVERSITY OF TECHNOLOGY, SYDNEY

Dear Lin,

UTS HREC REF NO 2007-127 – LOCK, Associate Professor Lin, HOMER, Professor Caroline (for BERRY, Ms Lois M Nursing student) - "Gestational Diabetes Mellitus: current practices in screening and diagnosis"

At its meeting held on 14/08/2007, the UTS Human Research Ethics Committee considered the above application, and I am pleased to inform you that ethics clearance has been granted.

Your clearance number is UTS HREC REF NO.2007-127A
Please note that the ethical conduct of research is an on-going process. The *National Statement on Ethical Conduct in Research Involving Humans* requires us to obtain a report about the progress of the research, and in particular about any changes to the research which may have ethical implications. This report form must be completed at least annually, and at the end of the project (if it takes more than a year). The Ethics Secretariat will contact you when it is time to complete your first report.

I also refer you to the AVCC guidelines relating to the storage of data, which require that data be kept for a minimum of 5 years after publication of research. However, in NSW, longer retention requirements are required for research on human subjects with potential long-term effects, research with long-term environmental effects, or research considered of national or international significance, importance, or controversy. If the data from this research project falls into one of these categories, contact University Records for advice on long-term retention.

If you have any queries about your ethics clearance, or require any amendments to your research in the future, please do not hesitate to contact the Ethics Secretariat at the Research and Innovation Office, on 02 9514 9615.

Yours sincerely,

Professor Jane Stein-Parbury
Chairperson,
UTS Human Research Ethics Committee