Diabetes in Pregnancy Advisory Group
West Midlands Perinatal Institute

Diabetes in Pregnancy:

addressing the challenge in the West Midlands

Final report on the West Midlands cohort and confidential enquiry into maternity care of women with type 1 and type 2 diabetes

May 2010

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Authors and acknowledgements

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Electronic copies of this report are available at www.pi.nhs.uk/diabetes/publications/report2010.pdf.

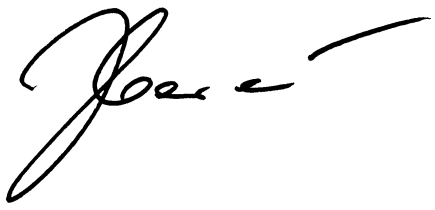
Foreword

This report represents the product of four years of work based on the West Midlands cohort study and confidential enquiry into diabetes in pregnancy. The regional focus, alongside the national enquiry, arose from the need to address particular challenges, such as our high rates of type 2 diabetes, inequality and social deprivation.

Preliminary findings from these Enquiries have already been published and presented at several regional, national as well as international meetings. In this comprehensive report, the results from the WM cohort and the confidential case reviews are set out in detail together with additional analyses, and recommendations are made on the actions needed. One strong message is the need to extend good care to pre-pregnancy, and hence into the community, to engage public health and primary care in prevention and in equitable provision of the best possible service for expectant mothers with diabetes.

The publication of this report is an important milestone towards using local evidence and expertise to inform commissioning and health service planning. The wide ranging stakeholder engagement with the confidential case reviews has facilitated important WM initiatives involving diabetologists, obstetricians, midwives, diabetes nurses, dieticians and other health professionals. This work is co-ordinated by DiPAG, the Diabetes in Pregnancy Advisory Group, administered by the Perinatal Institute. DiPAG has already successfully implemented regional, evidence based protocols which are consistent with NICE guidelines. It has established a successful series of educational days, assisted the development of standardised patient information, and implemented the award winning hand held diabetes in pregnancy notes which have since been endorsed by NHS Diabetes and Diabetes UK. Currently, DiPAG is undertaking a regional organisational survey to map West Midlands diabetes in pregnancy services.

These initiatives are good examples of productive multidisciplinary collaboration and regional networking to address particular challenges for the West Midlands. As a result of such engagement, we are able to plan important next steps, such as the routine collection of standardised data in line with the emerging national diabetes dataset. This information will in turn allow identification of inequalities and monitoring of service improvement, with the primary aim to inform commissioners and providers about optimising the care of diabetes in pregnancy.



Professor Jason Gardosi
Director, West Midlands Perinatal Institute
Chair, WM Diabetes in Pregnancy Advisory Group

Executive Summary

This is a summary of the report of the West Midlands Diabetes in Pregnancy project. Its purpose is to highlight the key findings and recommendations for the West Midlands, to improve clinical care and pregnancy outcomes for this group of mothers.

Data for this project were collected by the West Midlands Perinatal Institute for CEMACH [1] and for our own regional analysis in 2002/3. All 20 West Midlands (WM) maternity units participated, and all women with pre-existing type 1 and 2 diabetes in pregnancy were invited to participate. The analysis was based on a cohort study as well as confidential case reviews.

Key Finding 1 – Type 2 Diabetes: Different Needs

West Midlands has a higher incidence of type 2 diabetes in pregnancy than nationally

36% of all pregnancies in the study cohort were to women with type 2 diabetes, and 57% of these were of non-European ethnicity. Compared to type 1 diabetic mothers, they were:

- less likely to attend pre-pregnancy counselling,
- less likely to have had a pre-pregnancy glycaemic measurement, and
- less likely to have taken folic acid before or in early pregnancy

Suboptimal glycaemic control before pregnancy and in the 1st and 3rd trimesters is associated with adverse pregnancy outcomes. Women with type 2 diabetes are generally commenced on insulin in the 1st trimester and increased glycaemic testing is recommended. This presents a significant change in management for the woman and workload within the multidisciplinary clinic setting.

Deficiencies were apparent with the care of women with type 2 diabetes, which related particularly to glycaemic control and the planning and management of labour and delivery.

Recommendation:

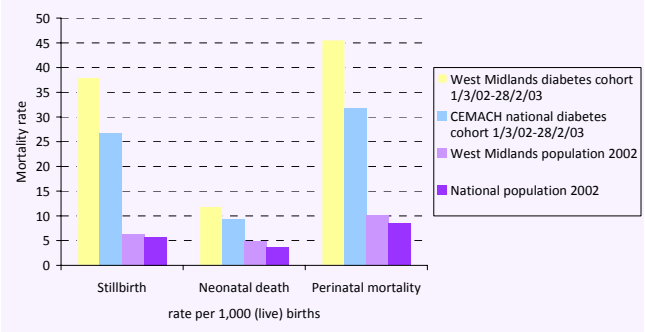
- *There is an urgent need to improve health care access before and in early pregnancy. Education to highlight the importance of pre-pregnancy counselling and glycaemic control for women with type 2 diabetes should be addressed.*

Key Finding 2 - Pregnancy Outcomes/Healthy Babies

Pregnancies with pre-gestational diabetes in the West Midlands have higher rates of adverse outcomes compared with diabetic women in the UK or the general WM maternity population

High congenital malformation (82.1/1000 births) and perinatal mortality rates (45.6/1000 births) confirms that we are a long way from achieving the aims of the St Vincent's Declaration [2].

Figure 1: *Stillbirth, neonatal death and perinatal mortality rates*



- **Major congenital anomalies** occur twice as commonly in WM compared to the rest of the UK diabetic population; fetal congenital heart disease and CNS malformations account for more than half of these. The risk of congenital malformation is highest in Anglo-European type 2 women, but was not different for type 1 or type 2 diabetic women overall. The antenatal detection rate for malformations was 60%.

- **Perinatal loss** was 4-5 times higher than in non-diabetic mothers in the WM. Ethnicity and a history of previous premature delivery should be seen as risk factors for perinatal loss. Stillbirth occurred more frequently in women with infrequent hospital appointments or little/no fetal monitoring after 34 weeks gestation.

Recommendations:

- *Type 1 & 2 diabetic women should have a detailed anomaly and cardiac scan performed by a trained professional at 20-22 weeks gestation.*
- *All diabetic women should be aware of an increased risk of stillbirth, and local services should provide antenatal monitoring of the fetus from 34 weeks gestation. Regional guidelines for monitoring should be developed, based on the available evidence.*

Key Finding 3 - Preconception Care

Women are often poorly prepared for pregnancy

The uptake of pre-pregnancy counselling is currently low (28%) and this is reflected in:

- low usage of folic acid pre and periconceptually (41%) and
- low levels of glycaemic testing (41%).

Recommendations:

- *There is a need to increase education and public health awareness of the importance of pre-pregnancy care.*
- *New avenues should be explored on where and how pre-pregnancy care is provided.*

Key Finding 4 - Clinical Care and Standards

West Midlands is in line with national performance on clinical standards of care in pregnancy & labour

For most clinical standards of care assessed, the WM was found to provide equivalent or better care than nationally; however there remains scope for improvement.

Recommendation:

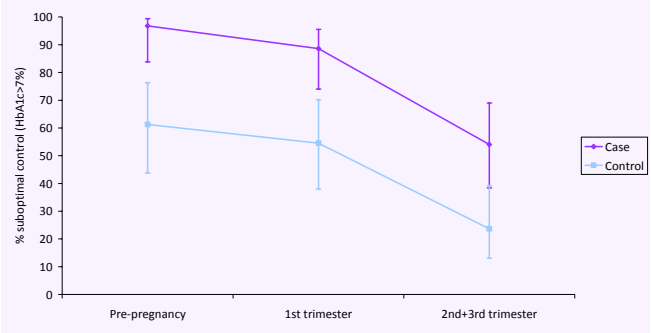
- *Regional guidelines should be produced to improve adherence to standards of "*best practice*"*

Key Finding 5 - Optimising Glycaemic Control

Maternal hyperglycaemia/sub-optimal glycaemic control is strongly associated with adverse pregnancy outcomes, especially major fetal malformations and/or perinatal death

In WM, 13% of mothers with pre-gestational diabetes commenced pregnancy with optimal glycaemic control (HbA1c <7.0%). There is a significant association between suboptimal glycaemic control and adverse perinatal outcomes, both in the case-control study and in comparison with the whole WM cohort. This association is most marked pre-pregnancy and in the 1st and 3rd trimesters.

Figure 2: *Suboptimal glycaemic control (>7% HbA1c) was related to poorer pregnancy outcome*



Recommendations:

- *All health professionals looking after women with pre-gestational diabetes should be actively involved in promoting tight glycaemic control before and during pregnancy.*
- *Women must be encouraged to plan pregnancies to optimise their glycaemic status.*
- *Optimal blood sugar control throughout pregnancy should be achieved through effective target setting, close home glucose monitoring and good communication.*

Executive Summary

Key Finding 6 - High Preterm Delivery and Caesarean Section Rate

Pre-gestational diabetic women in the WM have a high preterm delivery rate (32%) and a high caesarean section rate (72%)

Table 1 *Mode of delivery - WM compared to National dataset and general maternity population*

Mode of delivery	Type 1 (n=247) %	Type 2 (n=135) %	All women (n=382) %	National* (n=3,474)	General* Population
VAGINAL	23.5%	36.3%	28.0%	32.1%	78%
Spontaneous	17.8%	33.3%	23.3%	24.4%	67%
Instrumental	5.7%	3.0%	4.7%	7.7%	11%
CAESAREAN SECTION	76.1%	63.7%	71.7%	67.4%	22%
Emergency CS	43.3%	30.4%	38.7%	37.6%	13%
Elective CS	32.8%	33.3%	3.1%	29.8%	9%

**Pregnancy in women with type 1 and type 2 diabetes in 2002-2002, CEMACH 2005*
*** NHS Maternity Statistics, England 2002-2003, bulletin 2004/10*

Recommendations:

- *Women should be made aware of the increased risk of preterm and/or operative delivery.*
- *Obstetricians and midwives should consider induction of labour on an individual basis, providing the woman with the most accurate evidence of risks to her and her baby. Avoiding "routine" induction at 38 weeks will allow more women to labour spontaneously.*

Key Finding 7 - Large Babies/Complications of Labour

Type 1 & 2 diabetic women gave birth to larger babies than the general maternity population

Over half of birthweights were over the 90th customised centile. The incidence of shoulder dystocia was the same as nationally (7.4%) but represents a two-fold increase compared to the general maternity population. Non-European groups were also more likely to have growth restricted babies (<10th customised centile). Complications of delivery such as shoulder dystocia and Erb's palsy also occurred more commonly in this population.

Recommendations:

- *health professionals need to be aware of the increased risk of these complications;*
- *senior obstetricians should discuss and plan delivery with the mother; and*
- *they should be involved when labour deviates from the norm, to avoid birth trauma and intrapartum asphyxia/stillbirth.*

Key Finding 8 - Neonatal Care

Many admissions to neonatal care are unnecessary

60% of babies born in WM were admitted to a neonatal unit; 20% of term babies were admitted for special care for "*routine/observation only*". This occurred more commonly in babies of mothers with type 1 diabetes. Overall, 20-33% of all admissions to NNU could be avoided. This would reduce neonatal expenditure on this group of neonates and free up cot space within NNUs.

Recommendation:

- *Maternity units should provide transitional care wards with expertise in management of diabetic mothers and babies, to minimise separation of babies to those needing active neonatal care.*

Key Finding 9 - Breastfeeding

The West Midlands cohort had a lower rate of breastfeeding than nationally

Formula milk was more popular in the WM both as an intended and an actual feeding method. This was particularly the case in non-European type 2 diabetic women.

Recommendations:

- *There needs to be greater awareness of the importance of breastfeeding, both by mothers and health professionals. This message needs to be promoted in effective ways throughout pregnancy.*
- *Breast milk and breastfeeding confers particular advantages to the diabetic mother and her newborn. It should be encouraged as soon as possible following delivery, and additional support provided. Barriers to breastfeeding, such as maternal drugs, separation of baby, lack of arrangements on NNUs for expressed milk, should be reduced where possible.*

Key Finding 10 - Communication between Health Professionals

Confidential Enquiry panels found a number of instances of poor clinical care, which resulted from a breakdown in communication between health professionals

The CE demonstrated that failures in communication between health professionals and the woman, or between health professionals, occurred in both the confidential enquiry cases and controls. This was a recurring theme in each of three key areas:

- glycaemic management & target setting
- diabetic care
- maternity care: planning/management of labour and delivery

Recommendations:

- *Health professionals caring for diabetic women in pregnancy should work together within a single clinic setting as a multidisciplinary team.*
- *Members of the antenatal diabetes team should regularly discuss management protocols, cases, and service improvements.*
- *All staff, particularly medical staff working on delivery suite, should recognise that these women are at high risk of pregnancy and delivery complications: advice from medical, obstetric, and anaesthetic senior staff charged with antenatal diabetes care should always be sought.*

Key Finding 11 - Quality of Care

There were major differences in the quality of diabetic/obstetric care provided in WM

The Confidential Enquiry panels examined the quality of clinical care provided and the individual unit protocols, and found a number of discrepancies in management, especially in the areas of:

- glycaemic control/target setting
- investigation of diabetic complications
- timing and mode of delivery
- monitoring for fetal wellbeing
- antenatal steroid administration
- use of glucagons in pregnancy

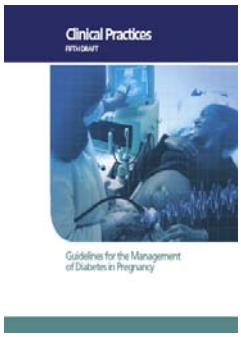
Recommendation:

- *There is a need for a regional approach to standardise diabetes care in pregnancy, including the production of regionally agreed guidelines.*

Current Regional Developments - DiPAG

The WM confidential enquiry and cohort study has stimulated a number of regional initiatives:

The Diabetes in Pregnancy Advisory Group (DiPAG) was formed in June 2007 and meetings are held 3-4 times a year at the Perinatal Institute. DiPAG is a multi-disciplinary group with representation from around the region, including diabetologists, obstetricians, diabetic specialist midwives, dieticians, and patient representatives. Its main aims are to advise on current clinical priorities and guidelines for improving the care of diabetes in pregnancy; to make regional recommendations; and to assist with projects that seek to facilitate the delivery of better care and improved pregnancy outcomes. The projects and resources are summarised on dedicated pages on the Institute's website - www.pi.nhs.uk/diabetes.



Protocols - West Midlands Clinical Practices: Guidelines for the Management of Diabetes in Pregnancy have been developed by members of DiPAG as a response to findings of the Confidential Enquiry. During this enquiry process, it was evident that there was great diversity across the region with regards to protocols and the management of diabetic/maternity care during the antenatal, intrapartum, and postnatal period. Comments included local NHS Trust protocols/guidelines being too basic, not providing sufficient guidance, or being poorly set out. Standardisation of care was felt to be an important issue in order to improve care and outcomes. This Clinical Practice document/CDrom provides detailed, referenced management plans and background information for health professionals to use at any stage of pregnancy or the puerperium www.pi.nhs.uk/diabetes/protocols.

Hand-held Notes - The new Diabetes in Pregnancy notes have been developed following the WM Confidential Enquiry and were launched formally in June 2008 after a successful pilot. Their aim is to standardise and improve care and communication by developing a better and clearer record of the care received and planned, and to make relevant information accessible for women. The contents are consistent with national and regional recommendations and the recently published NICE guidelines [3]. They are already in use in many units in the WM and other regions, alongside patient hand-held Pregnancy Notes. www.pi.nhs.uk/diabetesnotes.

Diabetes in Pregnancy Register – Interest in a region-wide Diabetes in Pregnancy register has grown with the development of the national diabetes in pregnancy dataset and DiPAG is one of the pilot sites for NHS diabetes to implement this in the West Midlands. The collection of standardised data dovetails well with the documentation In the hand held notes, and the data will be collected within a modified version of the Institute's Perinatal Episode Electronic Record (PEER).

Patient Information leaflets – This is another ongoing WM project, taking examples of good practice and written information from around the region and nationally, for the development of high-quality leaflets to inform patients and improve care during all periods before/during/after a pregnancy.

Address for correspondence: diabetes@pi.nhs.uk.

References (Executive Summary)

1 Pregnancy in women with type 1 and type 2 diabetes in 2002–2003, CEMACH 2005
2 Diabetes Care and research in Europe: The Saint Vincent Declaration. Diabet Med 1990:7;360
3 NICE guidelines Diabetes in Pregnancy www.nice.org.uk/nicemedia/pdf/DiabetesFullGuidelineRevisedJULY2008.pdf

Chapter 1 Introduction

Diabetes is the most common medical disorder complicating pregnancy. It affects about 1:264 pregnant women in England, Wales and Northern Ireland[1].

Type 1 Diabetes occurs mainly in children and young adults as a result of failure of the islet cells in the pancreas. These sufferers are totally insulin deficient and will always require insulin. Type 1 diabetes represents about 15% of all adult cases.

Type 2 Diabetes mainly occurs in older adults but there are several reports of it occurring in a younger population even in adolescent groups[2]. The increased number of reported cases appears to parallel the growing obesity rates. These sufferers have a relative deficiency of insulin as a result of partial pancreatic failure. In addition, the insulin produced does not work effectively due to the presence of insulin resistance in the liver and skeletal muscle. These patients may be treated with insulin and/or oral hypoglycaemic agents in addition to diet and exercise. This form of diabetes represents about 85% of all adult cases.

The number of cases of diabetes is increasing. Reported cases of type 1 diabetes in children under the age of 5 years are on the rise[3]. Type 2 diabetes is also more prevalent particularly in women of childbearing age and in different ethnic groups and with increasing obesity rates.

In this report, pre-gestational diabetes is defined as either type 1 or type 2 diabetes, which had been diagnosed at least 1 year before the woman's estimated date of delivery (EDD). Pregnancies complicated by pre-gestational diabetes have a less favourable outcome. Perinatal mortality rates along with congenital malformation rates are higher in the diabetic population. Data from the 1990s showed a 3-5 fold increase in perinatal mortality rate (PMR), and a 4-10 fold increase in congenital malformation rate (CMR) compared with that of the background population[4,5,6]. In the addition Dunne and colleagues showed poorer pregnancy outcomes in women with type 2 diabetes[7].

This study examines the data specific to the West Midlands, which were collected as part of the CEMACH national enquiry programme into maternity care and pregnancy outcomes in women with pre-gestational diabetes[1]. It sets out to:

- examine the care received by mothers and babies from pre-conception to the postnatal period, and the standards of clinical care achieved,
- report on the outcomes, including perinatal mortality and congenital malformations, and the findings of confidential panel enquiries of West Midlands cases, and
- make recommendations on next steps for service development to improve the care of pregnancies complicated by maternal diabetes.

All 20 maternity units within the West Midlands participated in this study. The number of cases submitted from each unit is summarised in Appendix B.

Chapter 2 Methodology and Data Quality

The West Midlands Diabetes in Pregnancy project collected and analysed data that were derived from the national CEMACH study. The data were collated at the Perinatal Institute prior to being forwarded to CEMACH.

Data Collection

A lead midwife for each maternity unit in the region registered each pregnancy with pre-gestational diabetes and sent a notification form to the West Midlands Perinatal Institute. Data was collected at any time from booking to delivery between 1 March 2002 and 28 February 2003. The midwife also completed a national standards dataset (SDS) during or after the pregnancy. The SDS included information on demographics, type of diabetes, pre-pregnancy care, pregnancy care before and after 23 weeks gestation, and care during labour and delivery. Infant outcomes were detailed and recorded up to and including 28 days post-natally. Prior to data collection, information leaflets were given to all women fulfilling the inclusion criteria. The data were validated and entered on a regional database.

Data Cleaning

The importance of high quality data was recognised early on, especially to ensure correct classification of deaths, anomalies, and diabetes subtypes. For the purpose of this project therefore, in addition to data cleaning at national level, further checks were carried out regionally by two diabetes project midwives. We considered that their relevant clinical experience and skills greatly added to the reliability of the data and accuracy of the analysis. The process was time consuming and involved many cross reference checks, revisiting units and rechecking entered data. A considerable number of problems were identified and corrected for the regional study, including:

- incomplete/insufficient follow up data after woman moved out of region,
- wrong classification: 4 women initially classified with type 1 were in fact found to have type 2 diabetes. Two cases with a diabetes classification of "*other*" were removed from the cohort,
- 2 stillbirths re-classified as legal abortion and as a neonatal death,
- 1 case mis-entered at source "*as baby alive at 28 days with an anomaly*" but was found to be an early fetal loss,
- 2 controls at the confidential panel enquiries were found to have major anomalies (see Chapter 4),
- 6 cases reported as congenital anomalies did not fit the ICD10 classification and were reclassified:
  - haemophilia case
  - short long bones at 22 week scan - later confirmed as fetal growth restriction not a congenital anomaly
  - 20 week scan suggested congenital cystic adenomatoid malformation of the lung - no anomaly detected postnatally
  - strawberry shaped head (scan) - normal postnatal examination
  - right renal hydronephrosis (scan) - normal postnatal renal scan
  - cardiac dilatation - not anomaly, and no cardiac anomaly detected postnatally.

Two separate databases were produced (the cohort dataset and the panel enquiry dataset). The data cleaning process allowed frequent cross-referencing and validity checks, and ensured accuracy and compatibility between the two databases.

As a result of these efforts, we believe that the data analysed in this study are as accurate and comprehensive as possible.

Chapter 3 The West Midlands Cohort

3.1 Prevalence of Diabetes in Pregnancy

The prevalence of pre-gestational diabetes in pregnancy was calculated by measuring the prevalence of babies born to women with diabetes in the West Midlands region (WM). This was calculated for the twelve month period 1 March 2002 to 28 February 2003 to allow comparison with national figures. During this year, there were in total 61,424 births in the West Midlands and 263 known births to women with type 1 or 2 diabetes, which represents a rate of 0.43% (1 in 236 births). This figure of 263 registerable births is different to that reported nationally by CEMACH (0.42%) for this period, because we present data based on delivery region, not postcode of residence. There were two cases excluded where the diabetes type was not identified as being type 1 or type 2.

There were 418 pregnancies; 269 were complicated by type 1 diabetes and 149 by type 2 diabetes. Table 3.1 shows the data analysis for the cohort.

Table 3.1 *Overall figures (cohort)*

Study population	Total n
Women in study	405
Pregnancies	418
Multiples	8
Total babies	426
Early fetal losses <20 weeks	30
Late fetal losses 20-23^{+6} weeks	6
Pregnancies ongoing ≥24 weeks	382
Live births delivered ≥24 weeks	373
Live births delivered <24 weeks	0
Total live births	373
Neonatal deaths	3*
Total live at 28 days	370
Stillbirths	17
All births registered	390
Congenital malformations	32

*includes 1 neonatal death identified by panel enquiry - see Chapter 4

3.2 Mothers' Details

KEY FINDINGS

1 **A significantly higher proportion of mothers with diabetes in pregnancy have type 2 diabetes in the West Midlands (35.6%) compared to national figures (27.3%).**

2 **The majority of women with type 2 diabetes were non-European (predominantly Asian), older, multiparous and mostly living in areas of high social deprivation.**

3 **No maternal deaths occurred within the West Midlands cohort.**

405 women who had type 1 or type 2 diabetes prior to pregnancy were registered in the study between 1 March 2002 and 28 February 2003. In total, these women had 418 pregnancies. Women who had more than one pregnancy in the study period were counted once for each pregnancy episode.

Maternal characteristics

Table 3.2.1 *Demographic characteristics of the women*

Characteristic	Type 1 n=269 (64.4%)		Type 2 n=149 (35.6%)		All women n=418		Difference type 2 v type 1 p/OR
Median age of mother at entry to study, years (IQR)	29	(9.0)	33	(8.0)	31	(9.0)	
MATERNAL AGE n (%)							
Age <20 years	23	(5.5)		0	23	(5.5)	p<0.01
Age 35+ years	48	(17.8)	52	(34.9)	100	(23.9)	p<0.01
ETHNICITY n (%)							
European	249	(92.6)	64	(43.0)	313	(74.9)	p<0.01
Black African		0	4	(2.7)	4	(1.0)	p<0.01
Black Caribbean	5	(1.9)	12	(8.1)	17	(4.1)	p<0.01
Indian	7	(2.6)	11	(7.4)	18	(4.3)	p<0.05
Pakistani	3	(1.1)	45	(30.2)	48	(11.5)	p<0.01
Bangladeshi		0	7	(4.7)	7	(1.7)	p<0.01
Other	5	(1.9)	6	(4.0)	11	(2.6)	p=0.2
PARITY n (%)							
Primiparous	136	(50.6)	33	(22.1)	169	(40.4)	p<0.01
Multiparous	133	(49.4)	116	(77.9)	249	(59.6)	p<0.01
Median age at onset of diabetes, years (IQR)	13	(13.3)	28	(9.0)	20	(16.0)	
Median duration of diabetes, years (IQR)	14	(13.3)	4	(4.0)	9	(13.0)	

OR: odds ratio

Type of Diabetes

There were 269 women with type 1 diabetes (64.4%) and 149 with type 2 (35.6%). The proportion of pregnancies complicated by type 2 diabetes is significantly greater in the West Midlands area than that reported in the national cohort[1] (27.3%, p<0.01).

Age

Women with type 2 diabetes were older, with a median age of 33 years compared to 29 years in type 1 women. The duration of diabetes was much shorter, on average 4 years in type 2 disease compared to 14 years in type 1 disease. This reflects the difference in disease profile between the two types of diabetes, and is the same as seen nationally.

There were 23 teenage pregnancies in total (5.5%, mean 18 years) all with type 1 diabetes. 6 pregnancies resulted in early fetal losses and 2 congenital anomalies were detected (neural tube defect where a legal abortion was performed and a renal anomaly, alive at 28 days) in this group.

There were 100 pregnancies to mothers who were aged 35 years and above (24%, mean 38 years). These were equally divided within each group.

Mothers aged 40 and above accounted for 27 pregnancies. There were 5 early fetal losses (4 European and one Black Caribbean) with no anomalies detected. There was one stillbirth that occurred in a woman with type 2 diabetes with no congenital anomaly. Two pregnancies alive at 28 days were both found to have cardiac anomalies.

Body Mass Index

Information relating to body mass measurements was not requested within the national cohort dataset.

Ethnicity

As Table 3.2.1 shows, many more mothers with type 2 diabetes were of non-European origin compared with type 1 diabetes (57.0% v 7.4%). 63 women with type 2 diabetes were of South Asian ethnicity (42.3%). In addition the proportion of non-European mothers with type 2 diabetes was higher in the West Midlands compared to the nationally (48.7%).

Parity

Overall, 169 women in the cohort (40%) were in their first pregnancy. However, mothers with type 1 diabetes were much more likely to be primiparous (50.6%) than mothers with type 2 (22.1%, p<0.001). This is partly explained by the higher median age of onset and by the higher proportion of ethnic minority groups with type 2 diabetes.

Maternal Deaths

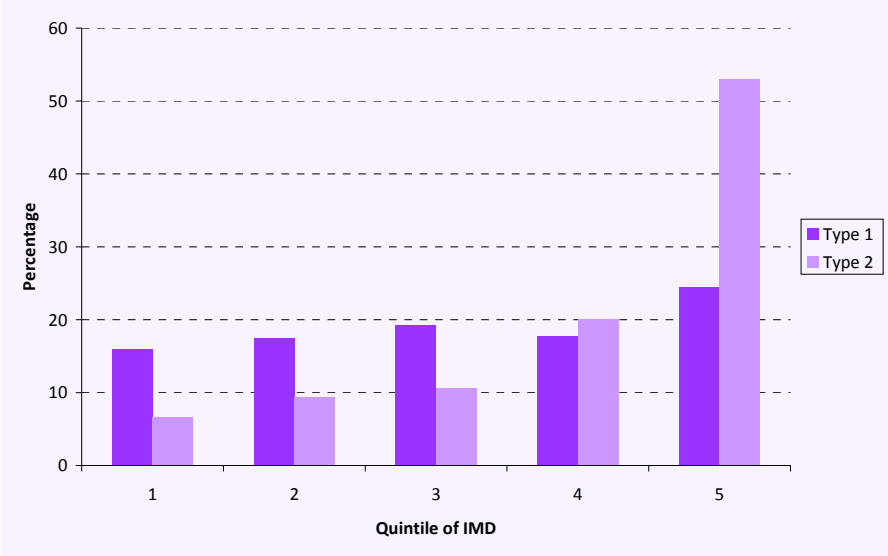
There were no maternal deaths within the West Midlands region in this cohort.

Deprivation scores and diabetes

Table 3.2.2 *Quintiles of deprivation score according to diabetes type*

Quintile of IMD	Type 1 (n=269) (%)		Type 2 (n=149) (%)		All women (n=418) (%)		Difference between type 2 v type 1
1	43	(16.0)	10	(6.7)	53	(12.7)	p<0.01
2	47	(17.5)	14	(9.4)	61	(14.6)	p<0.05
3	52	(19.3)	16	(10.7)	68	(16.3)	p<0.05
4	48	(17.8)	30	(20.1)	78	(18.7)	p=0.6
5	66	(24.5)	79	(53.0)	145	(34.7)	p<0.01
Unclassified	13	(4.8)			13	(3.1)	

Figure 3.2.2 *Quintiles of deprivation score according to diabetes type*



The relationship of diabetes in pregnancy with deprivation score was examined using the Index of Multiple Deprivation (IMD 2004). IMD scores are measured between 0 and 100 (100=most deprived) and are grouped in quintiles 1 to 5, where quintile 5 describes the 20% most deprived. The IMD scores were based on the West Midlands population.

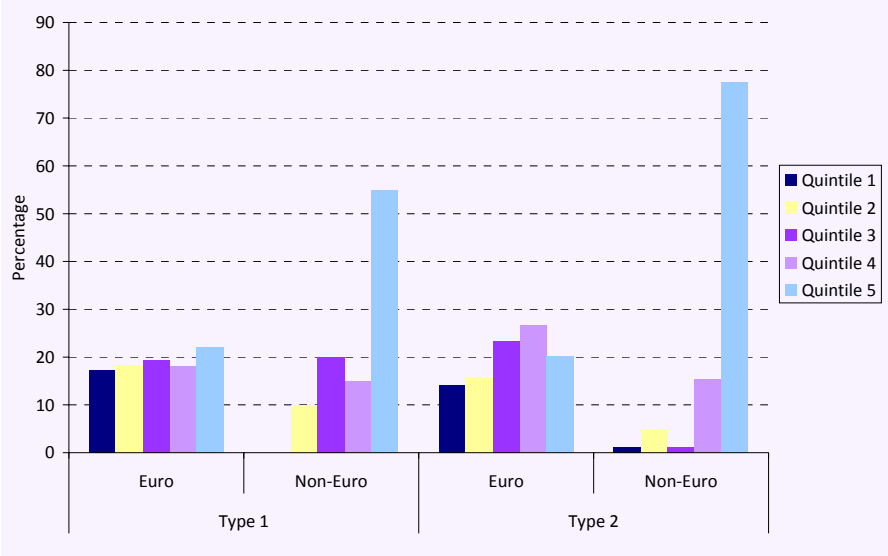
Table 3.2.2 shows the proportion of type 1 and type 2 diabetes allocated to each IMD. Table 3.2.3 breaks this down by ethnicity comparing European against the non-European populations.

The proportion of women with diabetes increased with deprivation (12.7 % in IMD Q1 to 34.7% in IMD Q5). The proportion in IMD Q5 was higher in the West Midlands population compared to national dataset (34.7% v 28.5%). This was mainly due to a higher proportion of women with type 2 diabetes in IMD Q5 at 53.0% compared to 24.5% of women with type 1. This difference was in the non-European subgroups, whereas European women with diabetes were more evenly distributed between the IMD quintiles. In both types of diabetes, non-European mothers were more likely to be in IMD 5. More than half of all women from ethnic minorities with type 1 diabetes and more than three-quarters with type 2 diabetes were found in IMD Q5, the most deprived 20% of the population. This compares to 36% and 59% respectively for non-European women in the national dataset.

Table 3.2.3 *Quintiles of deprivation score according to ethnicity*

Quintile of IMD	Type 1 Euro v non-Euro % (n=269)	Type 2 Euro v non-Euro % (n=149)	All women Euro v non-Euro % (n=418)
1	17.3 v 0	14.1 v 1.2	16.6 v 1.0
2	18.1 v 10.0	15.6 v 4.7	17.6 v 5.7
3	19.3 v 20.0	23.4 v 1.2	20.1 v 4.8
4	18.1 v 15.0	26.6 v 15.3	19.8 v 15.2
5	22.1 v 55.0	20.3 v 77.6	21.7 v 73.3
Unclassified	5.2 v 0	0 v 0	4.2 v 0

Figure 3.2.3 *Quintiles of deprivation score according to ethnicity*



Discussion

Within the West Midlands region, women with type 2 diabetes accounted for 35.6% of the total pregnancies in the study, a significantly higher proportion than nationally. These women were older and more likely to be multiparous than women with type 1 diabetes. They were also more likely to be of Asian ethnic origin (42%) and to be in the highest quintile of deprivation (53%). Women with type 1 diabetes were predominantly European (92.6%) and evenly spread across all quintiles of deprivation. The trends discussed in this chapter were similar to those shown in the national figures but more marked within the West Midlands region. Poor pregnancy outcomes and high perinatal mortality can be related to the level of maternal deprivation. Pregnancy outcome data are presented in section 3.6 and shows that the non-European mothers have more than twice the perinatal mortality rate compared to the European population in the West Midlands. Services need to be targeted to address the needs of Asian women in particular and this includes:

- Increasing local education about the importance of pre-pregnancy and antenatal care.
- Improving awareness of the key element of tight glycaemic control throughout pregnancy.
- Making access to medical services easier by being sensitive to the family and cultural needs of each local population.

3.3 Standards of Maternal Care

KEY FINDINGS

1 Care of women with pre-gestational diabetes before, during pregnancy and labour in the West Midlands is in line with that identified nationally.

2 Most women are poorly prepared for pregnancy and do not take up pre-pregnancy care.

3 There is scope for improvement in the implementation of each clinical standard and particularly those related to pre-conception care.

One of the aims of the West Midlands cohort study was to audit clinical standards of both obstetric and diabetes care for women with diabetes before, during and after pregnancy. Assessment of care was based on documentation available in routine medical records. All 418 pregnancy episodes were analysed.

Clinical Standards Analysed

1 Preconception counselling
2 Pre-pregnancy folic acid
3 First trimester ultrasound scan for accurate dating
4 Corticosteroid prophylaxis for preterm delivery
5 HbA1c <7% (standard reported on in Chapter IV)
6 Hypoglycaemic events/Glucagon use
7 Retinal screening in first trimester
8 Neonatal facilities
9 Mode and timing of delivery discussed
10 Continuous electronic fetal heart monitoring
11 IV glucose and insulin for delivery

These are referenced separately in Appendix C.

1 Pre-conception counselling

Standard: A pre-conception clinic should be run jointly by the adult diabetes service and the maternity service for women with diabetes wishing to become pregnant.

Table 3.3.1a *Documentation of pre-pregnancy counselling and control*

Counselling and control	Type 1 (n=269) (%)		Type 2 (n=149) (%)		All women (n=418) (%)	
Pre-pregnancy counselling documented	82	(30.4)	36	(24.2)	118	(28.2)
Pre-pregnancy HbA1c	125	(46.4)	48	(32.2)	173	(41.4)
Pre-pregnancy HbA1c <7% in those that had a test	31	(24.8)	22	(45.8)	53	(30.6)

Pre-pregnancy counselling was received by just over one-quarter (28.2%) of all women with diabetes, which is less than in the national cohort (34.5%).

On further analysis the rates were similar for type 2 diabetic women (24.2% v 24.8%) however less women with type 1 diabetes in the West Midlands received pre-pregnancy care compared to national cohort (30.4 v 38.2%).

A higher proportion for the type 1 and 2 diabetic women had a pre-pregnancy measurement of HbA1c in the 6 months prior to pregnancy compared to national figures (41.4% v 37.1%). Women with type 2 diabetes were less likely to be tested than women with type 1 diabetes (32.2% v 46.4%) a trend reflected nationally (29.4% v 40%).

Of the women having a pre-pregnancy HbA1c assessment, only 53 (30.6%) achieved a measurement within the target range (HbA1c<7%). This represents only 12.7% of the total number of pregnancies in the cohort. A higher proportion of women with type 2 than type 1 diabetes achieved this target (45.8% v 24.8%, p<0.01).

Section 3.4 gives further information on glycaemic control.

Table 3.3.1b *Description of pre-pregnancy counselling*

Pre-pregnancy counselling	Type 1 (n=82) (%)		Type 2 (n=36) (%)		All women (n=118) (%)	
Diabetic clinic	61	(74.4)	18	(50.0)	79	(66.9)
Pre-pregnancy clinic	9	(11.0)	6	(16.7)	15	(12.7)
GP	5	(6.1)	6	(16.7)	11	(9.3)
Other	5	(6.1)	6	(16.7)	11	(9.3)
Unknown	2	(2.4)	0		2	(1.7)

The majority of pre-pregnancy counselling was obtained from the adult diabetic services (Table 3.3.1b). The proportion attending a formal pre-conception counselling clinic is similar to that nationally.

2 Folic acid supplementation

> **Standard**: Women with diabetes have an increased risk of neural tube defects and should be offered pre-pregnancy folic acid supplements, continuing up to 12 weeks of gestation.

40.9% of all women were documented to have taken folic acid pre-conceptually. This is comparable to the general maternity population, where the uptake of folic acid is known to be about 50%[8]. Uptake of folic acid in the West Midlands is similar to that seen in the national cohort (40.9% v 39.2%). Fewer women with type 2 diabetes (32.9%) received folic acid compared with type 1 mothers (45.4%). However, uptake of folic acid among women with type 2 diabetes in the West Midlands is greater than uptake in a similar group nationally (32.9% v 29.4%). Although the optimal suggested dose of folic acid is 5 mg, this was not documented or audited.

Table 3.3.2 *Documentation of pre-pregnancy folic acid*

Pre-pregnancy folic acid	Type 1 (n=269) (%)		Type 2 (n=149) (%)		All women (n=418) (%)	
Yes	122	(45.4)	49	(32.9)	171	(40.9)
No	107	(39.8)	75	(50.3)	182	(43.5)
Not known	40	(14.9)	25	(16.8)	65	(15.6)

3 Dating the pregnancy and assessing for congenital anomalies

> **Standard**: All women with diabetes should be promptly referred for a first trimester scan to enable accurate dating of the pregnancy. They should all be offered a detailed anomaly scan between 18 and 22 weeks and serial ultrasound scans during the third trimester to monitor fetal growth.

A total of 402 of 418 women in the study had a dating scan (96.2%). This was performed in the first trimester in 90.4% of women with type 1 and 86.5% with type 2 diabetes. 36 (9%) scans were performed after 13 weeks of gestation. The main reasons given for these late scans were those who booked late or were poor attendees. The number of women receiving a first trimester scan is greater overall in the West Midlands at 89.1% compared to 73.3% nationally.

Of 389 pregnancies continuing beyond 16 weeks, 383 (98.5%) had an anomaly scan performed. There was no difference between type 1 and type 2 mothers or when the scan was performed (mean 20.5 weeks). 6 women did not have an anomaly scan (1.6%).

The investigators felt that in the vast majority of cases the anomaly scan was a mid-trimester screening scan usually performed by an ultrasonographer rather than a detailed fetal anomaly scan including cardiac assessment. This was assumed to be the case nationally where 97.6% of ongoing pregnancies after 16 weeks gestation were documented as having an anomaly scan. The original data collected did not provide an in-depth analysis for the level/type of anomaly scan performed or the level of expertise of the practitioner performing the scan.

Of the 382 pregnancies registered in the study ongoing after 24 weeks gestation, ultrasound scans for growth were performed in 372 pregnancies (97.5% equally in type 1 and type 2 women). A mean of 4 scans for growth were performed. Growth scans were not performed in 3 cases but no reasons were identified. Information was not available or not recorded in the remaining 7 cases.

The standard does not address methods of fetal monitoring late in the third trimester, although this is generally practiced within the majority of maternity units in the West Midlands. At the West Midlands Diabetes Forum in November 2006, this was discussed in depth and recommendations regards fetal monitoring are made later in the report.

4 Prophylactic antenatal steroids

> **Standard**: If delivery is indicated before 34 weeks, administration of corticosteroids should be considered to prevent neonatal respiratory distress syndrome.

382 pregnancies continued beyond 24 weeks, 34 of which delivered before 34 weeks (9.2%, nationally 9.4%). 5 were classified as stillbirths of which one received steroid therapy. Of the remaining pregnancies 18 (62.0%) received prophylactic antenatal steroids. This is less than in the national dataset (70.3%). Reasons for non-administration were due to *"no opportunity"* (17.2%) or *"chose not to be given"* (17.2%). There was 1 case out of the 34 for which not administering steroids was entered as *"don't know"*.

5 Glycaemic control

> **Standard**: Women should be encouraged and supported to monitor their blood glucose levels regularly and to adjust their insulin dosage, in order to maintain their blood glucose levels within the normal (non-diabetic) range. The aim should be for the woman to maintain her HbA1c <7%.

The information for this standard is evaluated under section 3.4.

6 Provision of a glucagon kit

> **Standard**: Hypoglycaemia should be discussed and glucagon made available with clear instructions on its use.

Table 3.3.3 details the use of a glucagon kit in pregnancy. Overall 40% of women had a glucagon kit for use in pregnancy (27.3% provided with one, 12.7% already had kit). In almost 40%, it was positively documented that a kit was not provided. Kits were provided equally to type 1 and type 2 diabetic women.

Significantly more women with type 1 diabetes had glucagon entering pregnancy when compared to women with type 2 diabetes (16.4% v 6.0%, $p<0.01$) although fewer compared to the national dataset (30.4%). Similarly, fewer women with type 2 diabetes in WM had a glucagon kit entering pregnancy than nationally (15.9%). Maternal mortality in diabetic pregnancy can be related to hypoglycaemia[9,10,11]. It is important that this risk is communicated to all women.

Table 3.3.3 *Glucagon kit in pregnancy*

Provision of a glucagon kit in pregnancy	Type 1 n=269 (%)		Type 2 n=149 (%)		All women n=418 (%)	
Yes	74	(27.5)	40	(26.8)	114	(27.3)
No	108	(40.1)	58	(38.9)	166	(39.7)
Already has kit	44	(16.4)	9	(6.0)	53	(12.7)
Not recorded	2	(0.7)		0	2	(0.5)
Not known	40	(14.9)	41	(27.5)	81	(19.4)
Not applicable	1	(0.4)	1	(0.7)	2	(0.5)

The reasons given for not issuing glucagon (Table 3.3.4) were either (a) not policy in 15.7% or (b) an alternative given (16.9%). With regard to policy of administration, this was very different in type 1 (21.3%) compared to type 2 diabetes (5.2%). This is in variance to the national dataset where this is given as a reason in 20.6% of women with type 2 diabetes. In the West Midlands, an alternative treatment for managing hypoglycaemia is given in one sixth of cases, compared to 6.6% nationally. 18% of women declined a kit or preferred to use other methods of raising blood glucose levels (e.g. Lucozade, biscuit, and bananas). It is obvious to the investigators, from discussions with the diabetologist in different units across the West Midlands, that the use of a glucagon kit is not uniformly accepted as a necessity. Glucagon is only appropriate where the woman is unable to safely correct hypoglycaemia herself orally. Its usage can be problematic (for instance, her partner/next of kin needs to be trained in its use). It is complementary to other methods of raising blood sugar, which the women can use themselves, rather than resulting to glucagon. This area of practice needs clarifying in future guidelines.

Table 3.3.4 *Reasons for not giving a glucagon kit*

Reasons given	Type 1 (n=108) (%)		Type 2 (n=58) (%)		All women (n=166) (%)	
Not policy/routine	23	(21.3)	3	(5.2)	26	(15.7)
Not necessary by professional	0	(0)	5	(8.6)	5	(3.0)
Not necessary by patient/maternal lifestyle issues	21	(19.4)	9	(15.5)	30	(18)
Alternative treatment by unit	19	(17.6)	9	(15.5)	28	(16.9)
Kit from GP		0		0		0
Not known	45	(41.7)	32	(55.2)	77	(46.4)

7 Detailed Retinal Assessment

> **Standard**: A full retinal assessment should be undertaken in all women with pre-existing diabetes during the first trimester or at booking if later.

Retinopathy may worsen during pregnancy and repeated assessment during pregnancy is an essential part of care. In the West Midlands cohort, 85.5% of women with type 1 and 82.6% with type 2 diabetes had a detailed retinal assessment. This is better than that recorded in the national dataset (79.9%) and is better than previous reported data (81%) in the UK[12]. It falls short of Scottish data where 97% of women have an assessment[13]. The investigators felt patients needed to be forewarned about the timing of each retinal assessment and the importance of pupil dilatation with fundoscopy. Recent advances in retinal screening mean that more pregnant women with diabetes in the West Midlands may be offered digital retinal photography now instead of fundoscopy.

8 Appropriate Neonatal Staffing and Facilities Available

> **Standard**: Labour and delivery should be undertaken in a maternity unit with facilities for the resuscitation and stabilisation of babies and with personnel skilled in advanced resuscitation immediately available on a 24-hour basis.

This was not assessed separately within the West Midlands Region.

9 Mode/timing of delivery

> **Standard**: The mode and timing of delivery should be determined on an individual basis, aiming to realise a spontaneous vaginal delivery by no later than 40 weeks of gestation if possible.

Table 3.3.5 *Mode of delivery in pregnancies (after 24 weeks)*

Mode of delivery	Type 1 (n=247) (%)		Type 2 (n=135) (%)		All women (n=382) (%)	
VAGINAL	58	(23.5)	49	(36.3)	107	(28.0)
Spontaneous	44	(17.8)	45	(33.3)	89	(23.3)
Instrumental	14	(5.7)	4	(3.0)	18	(4.7)
ABDOMINAL	188	(76.0)	86	(63.7)	274	(71.7)
Emergency CS	107	(43.3)	41	(30.4)	148	(38.7)
Elective CS	81	(32.7)	45	(33.3)	126	(33.0)
Not a vaginal delivery	1	(0.4)	0		1	(0.4)

28% of women achieved a vaginal delivery with a higher proportion being from type 2 pregnancies (36.3 v 23.5%). More than two thirds of women required a caesarean section, 38.7% emergency and 33.0% elective.

These figures are similar to the national dataset. For more details regarding delivery methods see section 3.5.

10 Intrapartum fetal heart rate monitoring

> **Standard**: Continuous electronic fetal monitoring (CEFM) should be offered to all women with diabetes during labour and fetal blood sampling should be available if indicated.

Current national practice recommendations are that CEFM should be used in any situation where there is a higher risk of fetal compromise. In the West Midlands 175 pregnancies (89.3%) were classified as being monitored in labour, 65% were in type 1 women (two of these resulted in intrapartum stillbirths) and 35% in type 2 women. This is significantly less ($p<0.01$) than that achieved in the national dataset (93.4%). The reasons for not carrying this out were not given.

The national dataset did not allow for a more detailed analysis. However, of the 107 vaginal deliveries 95 (88.7%) did have CEFM, 5 (4.6%) did not and 7 (6.5%) were identified as not applicable. Of the 86 who had an emergency caesarean section in labour, 78 (90.7%) received monitoring, 5 (5.8%) did not and 3 (3.5%) were not documented. Fetal blood sampling was not assessed in this study.

11 Use of intravenous dextrose and insulin

> **Standard**: Intravenous dextrose and insulin should be administered during labour and delivery following an agreed multidisciplinary protocol.

Table 3.3.6 *Intravenous infusion of insulin and dextrose at the time of delivery after 24 weeks of gestation (percentages are the proportion of women in the category out of the total number with a valid response; i.e. excluding "*missing*")*

Intravenous infusion at delivery	Type 1 (n=247) (%)		Type 2 (n=135) (%)		All women (n=382) (%)	
Yes	229	(92.7)	108	(80.0)	337	(88.2)
No	5	(2.0)	20	(14.8)	25	(6.5)
No time/opportunity	11	(4.4)	5	(3.7)	16	(4.1)
Not recorded/applicable/don't know	3	(1.2)	2	(1.5)	5	(1.3)

88.2% of women received an infusion of dextrose and insulin during labour and delivery, slightly more type 1 (92.7%) than type 2 (80%) women and similar to the national dataset. The women who did not receive this treatment when it was indicated were more likely to have type 2 diabetes than type 1 (14.8 v 2.0%). This was similar to the national group but the proportions were wider in the West Midlands.

Discussion

Preconception care

The overall standard of pre-pregnancy care for women with known diabetes is assessed using three criteria:

1 Preconception counselling,

2 Use of folic acid pre-conception,

3 Demonstration of an HbA1c of less than 7% prior to conception.

Women in the West Midlands with pre-gestational diabetes, as nationally, are not well prepared for pregnancy. Only 28% receive pre-pregnancy counselling.

41% had a pre-pregnancy HbA1c assessment and 30% of these were within the acceptable range of <7%. This represents only 1 in 8 pregnancies registered in the study.

41% of all women received folic acid in the pre-pregnancy period, the same as national figures, although the dose taken was not examined. This is less than the 50% folic acid usage in the background maternity population.

These findings suggest inadequate pre-pregnancy care. The Diabetes NSF recommends that a pre-conception clinic is available to all women with diabetes[14]. In the West Midlands survey only 15 (3.5%) of the pregnancies were preceded by care in a pre-conception clinic. Although there is debate about the value of pre-conception clinics, widespread agreement exists about the need to achieve excellent glycaemic control prior to conception. This will not occur without regular pre-conception counselling.

The rate of pre-conception counselling was lower in women with type 2 diabetes. A number of factors may contribute to this finding. Firstly, women with type 2 diabetes who do not use insulin are more likely to be looked after in primary care than women with type 1 diabetes. Clinicians with limited diabetes training in primary care may not consider pre-conception counselling to be an important clinical standard. Support for this hypothesis comes from the finding that, of the pregnancies in which pre-conception counselling was documented, 80% of the counselling occurred in specialist clinics. Secondly, women with type 2 diabetes are older than those with type 1 diabetes. Consequently,

clinicians may be less likely to consider possible future pregnancy when reviewing women with type 2 diabetes in the community. Thirdly, the West Midlands cohort of women with type 2 diabetes contained a substantial proportion from ethnic minorities (57%). Cultural and linguistic factors may have impeded pre-conception counselling in this group.

A programme of community education about the importance of pregnancy preparation is urgently needed. This needs to be ethnically sensitive in view of the number of women from ethnic sub-groups. This service needs to be provided by both primary and secondary care. More effort and resources needs to be targeted both at this education awareness agenda and in providing easier access and availability of pre-conception clinics.

Care during pregnancy

Only 40% of women with diabetes had a glucagon kit in the current pregnancy.

84.4% of women had a retinal examination, which is an improvement on previous data including the national dataset.

96% of women had a dating scan, 98.5% had an anomaly scan and 97% had one or more growth scans after 23 weeks gestation.

One third of women delivering a live birth before 34 weeks did not receive a full course of antenatal steroids. The effect of steroids on glycaemic control was felt to be a factor in failure to administer. This concern was expressed in the panel enquiries and again later within the forum discussion. The general opinion was that the proven benefits from antenatal steroids outweigh problems that can occur with glycaemic control. All patients receiving antenatal steroids should be admitted for glucose monitoring during this treatment, utilising an IV insulin infusion with regular monitoring of maternal blood glucose levels. All units should have protocols to guide those involved in administering this treatment. The region wide protocol (West Midlands Clinical Practices: Guidelines for the management of diabetes in pregnancy) should help in increasing compliance to the national standard.

Education is urgently needed on the serious risk of both hypoglycaemia and hyperglycaemia (DKA) and the appropriate management of these conditions. Glucose tablets and HypoStop should not be used as alternatives but in addition to glucagon. Glucagon can be used where the level of consciousness is reduced and has to be given by a third party. This requires information and training being given to those third parties to ensure the correct action would be taken if required. As a region, the West Midlands is not complying with this standard. Region-wide opinion as to whether glucagon use should be recommended universally or only targeted at particular groups (e.g. type 1 diabetics) needs to be gathered. Recommendations for its usage should then be made.

Care during labour and delivery

The majority of women in the West Midlands (88%), as nationally, received intravenous dextrose and insulin in labour. This is important to maintain normoglycaemia throughout labour, which is known to influence the rate of early neonatal hypoglycaemia and therefore admission of babies to a neonatal unit (NNU).

The majority of babies (89%) received CEFM in labour.

There is room to improve the implementation of both of these routine interventions for type 1 and 2 diabetic women in labour.

The issues related to mode of delivery and caesarean section rates are discussed in section 3.5.

3.4 Glycaemic Control

KEY FINDINGS

1 **Only 4 out of 10 women had an HbA1c measurement in the pre-pregnancy period.**

2 **Only 1 out of 8 women achieved a target HbA1c <7.0% pre-conception.**

3 **Women with type 2 diabetes were significantly less likely to receive a pre-pregnancy HbA1c test.**

4 **Where glycaemic testing was carried out the West Midlands region performed better than nationally for both type 1 and type 2 women with diabetes at all stages of pregnancy.**

Good glycaemic control is the cornerstone to a successful pregnancy outcome. Rates of perinatal morbidity and mortality approach those of the background population when HbA1c is within target especially in the pre-conception and peri-conception period. In an effort to reduce congenital malformations (a major contributor to perinatal mortality), it is important to maintain normal glucose status in the first 8 weeks following conception. Good glycaemic control is vital in the latter part of pregnancy to reduce the incidence of stillbirth.

A DCCT-aligned HbA1c is the measurement of choice as a marker of long term glycaemic control, as it is the only measure for which good data are available on the risk of subsequent diabetic complications.

An HbA1c<7% is recognised as showing good long term control and at a level associated with improved perinatal outcomes.

This section provides information on the levels of glycaemic control achieved at the different stages of pregnancy and the pre-pregnancy planning to achieve the defined targets. Measurements of glycaemic control as determined by HbA1c corresponding to pre-pregnancy, 10 weeks, 20 weeks and 34 weeks of gestation were analysed as documented on the CEMACH proforma. For each antenatal unit the specified laboratory normal ranges in 2002-03 was also requested.

Listed in Table 3.4.1 are reference ranges for HbA1c in each anonymised maternity unit in the West Midlands. The specified ranges were obtained directly from each unit relating to the time this study was undertaken. They show that the ranges for optimal control were variable.

Table 3.4.1 *HbA1c ranges in West Midlands units*

Hospital	HbA1c range (%)	Fructosamine range		Hospital	HbA1c range (%)	Fructosamine range
A	5.0-7.0			K	4.0-6.0 (or 7.2)	
B	4.6-6.2			L	4.5-5.7	
C	3.8-6.2			M	4.5-6.2	<275
D	4.3-6.5			N	3.5-5.5	
E	3.5-5.5			O	<5.0	
F	<5.0			P	<8.0	
G	3.6-5.5	205-285		Q	3.6-6.8	
H	4.5-6.1			R	4.0-6.5	
I	<7.2			S	4.5-6.1	
J	6.1-8.9			T	4.6-5.6	

Uptake of HbA1c test

Table 3.4.2a *Number of women with a recorded HbA1c measurement.*

Cohort	Pre-pregnancy		Test closest to 10 wks		Test closest to 20 wks		34 weeks onwards	
Type 1 (n=269)	125	(46.5%)	236	(87.7%)	226	(83.3%)	220	(81.8%)
Type 2 (n=149)	48	(32.2%)	111	(74.5%)	122	(84.0%)	116	(77.9%)
All women (n=418)	173	(41.4%)	347	(83.0%)	348	(81.9%)	336	(80.4%)

41.4% of women had a pre-pregnancy recording of HbA1c (compared to 37.1% nationally) with almost two thirds entering pregnancy poorly prepared or unplanned. The proportion of tests carried out increased to 83% at 10 weeks and then stayed relatively stable throughout the rest of pregnancy. In the pre-pregnancy period women with type 1 diabetes were more likely to receive the test compared to those with type 2 diabetes (46.5% v 32.2%, p<0.01). This difference persisted throughout the first trimester (87.7% v 74.5%, p<0.01). This suggests that type 2 women with diabetes are less well managed at this stage of pregnancy or they are failing to access available services. This is confirmed by a lower attendance for type 2 women at pre-pregnancy counselling, a lower uptake of folic acid and being less likely to be receiving insulin at the time of conception (32.2% v 99.6%).

Table 3.4.2b shows pre-pregnancy and first trimester glycaemic testing broken down into maternal characteristics such as diabetes type, ethnicity, age, and parity. On every grouping, the West Midlands shows improved and higher rates of glycaemic testing compared to the national dataset. This is seen across all age ranges and in both primiparous and multiparous women.

Statistical analysis (chi-square test, p<0.05) shows that documented pre-pregnancy testing was significantly higher in type 1 diabetes and in the European population. In addition, glycaemic testing in the first trimester was significantly more likely to have occurred within the West Midlands cohort (type 1 and type 2 women) and in the European and Asian populations compared to the national dataset.

Table 3.4.2b *Maternal characteristics and glycaemic control by 13 weeks.*

Characteristic	n	Documented pre-pregnancy test n (%) [p*]			Documented test by 13 weeks n (%) [p*]		
All women	418	173	(41.4)	[p=0.10]	347	(83.0)	[p<0.01]
DIABETES TYPE							
Type 1	269	125	(46.5)	[p=0.05]	236	(87.7)	[p<0.01]
Type 2	149	48	(32.2)		111	(74.5)	[p=0.01]
ETHNICITY							
European	313	147	(47.0)	[p=0.02]	267	(85.3)	[p<0.01]
Black	21	6	(28.6)		15	(71.4)	
Asian	73	17	(23.3)		58	(79.5)	[p<0.01]
Chinese & other	11	3	(27.3)		7	(63.6)	
AGE							
<20 years	23	11	(47.8)		19	(82.6)	
20-24 years	64	22	(34.4)		55	(85.9)	[p=0.02]
25-29 years	94	39	(41.5)		76	(80.9)	[p=0.12]
30-34 years	137	68	(49.6)	[p=0.01]	120	(87.6)	[p<0.01]
35+ years	100	33	(33.0)		77	(77.0)	[p=0.12]
PARITY							
Primiparous	169	73	(43.2)		146	(86.4)	[p<0.01]
Multiparous	249	100	(40.2)	[p=0.16]	201	(80.7)	[p<0.01]

* compared with national CEMACH report[15]

Glycaemic control as determined by HbA1c

Table 3.4.3 *Number of measurements within target (<7%) (irrespective of hospital range)*

Cohort	Pre-pregnancy n (%)	10 weeks n (%)	20 weeks n (%)	34 weeks n (%)
All women: Result within target*	53 (30.6)	155 (44.7)	244 (70.1)	230 (68.5)
Women with type 1 diabetes: Result within target*	31 (24.8)	95 (40.3)	149 (65.9)	141 (64.1)
Women with type 2 diabetes: Result within target*	22 (45.8)	60 (51.4)	95 (77.9)	89 (76.7)

*number of HbA1c tests with results below 7% as a proportion of all HbA1c tests for that period

In those that were tested, glycaemic targets were reached by less than half of the study population by the end of the first trimester. There was a significant improvement in the percentage achieving a target HbA1c as the pregnancy progressed. At all times the percentage of women with type 2 diabetes achieving the desired target was greater than for type 1 diabetes. Our ability to achieve glycaemic targets in the West Midlands region was better than that achieved in the national cohort in every category in Table 3.4.3. This was seen most in pre-pregnancy and first trimester rates of HbA1c tests below 7% (31 % v 27% pre-pregnancy, 45% v 38.5% at 10 weeks).

Discussion

Pre-pregnancy glycaemic control is accepted as an extremely important factor in determining pregnancy outcome. There is no universally accepted threshold that should be achieved, however it is generally accepted that HbA1c should be less than 7% prior to conception (see Chapter 4).

In the West Midlands cohort, pre-pregnancy HbA1c was recorded in the six months prior to conception in 41% of the pregnancies. A pre-conception HbA1c of less than 7% was recorded in only 53 (13%) of pregnancies. As HbA1c was not recorded before conception in 58.6% of the pregnancies, one cannot use this figure alone to conclude that pre-conception glycaemic control was generally poor. HbA1c measurement at 10 weeks gestation gives some indication of pre-conception glycaemic control as it reflects glycaemia during the preceding three months. In 347 (84.6%) pregnancies, HbA1c was recorded at 10 weeks gestation. HbA1c was recorded as below 7% in only 155 (45%) of the pregnancies tested at this stage. It is reasonable, therefore, to conclude that pre-pregnancy glycaemic control in the West Midlands, although better than nationally, is still suboptimal.

Women with type 2 diabetes were less likely to have had this test both in the pre-pregnancy period and in the first trimester. The proportion of women from ethnic minorities is greatest among those with type 2 diabetes. They are also within the quintile of greatest social deprivation. This suggests that those most at risk due to a combination of poverty and diabetes are not receiving the message of the importance of good pre-conception glycaemic control.

Glycaemic testing (HbA1c) improves considerably in pregnancy from the first trimester onwards. However, 1 out of 5 women do not have a documented HbA1c test performed in each trimester.

The West Midlands region shows improved glycaemic control in those tested compared to the UK at all stages of pregnancy and for all different maternal groups. However, the West Midlands compares poorly with other Northern European countries where 75% of women with type 1 diabetes achieve a target HbA1c at the end of the first trimester[16].

Considerable improvements are needed urgently. This will involve:

1 an improvement in service standards in accessibility and delivery of care.

2 exploring the use of short acting insulin analogues rather than conventional human insulin as these are associated with better post-prandial glucose levels without an increase in hypoglycaemic events.

3 exploring better delivery systems for insulin, e.g. pump delivery.

3.5 Labour and Delivery

KEY FINDINGS

1 **Delivery by caesarean section occurs in more than two thirds of women with diabetes in the West Midlands.**

2 **One third of women have their labours induced, primarily because it is "*routine*" hospital practice.**

3 **A vaginal delivery occurs in just over a quarter of women. Those with type 2 diabetes are more likely to achieve a vaginal delivery. Instrumental deliveries occur less commonly than nationally.**

The main aim of antenatal diabetes care is to achieve a normal pregnancy outcome for both the mother and baby. The aim is for a normal vaginal delivery as close to 40 weeks gestation as possible. This chapter provides a description of events surrounding labour and delivery for women with established diabetes in the West Midlands. Judging how long to continue a pregnancy and how to deliver are key decisions for women with diabetes and health professionals.

Table 3.5.1 *Onset of labour in women with diabetes compared to the general maternity population and National CEMACH dataset (pregnancies ongoing after 24 weeks gestation)*

Onset of labour	Diabetes in West Midlands n=382		Diabetes in National dataset n=3,474		Normal population* n=548,000	
Spontaneous	55	(14.4%)	625	(18.0%)	378,120	(69.0%)
Induced	132	(34.6%)	1,350	(38.9%)	115,080	(21.0%)
Elective & emergency CS before labour	188	(49.2%)	1,483	(42.7%)	60,280	(11.0%)
Not recorded/not known	7	(1.8%)	14	(0.4%)	0	

*source for national data: NHS Maternity Statistics, England 2002-2003, bulletin 2004/10[17]

Onset of labour for women with diabetes is significantly different from women without diabetes in the UK. Only 14% of diabetic women in the West Midlands went into spontaneous labour compared to 69% of the normal population.

Induction of Labour

34.6% of women with diabetes in the West Midlands were induced compared to 21% of non-diabetic women. The rate of induction is similar to that in the overall dataset at 39%. The reasons for induction of labour are given in Table 2.5.2a. In almost two thirds of women induction of labour occurs because it is "*routine*" hospital practice and is similar in type 1 and type 2 diabetes. This figure is significantly greater than that reported nationally (63% v 48%, $p<0.01$). The majority of inductions are performed between 38 and 38^{+6} weeks gestation. No inductions were carried out for known diabetes complications, whereas 12.9% of cases were induced because of specific obstetric complications.

Table 3.5.2a *Reasons for induction of labour*

Reason for induction of labour	Gestation at induction (completed weeks)								All IOLs n=132 (%)	
	<37 wks n=14 (%)		37^{+0}-37^{+6} wks n=26 (%)		38^{+0}-38^{+6} wks n=64 (%)		39+ wks n=28 (%)			
Routine for diabetes	1	(7.1)	10	(38.5)	49	(76.6)	23	(82.1)	83	(62.9)
General obstetric complications	1	(7.1)	5	(19.2)	3	(4.7)	1	(3.6)	10	(7.6)
Presumed fetal compromise†	1	(7.1)	3	(11.5)	3	(4.7)			7	(5.3)
Large baby/ polyhydramnios	1	(7.1)	2	(7.7)	1	(1.6)			4	(3.0)
Other clinical reasons‡	4	(28.6)	1	(3.8)	1	(1.6)	1	(3.6)	7	(5.1)
Premature rupture of membranes	0		0		0		0		0	
Diabetes complication	0		0		0		0		0	
Maternal request	0		0		0		0		0	
Reason unknown or inadequately described	6	(42.9)	5	(19.2)	7	(10.9)	3	(10.7)	21	(6.8)

*includes hypertensive disorder of pregnancy, antepartum haemorrhage, unstable lie and multiple pregnancy
†includes abnormal CTG, evidence of placental insufficiency, congenital malformation, rhesus isoimmunisation and obstetric cholestasis
‡includes intrauterine death, medical and surgical complications in pregnancy and previous obstetric history

Table 3.5.2b *Success of induction of labour in pregnancies ongoing ≥24 weeks*

Mode of delivery	Type 1 n=80)		Type 2 (n=52)		Total (n=132)	
SVD	30	(37.5%)	33	(63.5%)	63	(47.7%)
Ventouse	7	(8.8%)	0		7	(5.3%)
Forceps	5	(6.3%)	2	(3.8%)	7	(5.3%)
Emergency CS	38	(47.5%)	16	(30.8%)	54	(40.9%)
Elective CS	0		1	(1.9%)	1	(0.8%)

Almost half of all inductions resulted in a spontaneous vaginal delivery and a further 10% of inductions were delivered by instrumental forceps or ventouse. There is no comparative data within the national dataset.

Mode of Delivery

Table 3.5.3 *Mode of delivery for all women compared to National dataset and general maternity diabetic population.*

Mode of delivery	Type 1 (n=247) (%)		Type 2 (n=135) (%)		All women (n=382) (%)		National Dataset (n=3,474)	Normal Population* (n=548,000)
VAGINAL	58	(23.5)	49	(36.3)	107	(28.0)	32.1%	78%
Spontaneous	44	(17.8)	45	(33.3)	89	(23.3)	24.4%	67%
Instrumental	14	(5.7)	4	(3.0)	18	(4.7)	7.7%	11%
CAESAREAN SECTION	188	(76.1)	86	(63.7)	274	(71.7)	67.4%	22%
Emergency CS	107	(43.3)	41	(30.4)	148	(38.7)	37.6%	13%
Elective CS	81	(32.8)	45	(33.3)	12	(3.1)	29.8%	9%
Not vaginal delivery	1	(0.4)	0		1	(0.3)	0.2%	0%

*source for national data: NHS Maternity Statistics, England 2002-2003, bulletin 2004/10[17]

Only 28% of women delivered vaginally in the West Midlands compared to 32% nationally. Vaginal delivery was more likely in women with type 2 diabetes (36% v 23.5%) and they were twice as likely to labour spontaneously. An instrumental delivery was less likely to occur in the West Midlands data when compared to national figures (4.7% v 7.7%). The caesarean section rate was more than 3 times higher in diabetic women than in the general maternity population (72% v 22%). In type 1 diabetic women, three quarters delivered by caesarean section (the majority by emergency caesarean section). In women with type 2 diabetes, equal proportions delivered by elective and emergency sections. This was similar to national diabetic figures. There were similar proportions of elective and emergency sections in the West Midlands cohort overall.

Caesarean section (CS)

The indications for elective and emergency CS are listed in Tables 3.5.4a and 3.5.4b. The vast majority of caesarean sections are performed for common obstetric reasons. One quarter of cases occur because of previous CS and fetal compromise. The main reason for an elective CS was previous CS and fetal macrosomia. Ten cases were listed as routine practice for diabetic pregnancies. Almost half of emergency CSs were due to fetal compromise. This is similar to national dataset. Maternal diabetic complications and maternal request, as in the National data, remain relatively rare causes of CS.

Table 3.5.4a *Reasons for caesarean sections*

Indication for CS	Elective CS (n=126) (%)		Emergency CS (n=148) (%)		All CS (n=274) (%)	
Presumed fetal compromise	6	(4.8)	63	(42.6)	69	(25.2)
Previous caesarean section	50	(39.7)	11	(7.4)	61	(22.3)
General obstetric complication	16	(12.7)	28	(18.9)	44	(16.1)
Failure to progress in labour	0		21	(14.2)	21	(7.7)
Large baby	12	(9.5)	0		12	(4.4)
Other clinical reasons	7	(5.6)	10	(6.8)	17	(6.2)
Diabetes complication	5	(4.0)	5	(3.4)	10	(3.6)
Maternal request	5	(4.0)	2	(1.4)	7	(2.6)
Routine for diabetes	10	(7.9)	0		10	(3.6)
Reason unknown	15	(11.9)	8	(5.4)	23	(8.4)

Table 3.5.4b *Reasons for caesarean section <37 weeks*

Indication for CS	Elective CS (n=28) (%)		Emergency CS (n=65) (%)		All CS (n=93) (%)	
Presumed fetal compromise	4	(14.3)	26	(40.0)	30	(32.3)
Previous caesarean section	0		22	(33.8)	22	(23.7)
General obstetric complication	5	(17.9)	3	(4.6)	8	(8.6)
Failure to progress in labour	0		5	(7.7)	5	(5.4)
Large baby	6	(21.4)	0		6	(6.5)
Other clinical reasons	2	(7.1)	2	(3.1)	4	(4.3)
Diabetes complication	4	(14.3)	4	(6.2)	8	(8.6)
Maternal request	3	(10.7)	0		3	(3.2)
Routine for diabetes	1	(3.6)	0		1	(1.1)
Reason unknown	3	(10.7)	3	(4.6)	6	(6.5)

Preterm delivery

Table 3.5.5 *Reasons for premature delivery at less than 37 completed weeks of pregnancy*

Reasons for preterm delivery	Pregnancies known (n=115)	
SPONTANEOUS	27	(23.5%)
Spontaneous preterm labour	26	(22.6%)
Induced after premature rupture of membranes	1	(0.9%)
IATROGENIC	88	(76.5%)
Induction of labour for other reasons	13	(11.3%)
Caesarean section	75	(65.2%)
Not known	1	
Missing	2	

31% of pregnancies beyond 24 weeks delivered prematurely. This compares with a spontaneous preterm delivery rate of 7.1% in the general population. As nationally, the largest contributor to preterm delivery was iatrogenic preterm CS - the majority of which were emergency caesarean sections usually performed for previous sections or fetal compromise. Four preterm elective caesarean sections were performed for maternal request/routine practice in diabetic pregnancy.

Discussion

Current guidelines recommend that women with established diabetes should be delivered as close as possible to term. Delivery should be complete by 40 weeks to minimise the risk of stillbirth[18]. Timing and mode of delivery should be individualised on a case-to-case basis taking into consideration all relevant facts. This decision should be discussed with the woman and documented in the case notes.

The vaginal delivery rate is lower in the West Midlands in comparison to the National dataset (28% v 32%). Only 14% of pregnancies beyond 24 weeks resulted in spontaneous labour, half (27/55) delivered preterm.

The induction of labour (IOL) rate at 35% is more than 1.5 times higher than the general maternity population of England and Wales but similar to that reported in the national dataset (38.9%). In almost two thirds (63%) of women being induced, IOL occurs because it is "*routine*" hospital practice and in the majority of cases, this takes place during the 39th week of pregnancy. Therefore, delivery cannot be said to be individualised, as recommended, for many of these women. Routine IOL is associated with a higher chance of requiring a CS, which in turn is associated with a higher risk of neonatal respiratory distress syndrome. Routine IOL (63%) is significantly greater than that reported nationally (48%).

Almost 60% of all IOLs in the West Midlands do progress to a vaginal delivery, more commonly in type 2 women.

The total caesarean section rate was 72%, more than 3 times higher than in the normal population. This was similar to national dataset figures. There were similar proportions of elective and emergency sections. The main reasons for CS were previous CS, fetal compromise and general obstetric problems.

Strong consideration, on an individual basis, should be given to pushing IOL back to 40 weeks gestation instead of 38-38^{+6} weeks, which appears to be the "*routine*" choice for IOL in the West Midlands as nationally. This would have the effect of increasing the spontaneous onset of labour rate and reducing the emergency caesarean section rate by reducing the overall rate of IOL. Accurate evidence and figures regarding the risk of late stillbirth from 38 to 40 weeks gestation in this population is required to inform an individualised discussion on the merits and timing of IOL.

3.6 Pregnancy Outcomes

KEY FINDINGS

1 **The congenital malformation rate (CMR) in the West Midlands region is 82.1/1,000 births. This is twice that reported in the national dataset (41.8/1,000) and 4 times that of the background population of England and Wales (21/1,000). There is no significant difference in type 1 (78.7/1,000) and type 2 (88.2/1,000) disease.**

2 **Stillbirth, neonatal and perinatal mortality rates are all higher in the West Midlands region compared to the national cohort for the same calendar period.**

3 **A baby born to a mother with diabetes in the West Midlands is 6 times more likely to succumb to a stillbirth and 2.5 times more likely to suffer an early neonatal death compared to the background maternal population.**

One of the main aims of the data collection was to provide robust figures on regional perinatal mortality rates for babies of women with pre-gestational diabetes and details of congenital anomalies. This chapter provides these rates together with a description of the pregnancy outcomes. This is important, as it is known that these figures are greater in the West Midlands maternity population compared to national UK rates[19].

Congenital anomalies

Information was collected on detected congenital anomalies identified in the antenatal period and up to 28 days of life for all live births, all fetal losses, and all terminations of pregnancy at any gestation. Any reported anomaly was subsequently confirmed by post-mortem findings, genetic results, or correspondence between health professionals. Anomalies were coded according to the 10th revision of the International Classification of Diseases (ICD10). Individual groups were formed according to the classification system used by the European Surveillance of Congenital Anomalies (EUROCAT)[20]. Minor congenital anomalies were excluded.

The congenital malformation rate is calculated per 1,000 live and stillbirths.

Perinatal mortality

Stillbirth was defined as an in utero fetal loss delivering after 24 completed weeks of gestation, neonatal death as the death of a live birth (born at any gestation) up to 28 days after birth and perinatal death as a stillbirth or death of a live birth (born at any gestation) up to 7 days after birth.

Perinatal mortality rates (PMR) were calculated for 1 calendar year (deliveries between 1 March 2002 and 28 February 2003). This allows comparison with local and national perinatal mortality rates from the CEMACH 2002 perinatal death notification database, West Midlands Perinatal Institute perinatal mortality updates and the Office for National Statistics[21].

The PMR is calculated per 1,000 live and stillbirths.

Outcomes

405 women were registered in the study. There were 418 pregnancies in total resulting in 426 babies; including 8 sets of twins. 390 births were registered; 373 were live and there were 17 stillbirths, 10 of which occurred prematurely (<37 weeks). There were 3 neonatal deaths.

The multiple pregnancy rate for the West Midlands is 1.9%, which is similar to the background figure (1.5%).

Early Fetal Losses

In the 30 recorded early fetal losses (<20 weeks gestation) three of these had a CNS congenital anomaly; anencephaly, exencephaly and one with hydrocephalus and spina bifida (two - type 1, one - type 2). Legal abortions were performed in two of these cases and one miscarried. All mothers were of European descent.

Late Fetal Losses

There were 6 late fetal losses (20-24 weeks gestation). Five of these occurred in European women with type 1 diabetes and one to a Black African woman with type 2 diabetes. Four of the type 1 losses were found to have a congenital anomaly and a legal abortion was performed in each case. The anomalies identified were:-

- Chromosomal (Down's syndrome)
- Cardiovascular (hypoplastic left heart)
- Musculoskeletal (thanatophoric dysplasia)
- Nervous system (hydrocephaly)

In the other two cases, one resulted as a spontaneous miscarriage, and the other presented as an intrauterine death.

Legal Abortions

A total of 8 legal abortions were performed, all in European women (7 x type 1, 1 x type 2). Six had congenital anomalies diagnosed antenatally (as identified above). Two others were performed - one for social reasons, the other unknown.

Congenital Anomalies

There were 32 major congenital anomalies (CA) recorded.

7 of these were identified before 24 weeks gestation. There were 3 stillbirths, 2 neonatal deaths, and 20 babies alive at 28 days with a major congenital anomaly.

The CMR is 82.1/1,000 births. This is twice that reported in the national dataset (41.8/1,000) and 4 times higher than the EUROCAT data on England and Wales 2002/03 (21/1,000)[20].

Description of anomalies

Appendix D gives a fuller description of these anomalies however, the types of anomalies were similar to those seen in the national cohort. There were 11 cardiac (34%) and 6 CNS defects (19%) diagnosed; 3 babies had multiple defects affecting different body systems of which 2 were due to genetic defects.

Table 3.6.1 *Ethnicity in relation to major congenital anomaly*

Ethnicity	Type 1 (n=20) (%)		Type 2 (n=12) (%)		All women (n=32) (%)	
European	18	(90.0)	7	(58.3)	25	(78.1)
Black African	0		1	(8.3)	1	(3.1)
Black Caribbean	1	(5.0)	0		1	(3.1)
Indian	1	(5.0)	0		1	(3.1)
Pakistani	0		2	(16.7)	2	(6.3)
Bangladeshi	0		1	(8.3)	1	(3.1)
Other	0		1	(8.3)	1	(3.1)

Table 3.6.1 illustrates the distribution of major congenital anomalies by type of maternal diabetes and ethnicity. There is no significant difference in CMR rates between type 1 (78.7/1,000) and type 2 (88.2/1,000) disease. Ethnic distribution is very much in keeping with the ethnic makeup of type 1 and type 2 diabetes in the West Midlands (Table 3.2.1). Overall three quarters of CA occurred within the European population, predominantly to type 1 mothers (67/1,000 total pregnancies). The highest CMR was found in European type 2 diabetic women (109/1,000 total pregnancies), whilst the lowest rate was in South Asian type 2 mothers (48/1,000 total pregnancies).

There were 29 major congenital anomalies in pregnancies beyond 16 weeks gestation, all of these had a "*detailed*" fetal ultrasound scan. In 17 cases, the anomalies were diagnosed antenatally (16 by ultrasound, 1 by amniocentesis). In 12 cases, the "*detailed*" scan was reported as normal. The antenatal CMR detection rate is 59% in pregnancies beyond 16 weeks gestation. 12 cases of the undiagnosed anomalies included 5 complex cardiac defects (Appendix D).

Table 3.6.2 *Perinatal mortality in women with diabetes in one calendar year (1/3/02-28/2/03)*

Mortality	n	WM cohort			Total WM maternity pop†	WM cohort v WM region† RR	WM cohort v National CEMACH RR	WM cohort v National maternity pop RR
		All (n=297)	Type 1 (n=188)	Type 2 (n=109)				
Stillbirth rate per 1,000 births	10	38.0	35.7	42.1	6.2	6.0	1.4	6.7
Neonatal death rate per 1,000 live births	3	11.9	6.2	22.0	4.9	2.5	1.3	3.3
Perinatal Mortality rate per 1,000 births	12*	45.6	41.7	52.6	10.1	4.5	1.4	5.4

* comprises 10 stillbirths and 2 early neonatal deaths
†West Midlands Perinatal Mortality (Update March 2006)[19]
RR: relative risk

Table 3.6.2 (Figure 3.6.1) shows that the stillbirth, neonatal and perinatal mortality rates are all higher in the West Midlands region compared to the national diabetic cohort for the same calendar period. The overall PNMR is 45.6/1,000 births which is 4.5 times higher than in the general maternity population in the West Midlands and almost 5.5 times higher than in the national maternity population. Allowing for the higher background rates in the West Midlands region, diabetic women are 6 times more likely to suffer a stillbirth and 2.5 times more likely to suffer a neonatal death than their healthy counterparts.

Figure 3.6.1 *Comparison of stillbirth, neonatal death, and perinatal mortality rates*

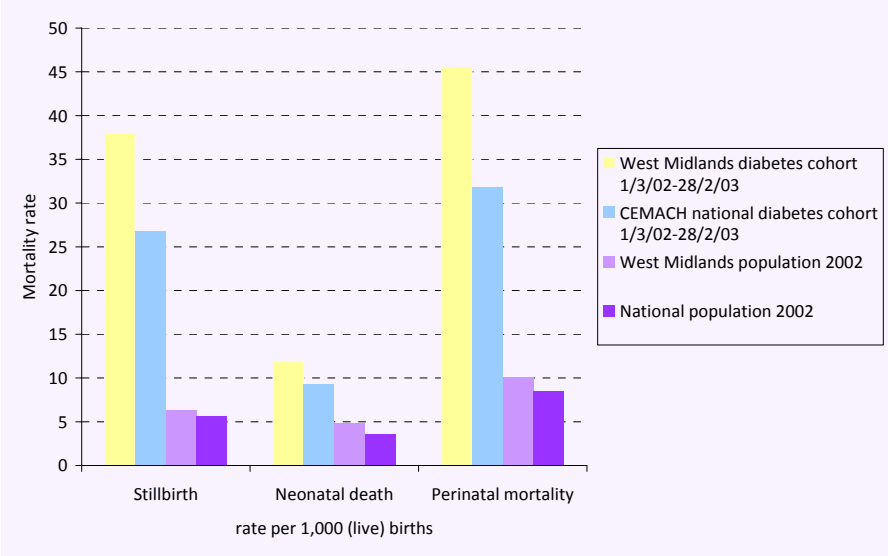


Table 3.6.3 *Perinatal Mortality during study period*

Ethnic group	Perinatal deaths	Registerable births (n=390)	PNM rate per 1,000 births
European	11	292	37.7
Non-European	9	98	91.8

Table 3.6.3 shows that non-European groups have a significantly higher perinatal mortality rate compared to Europeans ($p<0.01$), being more than twice as likely to suffer a perinatal death. Possible reasons for this are discussed below.

Discussion

The congenital malformation rate in the West Midlands region is 82.1/1,000 births. This is twice that reported in the national dataset and 4 times that of the background population of England and Wales. This is not a surprise finding when one considers that only one in eight women had a HbA1c<7% pre-pregnancy and only 1 in 4 women partook of pre-pregnancy counselling. However, pre-pregnancy glycaemic control was poor nationally also. The importance of optimising diabetic control pre-pregnancy and throughout the first 10 weeks of pregnancy has been shown in reducing the high incidence of fetal anomalies. The CMR is similar in type 1 (78.7/1,000) and type 2 (88.2/1,000) disease but differs according to location of the unit within the West Midlands, although the overall incidence does not allow any firm conclusions to be made.

The rate reported here is similar to other UK based studies[4,5,22] which report major and minor anomalies. Ours and the national dataset only includes major anomalies and may be an underestimate as it does not include major anomalies diagnosed after 28 days of life. However, we have included all congenital anomalies diagnosed before 20 weeks gestation rather than only those, which resulted in termination of pregnancy. In addition, there are more details included on the congenital anomalies diagnosed than in the CEMACH 2005 report[1]. Congenital cardiac defects remain the most commonly detected anomalies in diabetic pregnancies. Major central nervous system (CNS) defects, as in the national dataset, are also over-represented and it should be re-emphasised that type 1 and 2 diabetic women should be taking high-dose folic acid (5 mg) daily both pre-pregnancy and during the first trimester.

Type 2 European women are especially at risk of giving birth to a baby with a major congenital anomaly (11% risk) and the European population accounted for three quarters of all congenital anomalies detected.

The antenatal congenital anomaly detection rate in pregnancies beyond 16 weeks gestation for the West Midlands was 59%. The nature of the anomalies undiagnosed was varied, ranging from serious cardiac and thoracic anomalies to hypospadias. However, all of these cases with the exception of a case of facial dysmorphia, a case of hypospadias and two cases of trisomy 21 might have been expected to have been picked up by a detailed fetal anomaly and cardiac scan (including outflow tracts) at 20-22 weeks gestation. Even allowing for these cases, 40% of major malformations were undiagnosed antenatally. The CEMACH data do not identify the type of anomaly scan performed after 16 weeks gestation however, it is felt that in the majority of cases this was a routine mid-trimester screening scan. With an overall major CMR of more than 8% within the region and 4 out of 10 congenital anomalies being undiagnosed there is now a strong argument for recommending all women with pre-gestational diabetes receive a detailed scan performed by a practitioner with RCR/RCOG Higher Level obstetric scanning accreditation or by a sonographer trained to an equivalent level. The rate of major congenital anomalies in this population is far higher than in women judged to be at high risk from other indications, such as women with epilepsy or a previous child affected by a major anomaly.

The stillbirth, neonatal and perinatal mortality rates reported for babies of diabetic women are significantly higher than that observed in the general maternity population of the West Midlands. Stillbirths show the greatest difference. In all 3 areas, the relative risk ratio is greater in the West Midlands region than nationally. The reported SBR and PMR in this group of women is greater than previously reported rates in other UK based reports[4,23]. These figures are significantly worse than international figures[24,25].

To improve these outcomes we need to focus on glycaemic control throughout pregnancy, particularly in minority ethnic groups, and to focus on other contributory factors such as uptake and ease of access to medical care and the effects of deprivation. Adequately financed long-term projects to reduce PNM and to improve access to medical care within the wards with the highest social deprivation in the West Midlands will access the majority of type 2 diabetic women. These projects, some of which are occurring, need to be strongly supported by Primary Care Trusts (PCTs) and the strategic health authority. In addition, all maternity units in the West Midlands must be aware of the increased PNM associated with pre-gestational diabetes in pregnancy and adhere to a suitable protocol for third trimester maternal and fetal monitoring. Regional guidelines on fetal monitoring after 34 weeks gestation are anticipated in the future.

3.7 Babies' Details

KEY FINDINGS

1 **One third of babies were delivered preterm, similar to national cohort.**

2 **Macrosomia (>4,000 g) is twice as common in diabetic pregnancies compared to the general maternity population.**

3 **60% of babies of diabetic mothers were separated at birth and admitted to a neonatal unit.**

4 **20% of term babies were admitted for special care necessitating separation from the mother. This is less common than nationally (33%).**

It is well known that as well as the higher perinatal mortality in offspring of diabetic mothers, these babies are also at risk of higher morbidity due to a greater number of adverse outcomes. These adverse events include respiratory distress syndrome and hypoglycaemia[4,25,26,27]. In addition, they more frequently suffer from the effects of prematurity and operative or instrumental delivery. Due to macrosomia, they are at increased risk of shoulder dystocia and birth trauma[28]. This section provides a description of the babies born to women with diabetes in the West Midlands and some of these adverse outcomes.

Sex

Sex was recorded in 100% of all registerable births.

The sex ratio in the West Midlands (male: female) was 1.18, greater than the national dataset (1.03) and greater than the general population (1.05).

Gestation

There were 373 live births and 17 stillbirths. 32% of babies delivered preterm (<37 completed weeks of pregnancy) compared to national dataset figure of 36.7%.

5% of babies were delivered under 32 weeks gestation - the same as nationally. Interestingly there were only two neonatal deaths recorded between 24 and 37 weeks gestation.

Two thirds of babies were delivered after 37 weeks.

Table 3.7.1 *Gestation at delivery by outcome (percentages are proportions of babies in each category out of the total number of babies with a valid response, i.e. excluding "*not applicable*" and "*missing*")*

Gestation at delivery (completed weeks)	Alive at 28 days (n=370) (%)		Stillbirth (n=17) (%)		Neonatal death (n=3) (%)		Total (n=390) (%)	
24-27 weeks	1	(0.3)	1	(5.9)	2	(66.7)	4	(1.0)
28-31 weeks	13	(3.5)	2	(11.8)	0		15	(3.8)
32-36 weeks	98	(26.5)	7	(41.2)	0		105	(26.9)
37-41 weeks	258	(69.7)	7	(41.2)	1	(33.3)	266	(68.2)
42+ weeks	0		0		0		0	

Birthweight

Macrosomia is defined here as a birthweight over 4,000g and is more common in diabetic pregnancies. The rate was 11% in the general maternity population 2002-2003[17]. In the West Midlands 22.7% of births had a known birthweight >4,000g and 4.8% had a birthweight >4,500g (same as nationally). As shown in the Figure 3.7.1, type 2 had a marginally lower (non-significant) incidence than type 1. There was no difference between type 1 and type 2 diabetes in respect of birthweight.

Figure 3.7.1 *Distribution of birthweight by diabetes type*

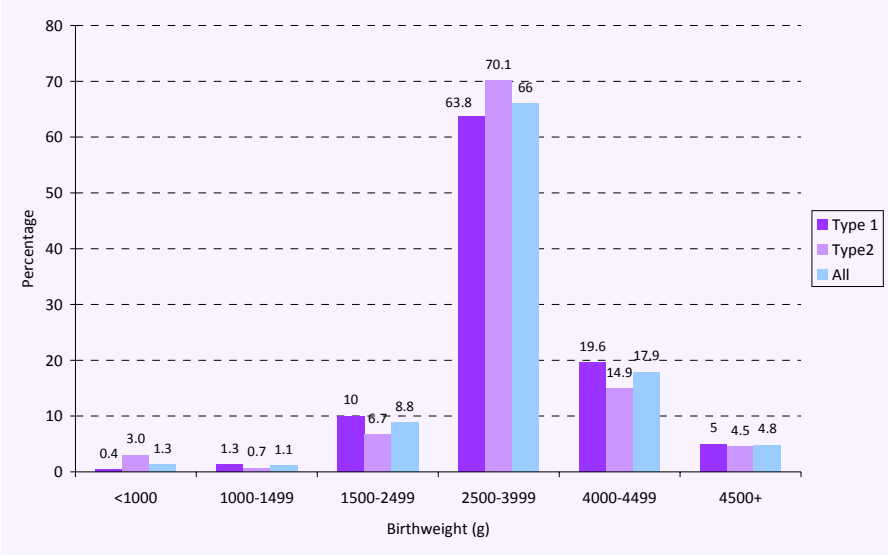
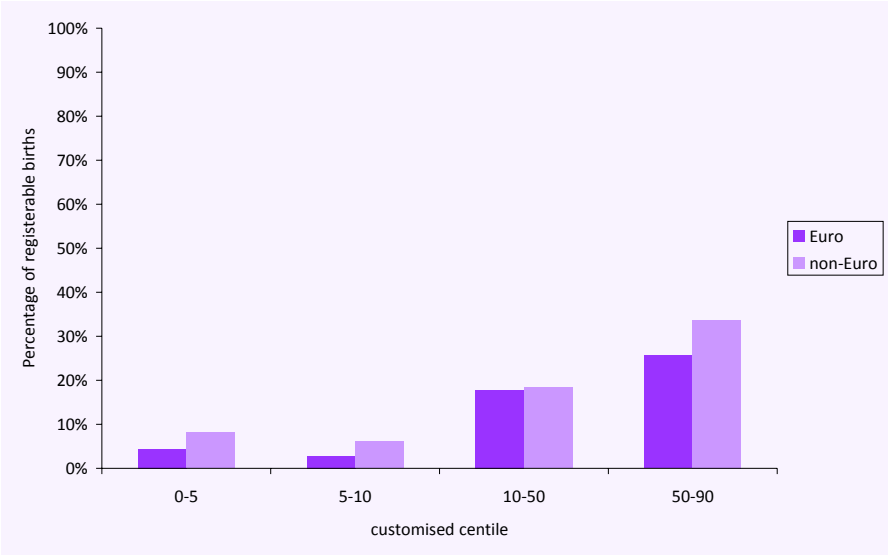


Figure 3.7.2 *Customised birthweight centiles by ethnicity*



Customised birthweight centiles were calculated using baby weight and gestation at birth, maternal height and weight, baby gender, ethnicity and parity[29]. Fetal growth restriction (<10th customised centile) occurred equally in type 1 and type 2 mothers. Figure 3.7.2 shows less fetal growth restriction in European than non-European women (0-5th centile - 4.5% v 8.2%; 5-10th centile - 2.7% v 6.1%). Also illustrated is the high incidence of macrosomia, if defined as a birthweight greater than the 95th centile, in both the European (43%) and non-European (29%) populations.

Birth Trauma

Birth trauma was documented in 4 babies; 3 cases of Erb's palsy and 1 of bruising to the forearm. 3 of the 4 cases occurred in women with type 2 diabetes. This gives an incidence of Erb's palsy of 7.6/1,000 births which is greater than that recorded nationally (4.5/1,000) and 18 times greater than in the general maternity population (0.42/1,000 births)[30]. One case of Erb's Palsy occurred without shoulder dystocia in a baby delivered by emergency caesarean section (customised centile 99.96).

The rate of shoulder dystocia (SD) found was 7.4% which is similar to the national dataset figure. 6 out of 8 cases of shoulder dystocia had a customised birthweight centile above the 90th centile.

Table 3.7.2 *Cases of shoulder dystocia*

Fetal trauma	Mode	Outcome	Birthweight	Customised centile
No	forceps	stillbirth	4,070	100.00
No	forceps	live	4,430	99.92
No	SVD	live	4,082	99.54
No	forceps	stillbirth	3,770	94.66
No	forceps	live	4,000	82.86
Erb's palsy	SVD	live	4,200	99.99
Erb's palsy	forceps	live	3,650	72.07
Other	forceps	live	4,320	99.99

Neonatal Admissions

Information on whether a baby was separated from its mother following delivery was available (Table 3.7.3).

148 (40%) remained with the mother on a postnatal ward and 222 (60%) were separated, all but 3 of whom were admitted to a NNU. Of those receiving NNU care, the mean length of stay was 7.4 days in both type 1 and type 2 pregnancies. This was greater than the national average of 4 days of care.

86% of babies born preterm were admitted to a NNU for some form of specialist care.

A higher proportion of babies born to type 1 mothers were separated (63%) compared to babies from type 2 mothers (46%). Reasons for admission to neonatal unit are found in section 3.8.

A higher proportion of babies were admitted to a NNU in the West Midlands compared to the national dataset principally because of the higher number of term babies admitted to a High Dependency Unit (HDU) or Intensive Care Unit (ITU) (26% v 10%). In fact fewer term babies (20%) were admitted for special care only compared to national figures (33%). This suggests there were less "*routine*" admissions to NNU simply because of a diagnosis of diabetes in pregnancy.

It is known that term infants (>37 completed weeks of gestation) rarely require care in a neonatal unit. In the background maternity population in the UK, about 10% of term babies will require NNU care[31]. When term babies require special care, several UK hospitals provide transitional care units to accommodate both mother and baby[32,33].

Table 3.7.3 *Neonatal admission at any time following delivery, by gestation at delivery (percentages are proportion of babies in category out of the total number of babies with valid response, i.e. excluding "*not applicable*" and "*missing*")*

Type of neonatal care	Gestation at delivery, completed weeks						All women (n=373) (%)	
	<32 weeks (n=16) (%)		32-36 weeks (n=98) (%)		37+ weeks (n=259) (%)			
Special care	4	(25.0)	39	(39.8)	54	(20.8)	97	(26.0)
High dependency care	5	(31.3)	28	(28.6)	45	(17.4)	78	(20.9)
Intensive care	6	(37.5)	16	(16.3)	22	(8.5)	44	(11.8)
Other specialist care	0		0	(##.#)	3*	(1.2)	3	(0.8)
Postnatal ward normal care with mother	0		15	(15.3)	133	(51.4)	148	(39.7)
Not known	1	(6.3)	0	(##.#)	2	(0.8)	3	(0.8)

*One baby was transferred to a specialist unit, one mother had a psychiatric history and was unable to care for her baby. One went to a postnatal ward that gave "*extra*" care for blood glucose monitoring.

Discussion

One third of all babies born were preterm which is 4 times higher than in the background maternity population. The pattern of widespread macrosomia seen nationally was mirrored in the West Midlands with 50% of births being greater than the 90th customised birthweight centile. This was more apparent in the European population and significantly, more babies had birthweights greater than the 95th centile than in the 90-95th centile group. Small for gestational age babies (<10th centile) were born more commonly to non-European type 2 mothers. As nationally both shoulder dystocia and Erb's Palsy are much more common in the pre-gestational population with 63% of shoulder dystocia cases and 67% of Erb's Palsy cases occurring in babies with birthweights greater than the 99th customised centile.

The high rate of admission to a NNU following delivery as seen nationally was, again, mirrored in West Midlands. Of note, is that more babies are admitted for HDU or ITU care after 32 weeks gestation than nationally whereas the term baby admission rate for special care only was significantly lower in the West Midlands (20% v 33%).

3.8 Standards of Care of Babies

KEY FINDINGS

1 **One quarter of babies were separated from their mothers and admitted for special care at delivery.**

2 **36% of babies received their first feed within 1 hour of life. 12% of babies did not receive a feed within the first 24 hours.**

3 **Exclusive breastfeeding was the choice in only 42% of women at delivery. This is lower than the national cohort (53%) and much lower than the 69% recorded in the general population.**

4 **Suboptimal tests to detect hypoglycaemia were used in 63% of all newborn babies.**

This chapter addresses standards of care for the babies of women with pre-gestational diabetes in the West Midlands region. The assessment of clinical care is based on documentation in the medical records.

Facilities at delivery

> **Standard**: Labour and delivery should be undertaken in a maternity unit with facilities for resuscitation and stabilisation of babies with personnel skilled in advanced resuscitation immediately available on a 24-hour basis.

There was no definite source of data relating back to 2002/3 for us to be able to accurately assess this standard. A telephone survey was undertaken in 2001 of all the maternity units in the West Midlands prior to the start of CEMACH study project, however the results did not facilitate analysis in this area.

Admission to a neonatal unit and separation from the mother

> **Standard**: All babies should remain with their mothers during the neonatal period unless there is a specific indication for admission to a neonatal intensive care unit.

Of the 373 live births for which information is available 222 (59.5%) were admitted to a neonatal unit for intensive, high dependency or special care. Over a quarter (97/373) of all live births were admitted for special care only.

Table 3.8.1 *Neonatal unit admissions by type of diabetes*

Type of neonatal care	Type 1 (n=245) (%)		Type 2 (n=128) (%)		Total (n=373) (%)	
Special care	75	(30.6)	22	(17.2)	97	(26.0)
High dependency	52	(21.2)	26	(20.3)	78	(20.9)
Intensive care	32	(13.1)	12	(9.4)	44	(11.8)
Other	1	(0.4)	2	(1.6)	3	(0.8)
Usual postnatal ward care	82	(33.5)	66	(51.6)	148	(39.7)
Not known	3		0		3	

The reasons for admission to a neonatal unit are given in Table 3.8.2 and 3.8.3. A higher proportion of babies born to mothers with type 1 diabetes (65.3%) were known to be admitted to a neonatal unit compared with those of mothers with type 2 diabetes (48.4%). The first stated reason for admission was documented and counted as the main reason although in some cases several reasons were given.

In one quarter of all cases the reason given was "*routine*" or for observation. Close to another quarter were admitted because of prematurity (23.4%). The most common indication was that of observed hypoglycaemia or treatment of persistent hypoglycaemia (38.3%). Respiratory problems accounted for 10%. Other infant medical problems as a reason for admission were rare. Macrosomia did not feature as a reason.

This would suggest that at least 25% of all admissions might be avoidable. In term babies, of those admitted to a NNU one third are admitted for observation only. In addition, 20% of term baby admissions are for isolated, non-documented hypoglycaemia. Better glycaemic control (already identified as an issue) could potentially reduce admissions further as antenatal glycaemic control in the mother is closely linked to neonatal hypoglycaemia. The latter is also associated with glucose control around the time of delivery. We have already shown that the use of IV insulin and glucose at delivery occurs in 80% of women. We do not know however if this achieved normoglycaemia at this time.

Table 3.8.2 *Reasons for admission to special care in 222 babies where information is given*

Reason for admission	All infants (n=222) (%)	
Routine/observation/infant of diabetic mother/maternal/not known	54	(24.3)
Hypoglycaemia/feeding problem	85	(38.3)
Prematurity	52	(23.4)
Respiratory/ventilated	23	(10.4)
Other infant medical problems	8	(3.6)

Table 3.8.3 *Reasons for admission to neonatal unit (37+ week)*

Reason for admission	Number (n=124) (%)	
Infant of diabetic mother	33	(26.6)
Observation/monitoring alone	6	(4.8)
Routine/hospital guideline	2	(1.6)
Isolated documented blood glucose <2.6 mmol/l	9	(7.3)
Isolated non-documented hypoglycaemia	25	(20.2)
Hypoglycaemia with hypothermia	6	(4.8)
Hypoglycaemia with jaundice	0	
No mother-baby facilities available	0	
Hypoglycaemia needing treatment	18	(14.5)
Ill mother/adoption process	0	
Other medical conditions	7	(5.6)
Dusky/cyanotic episode	2	(1.6)
Feeding difficulties	5	(4.0)
Respiratory symptoms	6	(4.8)
Suspected or confirmed sepsis	3	(2.4)
Blank	2	(1.6)

Infant Feeding

Timing of first feed

> **Standard**: Babies born to women with diabetes should be fed as soon as possible after birth and all should receive their first feed within 4 hours of birth, unless contraindicated for medical reasons.

The median time to first feed was 60 minutes, interquartile range (110-33.75).

36% of all infants were fed in the first hour and by 4 hours, 78.5% had received their first feed as set out in the standard, identical to the national cohort. Proportionally, more babies from type 2 compared to type 1 mothers were fed early. Of concern are the 12% of babies who received no feed in the first 24 hours. These are likely to be preterm neonates for whom the benefits of breast milk are the greatest.

Table 3.8.4a *Time to first feed by gestation*

Time (hours)	<37 weeks (n=114) (%)		37+ weeks (n=259) (%)		All babies (n=373) (%)	
1	18	(19.4)	101	(42.4)	119	(36.0)
4	47	(50.5)	213	(89.5)	260	(78.5)
24	62	(66.7)	230	(96.6)	292	(88.2)
No feed in first 24 hours	31	(33.3)	8	(3.4)	39	(11.8)
Not known	21		21		42	

Percentages exclude "*not known*"

Table 3.8.4b *Time to first feed by diabetes type*

Time (hours)	Type 1 (n=245) (%)		Type 2 (n=128) (%)		All babies (n=373) (%)	
1	68	(31.9)	51	(44.0)	119	(36.2)
4	160	(75.1)	100	(86.2)	260	(79.0)
24	185	(86.9)	105	(90.5)	290	(88.1)
No feed in first 24 hours	28	(13.1)	11	(9.5)	39	(11.9)
Not known	32		12		44	

Percentages exclude "*not known*"

Breastfeeding

> **Standard**: Breastfeeding is recommended but all mothers should be supported in the feeding method of their choice.

Breast milk appears to promote ketogenesis[34]. It should therefore be the food of choice for babies of mothers with diabetes who are at risk of hypoketonaemic hypoglycaemia[35]. Exclusive breastfeeding was the choice at birth for 42% women where the information was available from this cohort. This choice was independent of the type of maternal diabetes. This is much lower than the 53% recorded nationally and it is significantly less than the 69% UK general population prevalence of breastfeeding[36]. By 28 days post delivery only 17% of women were exclusively breastfeeding, less than 40% of those who had intended to breast feed at delivery.

The West Midlands rates for bottle and breastfeeding were the same as nationally by 28 days post delivery.

Formula milk is more popular, both as an intended and as an actual feeding method, in the West Midlands than nationally (67% v 48%).

Table 3.8.5a *Chosen method of feeding at delivery intention to breastfeed*

Feeding method	<37 wks (n=114) (%)		37+ wks (n=259) (%)		All babies (n=373) (%)	
Breastfeeding	40	(36.7)	115	(44.9)	155	(42.5)
Formula milk	52	(47.7)	112	(43.8)	164	(44.9)
Breastfeeding & formula milk	17	(15.6)	29	(11.3)	46	(12.6)
Not known	5		3		8	

Percentages exclude "*not known*"

Table 3.8.5b *Feeding method at 28 days*

Feeding method	<37 wks (n=114) (%)		37+ wks (n=259) (%)		All babies (n=373) (%)	
Breastfeeding	17	(15.9)	43	(17.3)	60	(16.9)
Formula milk	69	(64.5)	169	(67.9)	238	(66.9)
Breastfeeding & formula milk	19	(17.8)	37	(14.9)	56	(15.7)
Other	2	(1.9)	0		2	(0.6)
Not known	5		9		14	
Not applicable (NND)	2		1		3	

Percentages exclude "*not known*" and "*not applicable*"

Management of feeding

> **Standard**: Interventions for the management of hypoglycaemia should be guided by blood glucose level and clinical assessment.

Accepted best practice for intervention with supplemental milk in normal term infants is as follows:

- Persistent hypoglycaemia.
- Persistent hypoglycaemia after a feed.
- Clinical signs of hypoglycaemia.
- Both low blood glucose and clinical signs of hypoglycaemia.

The main reason for giving supplemental milk or glucose in the first 24 hours in the West Midlands was a history of a low blood glucose level (33%). Babies identified clinically as having hypoglycaemia made up only a small number of cases (1.6%). Of some concern are the 10% of babies that had this treatment because of routine local practice.

Further data analysis on breastfeeding is given in section 5.7.

Blood glucose testing

> **Standard**: The diagnosis of hypoglycaemia should be made using a ward-based glucose electrode or laboratory method and not by reagent strip testing.

Glucose reagent strips may not be reliable and are contraindicated for use in neonates[37,38]. At least one reliable laboratory value should be obtained when considering the diagnosis of hypoglycaemia. Portable glucose meters may be used as a screen in susceptible cases but should be confirmed by a laboratory measurement. Suboptimal tests using reagent strips or HaemoCue were used in 63% of babies (236/373). One third of babies (33%) were monitored using optimal methods.

Table 3.8.6 *Method used to detect hypoglycaemia*

Method of testing	Type 1 (n=245) (%)		Type 2 (n=128) (%)		All babies (n=373) (%)	
OPTIMAL TESTS						
Laboratory	27	(11)	11	(9)	38	(10)
Electrode	53	(22)	43	(34)	96	(26)
SUBOPTIMAL TESTS						
Reagent strip	79	(32)	41	(32)	120	(32)
HaemoCue	87	(36)	30	(23)	117	(31)

Percentages are calculated on babies born alive
Babies were able to have more than one test

Discussion

Admission to NNU is more common in babies from type 1 mothers and this is particularly evident in babies for special care only. At least 20-33% of all admissions to NNU could be avoided by abandoning a routine policy of admission for observation, using optimal tests for detection of hypoglycaemia, and avoiding performing these tests too early following delivery. There is a physiological fall in neonatal blood sugar levels in the first hour of life and testing at this time is more likely to reflect this event and not a true hypoglycaemic trend. Improved staff training and the provision of transitional care facilities to keep Mums and babies together would also reduce knee-jerk admissions to the NNU following an isolated episode of hypoglycaemia.

Almost 80% of newborn babies are fed within the first 4 hours of life.

Early breastfeeding should be positively recommended to diabetic mothers as the feeding method of choice to promote neonatal ketogenesis and reduce the risk of hypoglycaemia. This should occur as early as possible following birth. However, in the West Midlands diabetic population breastfeeding rates are less than the general maternity population. This may be because of poor patient and midwifery education regarding the importance of early breastfeeding especially in preterm babies on NNU. Positive encouragement and help in expressing breast milk should be given to all diabetic mothers to allow early and effective establishment of breastfeeding even when the baby has been separated from the mother.

Chapter 4 West Midlands Confidential Enquiry Panel Findings

The confidential enquiry component of the WM Diabetes in Pregnancy Project was derived from the CEMACH enquiry module[39]; a case-control study comparison of pregnancy in type 1 and type 2 maternal diabetes and an audit of care. This format was used to examine any differences in demographic factors, social and lifestyle issues, and clinical care between pregnancies resulting in an adverse or good pregnancy outcome.

The confidential enquiry examined four groups of selected pregnancies.

Anomalies - pregnancy to a woman with type 1 or type 2 diabetes resulting in a singleton baby (including terminations of pregnancy at any gestation, late fetal losses, stillbirths and live births) with a confirmed major congenital anomaly, diagnosed up to 28 days of life.

Deaths - pregnancy to a woman with type 1 or type 2 diabetes resulting in a death of a singleton baby from 20 weeks of gestation up to 28 days after delivery, excluding terminations of pregnancy and confirmed congenital anomalies.

Controls - pregnancy to a woman with type 1 or type 2 diabetes resulting in a singleton birth delivering at 20 weeks of gestation onwards and surviving to 28 days of life, excluding those with a confirmed congenital anomaly.

Additional type 2 sample - pregnancy to a woman with type 2 diabetes resulting in a singleton birth delivering at 20 weeks of gestation onwards and surviving to 28 days of life, excluding those with a confirmed congenital anomaly.

Controls were randomly sampled from the group of pregnancies reported in the WM Cohort descriptive study fitting the definition of a control in order to sample one control per case.

Case notes (for purposes of confidentiality and anonymity) were assessed by a different Strategic Health Authority for each of the three panel groups.

Overall there were 56 multidisciplinary professionals who participated in the panel process (Table 4.0.1) - 14 obstetricians, 12 physicians, 18 midwives and 12 diabetic specialist nurses (DSN). These professionals attended between 1-8 panel meetings in total to usually discuss four sets of selected case notes (combination of controls and cases) at each panel forum. At least two weeks prior to the panel enquiry each panel member received the following documentation:

- Anonymised case notes
- A completed anonymised Pre-Pregnancy Care Proforma (PPCP)
- Anonymised Hospital Protocols
- A blank Diabetes Enquiry Proforma (DEP)
- Panel Methodology Guidance

The DEP was completed by each panel member prior to the meeting. The PPCP was a retrospective proforma requesting information related to the pre-pregnancy period of each case. This information was provided by a lead professional directly involved in delivering care (midwife/DSN/GP). However, this information was requested following case selection and not at the time of initial project data gathering. Information relating to body mass measurements was incomplete and therefore unavailable for meaningful analysis. The authors felt that PPCP information and its incomplete nature was not robust or reliable. A decision was made not to report or use these data within this analysis.

At each meeting, 40 minutes were allocated for each case with a short, initial, five minute case history presentation used to summarise and focus panel members of the details of each set of case notes. This was used as an introduction at the beginning of each enquiry.

Table 4.0.1 *Regional Panels and Assessors*

SHA	Number of Panels (n=19)	Panel Assessors (n=56)
BBC	9	24
North	5	15
South	5	17

Panel members engaged in discussion regarding each case and the care received. A final DEP was completed by the panel chairs with the consensus views of the panel members, a CESDI grading (see Table 4.0.2) was also applied to each case discussed. A database was created and data entered to facilitate analysis and reporting of the findings.

Table 4.0.2 *CESDI Grades*

Grade	Definition
Grade 0	No suboptimal care
Grade 1	Suboptimal care, but different management would have made no difference to the outcome
Grade 2	Suboptimal care - different management *might* have made a difference to the outcome
Grade 3	Suboptimal care - different management *would reasonably have been expected to* have made a difference to the outcome

From experience and insights gained during previous confidential enquiries, CESDI grading has been shown to improve outcomes in maternal and infant health. The ability of this method to generate general guidance has been one of the key features of CESDI proving it to be an invaluable tool that could equally be applied to the Diabetes in Pregnancy enquiry.

Following completion of the panel enquiry process, an evaluation sheet was distributed to each professional for feedback and comments with a 92% response rate.

Outlined below are positive and negative aspects and particular *"points of learning"* as highlighted by those participating in the panel assessment process:

Documentation

Documentation and record keeping were acknowledged as an area where there was room for much improvement particularly in the following areas:

- Attention to detail and note keeping to facilitate auditing of outcomes.
- The need for clear and accurate records; this was considered to be essential for communication between professionals and non-team members involved in the delivery of patient care throughout the pregnancy and for future consultations. The effectiveness of a multidisciplinary approach was not always apparent or reflected in the record keeping. It was felt that professionals often failed to document in multiple places or records were not always filed together or went missing and it was difficult to piece together the whole picture.
- The importance of recording all verbal communication and not making presumptions about advice given to the women. The facility for the woman herself to record specific events and concerns, for example hypoglycaemic episodes.
- Examples of documents which were frequently omitted from records were highlighted such as the patients own blood glucose diary and records of consultations with the GP, Ophthalmologists and Dietician.
- There was frustration by panel members that they felt there was information missing in many of the case notes.
- One panel member commented that the proforma made assumptions and there was lack of evidence to support this.

The panel process provided members with a learning tool to aid comparison and assessment of their own practice and as a result they were able to improve personal standards and some units have since redesigned local documentation. The need for a more formal regional/national document was recognized to improve standards of care. Suggestions were made for a more comprehensive record such as inserting a separate document relating to pregnancies complicated with diabetes into the current hand-held pregnancy notes. This could be used by all professionals, multidisciplinary teams and by the woman herself.

When reviewing guidelines/protocols pertaining to each individual unit (n=20 units), it was accepted there was great diversity. There is therefore a need to create evidence based guidelines that would enable professionals to give standardized care across the region. Within the region, intrauterine transfers occur from district general hospitals to regional centres offering specialist care.

Multidisciplinary Teams

- The panel recognized the importance of teamwork - the whole team being available to input into the woman's care, for example it was noted that a dietician was not available in the majority of multidisciplinary antenatal clinics.
- The need for multidisciplinary pathways.
- The need to raise the profile of high risk groups. For example, all professionals and women need to understand the importance of conveying the high risk status of pregnancies complicated by diabetes.

Education

- Sharing good practice, learning from colleagues.
- Sharing good practice from other units - regional forums.
- Standardized guidelines - evidence based.
- Support processes for all staff.
- Reflection of case outcomes.

Panels

- They felt the meetings were a very valuable learning tool for sharing experiences. Many appreciated the opportunity to participate in several of the diabetes panel enquiries.
- It was motivating to meet and network with other interested professionals. There was mutual respect for each other's professional status and workload and they welcomed the opportunity to learn from their colleagues. Overall the meetings were described as fun, enjoyable, inspirational, and interactive.
- A few panel members (5.8%) felt intimated and did not contribute much at their first panel meeting, however this was their first experience of participating in a panel enquiry. The majority stated they did not feel this way after a second opportunity to participate.
- Some panel members were found to be very assertive and dominated the views of other panel members.
- There was lack of agreement by some panel members regarding the care given (although it was commented that the panel went with the majority decision in these cases).
- One comment stated "*sometimes judgments tempered by sympathy for clinicians, so they did not wholly reflect the standard of care objectively*."
- Another comment stated that a paediatrician should have been involved in the meetings.
- Further findings from the panel evaluations indicated that the panel members would have appreciated receiving their evaluation forms sooner than they did.

Time

- Most professionals prepared for the meetings in their own time, very few were given dedicated time for preparation of case notes; reading through notes and completing the DEP. The time each person spent varied between 1-48 hours. 50% of panel assessors spent a minimum of 4 hours in preparation. 35% attended panel meetings in their own time.
- Meetings were generally held at the West Midlands Perinatal Institute as this was deemed to be a central, available venue. However, it was acknowledged that professionals had clinical commitments within their own units and so there were issues surrounding time for travelling to and from panel meetings.
- Some members felt that there was not enough time allocated to discuss each case, however others felt there was too much time allowed.

Conclusions

98% of all panel members felt supported as they progressed through the panel enquiry route. Generally the enquiry process had a positive influence on clinicians, they felt it reflected current services being offered and has helped shape practice. Overall 96% agreed that they would like to participate in any future confidential enquiries.

4.1 Characteristics of Cases and Controls

Introduction

77 pregnancies from the West Midlands cohort were selected for the Confidential Panel Enquiry process. Multiple pregnancies were excluded. These were chosen by CEMACH central office and details of each case sent to the Perinatal Institute to establish the Panel Enquiry.

There were 39 cases, all resulting in a poor perinatal outcome and 38 controls, all of which ended in a good perinatal outcome (alive at 28 days). The breakdown of the pregnancy outcomes for cases/controls are shown in Table 4.1.1. Within the 39 cases there were 24 listed as a major congenital anomaly including all 13 cases that were alive at 28 days. However, two of the congenital anomalies on detailed post panel analysis were found not to satisfy the ICD 10 classification criteria. They were subsequently taken out of all analysis on anomalies (cohort or panel) but are still included as cases in this chapter as they had been analysed as such at panel enquiry.

Table 4.1.1 *Outcomes of pregnancies selected for panel*

Cohort	Early fetal loss <20/40	Late fetal Loss ≥20-23+6	Stillbirth	Neonatal death	Alive at 28 days	Total
CASES	2	6	15	3	13*	39
Type 1	1	5	8	1†	8	23
Type 2	1	1	7	2	5	16
Congenital anomalies	2	4	3	2	11	22
CONTROLS	0	0	0	0	38	38
Type 1	0	0	0	0	20	
Type 2	0	0	0	0	18	

* two cases alive at 28 days reclassified as having no congenital anomaly
† one case Initially reported and considered to be a legal abortion/stillbirth, however at panel review found to be a ENND

CESDI Grading

Table 4.1.1a *CESDI grade allocated to cases and controls assessed at panels*

CESDI grade	Cases n=39	Control n=38	All n=77
Grade 0	5	13	18 (23%)
Grade 1	6	23	29 (38%)
Grade 2	22	1	23 (30%)
Grade 3	6	1	7 (9%)

Each case and control was allocated an agreed CESDI grading by the panel members. Table 4.1.1a shows that 77% of pregnancies assessed were judged to have received suboptimal care (CESDI grades 1-3).

Overall in 39% of these pregnancies different management might have/would reasonably have been expected to alter the outcome.

Within the cases selected 28 (72%) were allocated a CESDI Grade 2/3.

In the controls selected only two (5%) were graded 2/3. This is despite the fact that there were many panel comments relating to the controls in the areas of diabetic and labour/delivery management. However, these deficiencies in care were not considered likely to have changed the overall pregnancy outcome.

Contributory factors and issues of clinical management are discussed in this chapter and in the appendices.

The Women

Table 4.1.2 *Characteristics of cases and controls selected for confidential panel review*

Characteristic	Cases (n=39)		Controls (n=38)		All women (n=77)	
DIABETES TYPE						
Type 1	23	(59.0%)	20	(52.6%)	43	(55.8%)
Type 2	16	(41.0%)	18	(47.4%)	34	(44.2%)
PARITY						
Primip	15	(38.5%)	13	(34.2%)	28	(36.4%)
Multip	24	(61.5%)	25	(65.8%)	49	(63.6%)
ETHNICITY						
European	26	(66.7%)	27	(71.1%)	53	(68.8%)
Black African	2	(5.1%)	0		2	(2.6%)
Black Caribbean	3	(7.7%)	3	(7.9%)	6	(7.8%)
Indian	1	(2.6%)	2	(5.3%)	3	(3.9%)
Pakistani	5	(12.8%)	5	(13.2%)	10	(13.0%)
Bangladeshi	1	(2.6%)	0		1	(1.3%)
Other	1	(2.6%)	1	(2.6%)	2	(2.6%)
Median age at entry to study in yrs (IQR)	31	(8.5)	30	(9.5)		
Age at onset of diabetes in yrs (IQR)						
Type 1	12	(10.5)	13.5	(16.5)		
Type 2	25.5	(8.3)	30	(7.5)		
Duration of diabetes in yrs (IQR)						
Type 1	15	(15.0)	16.5	(14.5)		
Type 2	6	(3.5)	3.5	(3.5)		
Deprivation Quintiles						
1	1	(2.6%)	2	(5.3%)	3	(3.9%)
2	7	(17.9%)	5	(13.2%)	12	(15.6%)
3	8	(20.5%)	7	(18.4%)	15	(19.5%)
4	7	(17.9%)	8	(21.1%)	15	(19.5%)
5	15	(38.5%)	16	(42.1%)	31	(40.3%)
Outside area	1	(2.6%)	0		1	(1.3%)

Type 1 and type 2 diabetic women were similarly represented in the case and control group. In addition, socio-demographic characteristics such as ethnicity and residential deprivation quintiles were very similar for both cases, controls, and for the total panel enquiry, compared to the WM Cohort (Table 3.2.1).

Access to Health Services

There was no difference in early pregnancy access to health care for cases or controls, or the date of the first hospital appointment (Table 4.1.3). There was also a similar range of health professionals involved in the care in both groups.

Overall, antenatal care was carried out in a dedicated multidisciplinary clinic in 75% of all cases.

Table 4.1.3 *Calculated time of access to health and professional services (days)*

Time of access/health professional	Cases (n=39)		Controls (n=38)	
First contact with health professional (from EDD) Days/IQR	47	(25.5)	48.5	(17.75)
First hospital appointment (from EDD) Days/IQR	62	(19)	67	(31)
HEALTH PROFESSIONAL INVOLVED WITH CARE (%)				
Diabetic Nurse Specialist	33	(85)	31	(82)
Physician	37	(95)	37	(97)
Dietician	19	(49)	18	(47)
Midwife	5	(13)	5	(13)
Obstetrician	37	(95)	36	(95)

Consanguinity

Information on consanguinity was retrospectively collected from the case-notes.

There were 8 (10%) documented cases of women in consanguineous marriages and 7 of these women had type 2 diabetes. Four were cases (all type 2) and four controls (three type 2, one type 1). There were two major congenital anomalies in this group one resulting in a Stillbirth and one alive 28 days.

Planning a Pregnancy

In answer to the proforma question 2 "*was the current pregnancy planned?*" 52% of pregnancies (30/58) were documented as being planned (19 not answered). However, only 11 women were shown to be using contraception prior to pregnancy and in the majority there was no evidence of pregnancy planning taking place.

4.2 Diabetes Care Pre-Pregnancy and Pregnancy Care

Data relating to pre-pregnancy care were derived from the Diabetes Enquiry Proforma (DEP) focusing on the panel's assessment of the level of care given and the use of folic acid only.

I Preconception counselling

Pre-conception counselling was documented in only 20 of the 77 pregnancies (26%) that went to panel enquiry, which is in line with the cohort findings (28%). The majority received this advice in an adult diabetes clinic and only 1 woman was seen in a formal pre-pregnancy clinic. The frequency of pre-conception counselling was higher in women with type 2 diabetes (35%) compared with that for type 1 diabetes (19%). This is different to the WM cohort where more women with type 1 were accessing pre-pregnancy counselling. More of those in the control group had documented counselling (14/38, 37%) compared to the cases (6/39, 15%).

II Advice and usage of folic acid

Pre-conceptual folic acid has been given in 8 cases and 16 controls (31% overall), while the rest were not recorded or had not taken folic acid. However, as Table 4.2.1 shows, in only 11 of these cases (14%) was this recorded to be the recommended dose of 5 mg.

Table 4.2.1 *Folic Acid Intake*

Folic acid intake	Cases (n=39) (%)		Controls (n=38) (%)	
PRE-PREGNANCY				
None	28	(71.8)	18	(47.4)
400 mcg	2	(5.1)	5	(13.2)
5 mg	5	(12.8)	6	(15.8)
Dose not specified	1	(2.6)	5	(13.2)
Not recorded	3	(7.7)	4	(10.5)
FIRST TRIMESTER				
None	8	(20.5)	7	(18.4)
400 mcg	5	(12.8)	5	(13.2)
5 mg	10	(25.6)	10	(26.3)
Multivitamin	1	(2.6)	1	(2.6)
Folic acid taken but dose not spec.	9	(23.1)	10	(26.3)
Not recorded	6	(15.4)	5	(13.2)

The number of women who were recorded as taking folic acid in the first trimester increased to 51 (66%). Of those 20 (26%) were recorded as taking the recommended 5 mg dose. These were equally divided between the cases/controls and type 1/type 2 women. Where the gestation was recorded, folic acid was commenced between three and ten weeks of pregnancy.

III Glycaemic testing and achieving a HbA1c<7%

Pre-pregnancy glycaemic control was recorded in 36% of women.

Glycaemic control was evaluated in two ways throughout the pregnancy. HbA1c values solely were examined pre-pregnancy and within each trimester. An HbA1c <7% showed optimal control, 7 to 8% adequate and >8% poor control. In addition, the panel gave their own separate coding of glycaemic control (optimal, adequate, or poor) by considering all available information including HbA1c values, home blood glucose testing, and episodes of hypoglycaemia. Therefore, on occasions, the panel enquiry indicated a different assessment of glycaemic control to the HbA1c assessment and this reflects the influence of this additional information gathered from the casenotes and available to the panel.

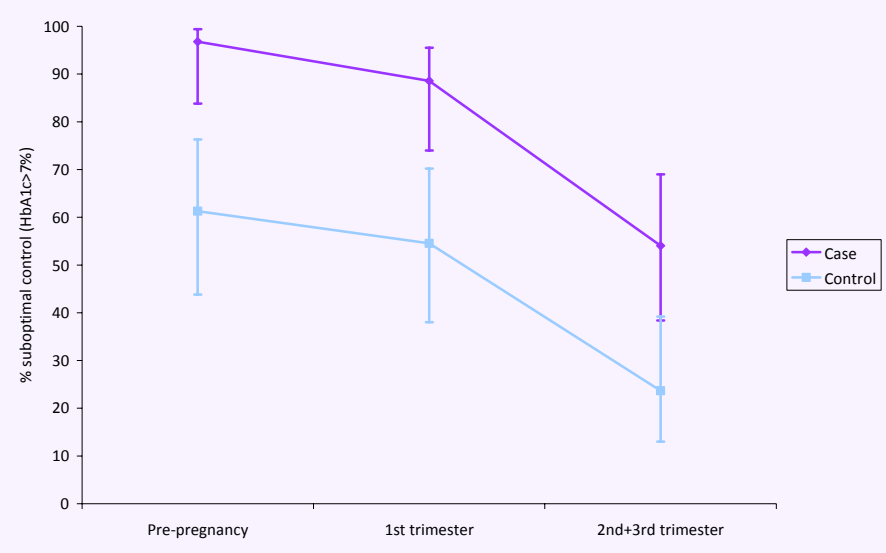
Table 4.2.2 *Suboptimal glycaemic control for cases and controls in each trimester (where there is sufficient information)*

Suboptimal control	Cases %		Controls %		OR (95% CI)
Pre-pregnancy	30/31	96.8	19/31	61.3	18.9 (2.3-157.8)
First trimester	31/35	88.6	18/33	54.5	6.5 (1.9--22.5)
Second trimester	20/37	54.1	9/38	23.7	3.8 (1.4--10.2)

OR: odds ratio

Table 4.2.2 shows suboptimal glycaemic control for cases and controls assessed by panel coding. Glycaemic control was shown to be significantly worse in cases compared to controls. This was more evident pre-pregnancy and in the first trimester, while there was no difference by the time third trimester had been reached (Figure 4.2.2a). The largest discrepancy was in the pre-conception period where the panel found that glycaemic control was suboptimal in 97% of cases. Suboptimal glycaemic control was almost 20 times more likely to be present in a case resulting in a fetal/neonatal death or congenital anomaly than in a control. Overall there was optimal glycaemic control in 13 of the pregnancies examined with 12 of these being in the control group.

Figure 4.2.2a *Panel assessment of suboptimal glycaemic control (>7.0%, 95% CI)*



Main reasons for poor or adequate control were coded as being due to the woman's actions detracting from optimal management such as infrequent home blood glucose monitoring or not following dietary instructions (30% of cases). In addition, there were communication issues involving the health professionals looking after the woman. 20% of panel comments highlighted no clear glycaemic targets set in pregnancy, no dietician referral, not referred early enough/urgently to a multidisciplinary clinic.

Box 4.2.1 *Panel comments relating to glycaemic control in pregnancy*

'Non-acceptance of her diagnosis. Input from clinical psychologists would have helped'

'woman not testing, 'recurrent hypoglycaemia'

not taking diabetes seriously'

'Insulin regime inappropriate'

'No dietician. No targets' 'Only one HbA1c recorded in second trimester'

'patient unhappy with close monitoring, no HbA1c after 24 weeks'

'Poor attendance and doubtful compliance'

'communication issue, should have had QDS insulin earlier, too long between appointments'

IV Assessment of diabetic complications

For pre-pregnancy care other than glycaemic control the panel were asked to consider the assessment and treatment of complications, advice given, use of folic acid, and other information recorded in the DEP. Pre-existing diabetes complications were documented to have been present 12 months prior to pregnancy in 15 women (21%). These were primarily in type 1 diabetic women (80%) and in two women there was more than one complication documented (Table 4.2.3). In type 1 diabetic women, episodes of DKA and retinopathy were more common in comparison to type 2 women where hypertension accounted for 2 of the 3 pre-existing complications.

Table 4.2.3 *Pre-existing Diabetes Complications and medical/surgical complications requiring treatment in year prior to pregnancy*

Diabetes Complications	Type 2			Type 1			
	Case n	Control n	All n=3	Case n	Control n	All n=12	
DKA			0	2	3	5	
Hypertension	1	1	2	0	1	1	
Hypotension			0	1	0	1	
Nephropathy			0	1	1	2	
Neuropathy			0	0	1	1	
Retinopathy	0	1	1	3	1	4	
							Type 1 - 12 women with 14 diabetes related complications

Medical/ Surgical Complications	Type 2			Type 1			Total n=37 (%)
	Case n=7/16 (%)	Control n=11/18 (%)	All n=18 (%)	Case n=11 (%)	Control n=8 (%)	All n=19 (%)	
Asthma	4 (57)	3 (27)	7 (39)	1 (9)	3 (38)	4 (21)	11 (28)
Depression/MH	2 (29)	2 (18)	4 (22)	5 (46)	0	5 (26)	9 (24)
Hypertension	3 (43)	1 (9)	4 (22)	0 (#)	0	0	4 (11)
PCOS	1 (14)	2 (18)	3 (17)	0	0	0	3 (8)
Others							

Prior to pregnancy type 2 women, had more medical/surgical complications in comparison to type 1 women (53% 18/34 v 44% 19/43). Half of these type 2 women were located in the quintile of greatest deprivation. This compares to 20% type 1 diabetic women.

Depression/mental health illnesses are more prevalent in the case group than in the control group (7/9). Of these seven cases, 5 were European and 5 lived in IMD 4/5. Even allowing for the selected nature of these cases mental health problems may be contributory factors to poor diabetic control leading to a poor pregnancy outcome.

Asthma was found to be the most common medical condition complicating pre-existing diabetes as it is in the general maternity population. One case was documented by the panel to have received oral steroids, which is recognized to affect glycaemic control.

In Pregnancy

The panel also assessed diabetic complications during the pregnancy (Table 4.2.4).

Recurrent hypoglycaemia in pregnancy was found to be a significant problem being found in 52% of all panel cases. This occurred equally in the case and control groups but, as expected, was more prevalent in those women with type 1 diabetes (75.5% documented recurrent hypoglycaemia). However, in type 2 women 25% also documented recurrent hypoglycaemia.

21% of all panel cases had at least one episode of hypoglycaemia requiring help from another person. These figures are the same as the national CEMACH figures. Nephropathy occurred rarely in the WM population as compared to national figures (4.2% v 12.0%). Diagnosis of nephropathy classification can be seen in question 14 of DEP (Appendix E).

Table 4.2.4 *Diabetes complications occurring during pregnancy*

Specific diabetes complication	Women in the enquiry n/N (%)
Recurrent hypoglycaemia during pregnancy	37/71 (52.1)
Hypoglycaemia requiring external help	12/56 (21.4)
Retinal assessment performed in 1st trimester	43/65 (66.2)
Evidence of retinopathy in pregnancy	22/55 (40.0)
Pre-existing retinopathy	9/55 (16.4)
Pre-existing retinopathy - deteriorating	4/55 (7.3)
New retinopathy	7/55 (12.7)
Nephropathy	3/71 (4.2)

Retinal assessments were documented to have been performed in two-thirds of women (43/65) in the first trimester. Retinopathy was present in 40% of cases and controls in pregnancy. Table 4.2.5 shows the type of retinopathy diagnosed within the case and control groups. Of these only 8 cases were referred to an Ophthalmologist.

Table 4.2.5 *The presence of retinopathy and level of severity diagnosed*

Retinopathy type	Control	Case	Total (%)
1 pre-existing no change	2	7	9 (41)
2 pre-existing, deteriorating	3	1	4 (18)
3 new finding	5	2	7 (32)
blank	1	1	2 (9)
Total	11	11	22

V Panel assessment of diabetes care

The panels gave an overall assessment of the quality of diabetes care (other than glycaemic control) both pre-pregnancy and during pregnancy. Suboptimal care in pre-pregnancy was documented in 43 cases (80%) and was not significantly higher in the case group (83 v 75%). During the pregnancy, suboptimal care is judged to have been present in 48/75 panel cases (64%). This was evenly distributed between cases and controls (Table 4.2.6). One third in each group were deemed to have received poor care.

Table 4.2.6 *Suboptimal diabetic and maternity care during pregnancy*

Suboptimal care	Cases n=39 n (%)	Controls n=38 n (%)
Diabetic care during pregnancy (other than glycaemic control)	23/37 (62)	25/38 (66)
Maternity care - antenatal	23/39 (59)	15/38 (40)
Maternity care - delivery	13/37 (35)	14/37 (38)
Diabetic care - postnatal	14/32 (44)	16/29 (55)

In Table 4.2.6, the denominator figures are different for each category of care as there were occasionally instances where the panel felt there was insufficient information to classify the care as being optimal, adequate, or poor.

4.3 Maternity Care

Antepartum Care

Panels examined a range of indicators of good maternity care in diabetic pregnancy and found a trend towards a higher rate of suboptimal care in cases (23 or 59%) than controls (15 or 40%) which however did not reach statistical significance (p=0.09).

Table 4.3.1 *Suboptimal maternity care*

Suboptimal care	Cases (n=23)	Controls (n=15)
Issues relating to provision of health service		
CLINICAL PRACTICE		
Fetal surveillance	7	5
Management of pregnancy complications	4	10
Mode/timing of delivery	2	2
Use of steroids	2	1
Need for senior Obstetric input	0	1
Poor/no management plan	3	2
Blank	3	2
RESOURCES		
In-appropriate appointments	3	0
Use of interpreter	1	0
Neonatal cots	0	1
COMMUNICATION		
Between professionals	3	1
Between professionals & woman	0	0
ISSUES RELATING TO WOMAN/FAMILY		
Maternal actions – smoking	1	1
Maternal compliance	1	0
Poor attendance	1	0
Total comments	31	26

Table 4.3.1 illustrates comments pertaining to suboptimal care during maternity care. There was no significant difference in the number of comments relating to case or control groups - most instances of suboptimal care in both groups were associated with clinical practice issues. In particular fetal surveillance (reduced/no third trimester fetal assessment scans performed, poor interpretation of CTGs) and the management of pregnancy complications (treatment of PET, hypertension, proteinuria, DKA, maternal pyrexia) were the most common issues highlighted being 68% in the case group and 89% of comments in the control group. However, in the case group a greater proportion (23% v 8%) of comments related to hospital resource provision and communication between health professionals. A list of comments from panel assessments is listed in Appendix F Tables 1 and 2.

An important issue of antenatal maternity care for women with pre-existing diabetes is the discussion of the timing and mode of delivery with the woman. This occurred in 74% of all the panel cases and was equally distributed between case and controls, 60% of discussions occurring in the third trimester.

Labour and delivery

A similar proportion of cases and controls were considered to have received suboptimal care (38%), and these rates were overall smaller than in the pre-pregnancy and antenatal periods (Table 4.9).

The chosen mode of delivery was considered to be appropriate in 88% of the pregnancies examined, and the timing in 82%.

Table 4.3.2 illustrates comments pertaining to suboptimal care during labour and delivery. The most frequent issues highlighted were inappropriate decisions and actions during a woman's labour or at the point of delivery. Some of these related to failure to actively manage labour or an inappropriate decision for caesarean section.

Appendix F Tables 3 lists the categories of comments made by the panels.

Table 4.3.2 *Suboptimal labour/delivery care*

Suboptimal care	Cases (n=15)	Controls (n=15)
Issues relating to provision of health service		
CLINICAL PRACTICE		
Fetal surveillance (CTG use/interpretation)	1	3
Management of maternal complications	2	3
Inappropriate decisions relating to delivery	3	4
Inappropriate management of labour	2	6
Need for senior Obstetric input	2	1
Poor/no management plan	2	0
Blank	4	3
RESOURCES		
Drug/treatment availability	1	1
Neonatal cot availability	0	1
Blank	2	0
COMMUNICATION		
Between professionals	0	0
Between professionals & woman	2	1
Issues relating to woman/family		
Maternal compliance	0	0
Total comments	21	23

78% of all panel cases had intravenous dextrose and insulin sliding scales administered during labour and delivery. In addition, target blood glucose levels were documented in 78% of panel cases. In those women who delivered vaginally or by emergency caesarean section, 43% were judged to have had suboptimal management of their blood glucose. 26% of women delivered by elective caesarean section had suboptimal blood glucose management. There was no difference between cases or controls in any of these areas.

Table 4.3.3 shows the breakdown of enquiry cases by mode of delivery and gestation. All early and late fetal losses (<24 weeks gestation) within the case group were delivered vaginally and 5 of these were as part of a legal abortion.

There were 24 babies delivered between 24 and 36^{+6} weeks gestation of which 9 were stillbirths. Therefore there were 15 live births occurring prematurely giving a preterm delivery rate of 28%, which is very similar to the main cohort analysis. Four babies were born by elective caesarean section before 37 weeks (2 cases and 2 controls). Fifteen babies were delivered vaginally (spontaneous/instrumental delivery) resulting in a vaginal delivery rate of 28% (15/54). For term babies the vaginal delivery rate was slightly improved at 31% (13/39).

Table 4.3.3 *Gestation and mode of delivery*

Mode of delivery	Gestation					Total
	<24 wks	24-27^{+6} wks	28-31^{+6} wks	32-36^{+6} wks	37 + wks	
SVD	8	1	1	6	9	25
Ventouse					3	3
Forceps				1	4	5
Emergency LSCS		1	1	8	15	25
Elective LSCS				4	14	18
Other - hysterotomy		1				1
Total	8	3	2	19	45	77

When those neonates alive at 28 days with a CA are analysed 64% (7 of 11) were born at term (after 37 weeks gestation), all by CS (50% elective). Of the 4 cases born preterm 3 delivered by emergency CS. Those cases with CA resulting in stillbirth or neonatal death are analysed later in this chapter.

77% of panel enquiry cases resulted in the baby being separated from mother soon after birth. Most usually, this was for neonatal unit care, often special care only. 28 of the 43 babies separated were in the control group and 50% of these admissions were for documented hypoglycaemia, however seven babies were admitted to a neonatal unit either because it was hospital protocol or for a reason not stated. In those babies found to be hypoglycaemic by reagent stick testing (<2.6 mmol/l), half went on to have a laboratory blood glucose test. Fifteen babies in the case group were separated from mother, most usually this was for management of a known congenital anomaly.

35/56 (63%) of women had a documented method of feeding in the notes, of these 16/35 (46%) exclusively breastfed with a further 14% mix feeding. Seven mothers continued to breastfeed beyond 28 days postpartum.

Postnatal care of mother

Overall two thirds (65%) of women had a written plan recorded in their postnatal notes for future diabetic management and obstetric care, such as the mode and timing of delivery. In total, there were 27 women who chose to breastfed at delivery but only 16 were able to carry this out in practice in the immediate post partum period. Only five of these received documented advice in regards to their glycaemic control whilst breastfeeding.

79% had a follow-up appointment for diabetic management prior to hospital discharge. There was no difference between cases and controls for these outcomes.

47% of women had documented contraceptive advice prior to discharge, however this was much more commonly given to those cases that had had a good outcome (71%) compared to the panel cases (23%).

Panel enquiries assessed the overall postnatal care and advice given. Half of the enquiries (30/61) were judged to have had suboptimal care and this was equally spilt between panel cases and controls. The vast majority of panel comments relating to those cases of suboptimal postnatal care focused on glycaemic control and insulin regimes, which either were not documented or discussed with the woman prior to the delivery or inappropriate regimes were used.

Box 4.3.1 *Panel comments relating to postnatal care*

'insulin omitted overnight, day 1 post partum hypo's whilst breast feeding'

'Poor monitoring of ketonuria, poor monitoring of sugars'

'no advice re insulin & breast feeding'

4.4 Stillbirths and Neonatal Deaths

There were 15 stillbirths (SBs) examined within the West Midlands CE in association with pre-gestational maternal diabetes and 3 early neonatal deaths (NNDs).

These were equally distributed between mothers with type 1 and type 2 diabetes.

11 of 15 SBs occurred antepartum (73%) and 4 occurred intrapartum.

3 SBs and 2 NNDs were diagnosed antenatally with a major congenital anomaly.

In 3 of these, the mothers gave a history of a previous pregnancy complicated by fetal anomalies.

12 (80%) of the SBs and 2 of the NNDs (66%) were allocated a CESDI grading 2-3 by the panel.

Maternal and Pregnancy Characteristics

Table 4.4.1 *Pregnancy details on stillbirths, neonatal deaths, and controls*

Characteristic	Stillbirth (n=15) (%)		Neonatal Death (n=3) (%)		Controls (n=38) (%)	
Type 1 DM	8	(53)	1	(33)	20	(53)
Type 2 DM	7	(47)	2	(66)	18	(47)
Preterm delivery	9	(60)	2	(66)	9	(24)
Fetal CA	3	(20)	2	(66)		0
EFW >90th centile	6	(40)	1	(33)	17	(45)
Multiparous	8	(53)	3	(100)	32	(84)
Previous preterm delivery	5	(53)	2	(66)	4	(11)
Diabetic complications	4	(27)		0	8	(21)
Medical/surgical complications	7	(47)	2	(66)	19	(50)
Quintile of IMD						
1	1	(7)			2	(5)
2	3	(20)	1	(33)	5	(13)
3	2	(14)			7	(18)
4	1	(7)			8	(21)
5	8	(53)	2	(66)	16	(42)

There was no difference between the groups in respect of maternal demographics or pregnancy characteristics in each of the categories in Table 4.4.1 except for a history of previous preterm delivery. Maternal age, duration, and type of diabetes, as well as medical/diabetic complications in the 12 months prior to pregnancy, were the same for each group.

56% (10/18) of mothers lived in an area of highest social deprivation in comparison to 42% of the controls.

Smoking

There was no difference in smoking rates during pregnancy between groups.

Gestation

Table 4.4.2 shows the spread of SBs and NNDs by gestation and type of delivery undertaken.

Half of the SBs without anomalies (6 cases) and all of those with a known congenital anomaly were delivered preterm. The three SBs with a CA had all been diagnosed/significant clinical suspicion during the pregnancy and were all delivered between 32 and 37 weeks gestation. 2 of the 3 were delivered by a planned CS - one due to a history of previous CSs and one due to maternal request in a mother in her first pregnancy. One of these 3 SBs delivered vaginally.

5 of the 6 SBs without CA delivered vaginally (one by forceps). 3 of these (60%) were between 32 and 37 weeks gestation (including one intrapartum SB). Only one of these cases was delivered by CS at 29 weeks gestation. The stated indication was for maternal request.

Two early NNDs followed premature delivery at 24 to 28 weeks. One of these (hysterotomy) resulted from a late diagnosis of CA and decision to terminate the pregnancy (without feticide procedure). The other was delivered by emergency CS after a diagnosis of severe fetal growth restriction resulting in a 400g neonate.

Table 4.4.2 *Stillbirths and neonatal deaths - distribution by gestation/mode of delivery.*

Outcome	Mode	Gestation (complete weeks)				Total
		24 -27	28-31	32-36	37+	
Stillbirths	SVD	1	1	3	3	8
	Forceps			1	1	2
	Emergency CS		1		2	3
	Elective CS			2		2
subtotal		1	2	6	6	15
Neonatal deaths	Emergency CS	1				1
	Elective CS				1	1
	Hysterotomy	1				1
subtotal		2			1	3
Total		3	2	6	7	18

Six SBs occurred between 37 and 40 weeks gestation, with 2 cases occurring in each completed week of pregnancy during this period. The mode of delivery was felt to have been appropriate by the panel enquiry in all of these cases. 3 of these SBs occurred intrapartum, 2 being delivered as emergency CSs. In both cases, a fetal heart was confirmed prior to the operation commencing.

In the 6 cases of SB without CA at Term, only one case had evidence of regular fetal wellbeing monitoring in the third trimester. In the other cases, no monitoring was undertaken, with some gaps between hospital appointments as long as 2-3 weeks.

Only one set of case notes had any reference to the need to monitor fetal movements or report any maternal concerns. At least 3 of those presenting with no fetal heart/fetal movements had a history of more than 24 hours of reduced movements beforehand (based on maternal recollection).

Other panel comments in relation to term stillbirths, both antepartum and intrapartum cases, are shown in Box 4.4.1.

Box 4.4.1 *Panel comments surrounding term stillbirths*

'No plan of delivery which caused confusion/problems in labour. Inadequate growth/fetal monitoring'

'No communication about risks of large baby & glycaemic control'

'protocols breached – e.g. CTGs' *'Advised not to attend hospital immediately when in early labour'*

'lack of interpretation of obs findings'

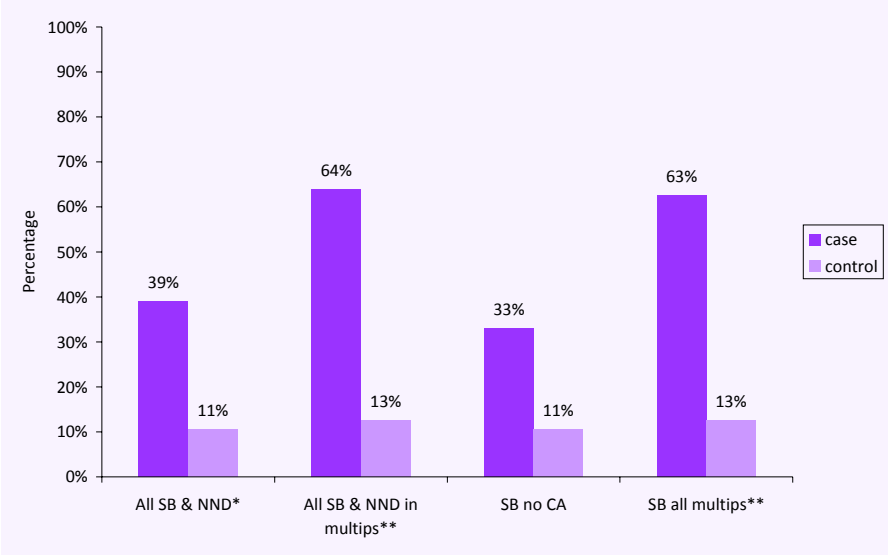
'plan for delivery inappropriately changed by junior staff'

'no care plan/poor documentation/conflicting advice for diabetic control in labour' middle grade anaesthetist, no mental health documented'

Previous Preterm Delivery

A significant association was found between a maternal history of previous preterm delivery (before 37 completed weeks of pregnancy) and a poor pregnancy outcome in the index pregnancy analysed.

Figure 4.4.3 *Previous history of a preterm delivery*



* significant p<0.05
** significant p<0.01

Figure 4.4.3 shows a statistically significant difference when the numbers of all SBs and NNDs (7 of 18 cases), all SBs and NNDs in multiparous women (7 of 11 cases) and only SBs in multiparous women (5 of 8 cases) with a previous history of a preterm birth were compared to the controls (with similar history of previous preterm birth). Only one case of a mother with a previous preterm birth was complicated by fetal congenital anomaly.

Glycaemic Control

Table 4.4.4 shows mean and median HbA1c values pre-pregnancy and within each trimester for SBs and NNDs with no CA, all cases with CA examined in the CE, panel controls and the larger WM cohort of live births excluding NNDs and CAs.

Table 4.4.4 *Comparison of outcomes and HbA1c values during Pregnancy*

HbA1c values		SB/NND (no anomaly) n=13	Panel anomaly* n=22	Panel control n=38	Cohort - live exc NND & anomaly n=350
Pre-pregnancy	Mean	13.6	9.4	7.4	7.9
	Median	13.6	9.1	7.6	7.7
10 weeks	Mean	8.1	8.2	7.2	7.1
	Median	7.8	7.9	7.2	7.1
20 weeks	Mean	6.6	6.7	6.3	6.3
	Median	6.6	6.1	6.3	6.2
34 weeks	Mean	7.4	7.0	6.3	6.4
	Median	7.1	6.8	6.3	6.3

All outcome groups embarked on a pregnancy with either adequate or poor glycaemic control (HbA1c <7.0% optimal; 7-8% adequate; 8.0% poor), the adverse outcome groups having greater suboptimal glycaemic control.

In the selected cases of SB/NND with no CA (A) there was significantly higher HbA1c's in the first and third trimesters in comparison to the control group (C; $p<0.05$) or the main WM cohort of live births (D; $p<0.05$).

The cases of CA (B) also showed significantly poorer glycaemic control in the first and third trimesters to controls (C; $p<0.05$) or main cohort (D; $p<0.01$).

All outcome groups demonstrate signs of improvement obtaining optimal glycaemic control by the second trimester.

It is interesting to note that both groups with adverse outcomes (A & B) revealed an increase in HbA1c in the third trimester whereas those with good outcomes (C and D) have more stable/consistent glycaemic control measurements.

Post Mortem Examination

Perinatal postmortems are an important investigation into the cause of a pregnancy loss at any gestation. The panel enquiry assessed whether PMs were offered to all SBs (15), NNDs (3) and pregnancy losses (8) included in the CE.

7 of 8 pregnancy losses below 24 weeks gestation were offered a PM (88%) and 4 of these (57%) agreed to the examination.

14 of 15 SBs (after 24 weeks gestation) were offered a PM (93%). In one case the question was not answered. 5 of these agreed to the PM (36%).

66% of the PMs (6 cases) were performed by a recognised Perinatal Pathologist at the regional referral centre with 3 others being performed by local Pathologists only.

There was no evidence that any of the NNDs were offered a PM.

In those cases where a PM was offered but not performed (12), seven were because of parental non-consent, in four no reason was documented, and in one case parental consent was obtained however the baby was released from the mortuary before the examination had taken place.

Summary

There is no effective fetal monitoring to identify fetuses at increased risk of SB that contributes the majority of perinatal deaths. Maternal and diabetic risk factors can be used to identify those pregnancies that may be at higher risk of perinatal loss than others complicated by maternal type 1 or type 2 disease.

In this case-control CE study broad ethnicity and a history of previous preterm delivery were associated with SB/NND in the absence of fetal CA. In allayed work within the WM Diabetes in Pregnancy project poor glycaemic control has been seen to be associated with poor pregnancy outcomes. Again, in this study, SB/NND was significantly higher with poorer glycaemic control, particularly in the first and third trimesters, compared to a good pregnancy outcome group (controls). Other risk factors such as maternal diabetic complications (hypoglycaemic episodes, retinopathy, and nephropathy) and previous maternal medical conditions (asthma, depression) were not associated with a poor pregnancy outcome in this group.

4.5 Panel Enquiry Comments relating to issues surrounding care

As part of the confidential enquiry the panel chair completed the enquiry proforma with the panel's consensus for the assessment of care given, including the assessor's comments pertinent to the relevant stage of pregnancy care received. They were asked to use codes in relation to issues applicable to either health service provision or those directly relating to the woman/family issues.

More detailed comments can be found in the appendices of this report including the DEP form and coding used. Below is a brief summary of some of the areas the panel thought significant.

Concerns relating to health professionals and the services provided

The main issues identified by the assessors relating to health service provision impacting clinical care were centred on the following aspects;

- Poor communication
  - Between health professionals and the woman; advice, choices and risks not being discussed.
  - Lack of advice and unclear targets often meant women were unable to comprehend reasons for good adherence.
  - Between professionals (fertility specialists, diabetologists, Obstetricians, teams, GP, Haematologist, Ultrasonographers, social workers, Psychiatrists, Dermatologists, Dieticians).
  - Lack of recognition of diabetes being a "*high risk*" status.
  - Interpreter services; lack of or the use of male interpreters.
- Preconception
  - Folic Acid: Pre-pregnancy intake and prescription of correct 5 mg dose.
  - No pre-pregnancy care or not sent for early assessment.
  - Medication: Inappropriate use of ACE inhibitors and metformin.
- Antenatal Clinics
  - Identified as not being a multidisciplinary antenatal clinic.
  - Infrequent clinic appointments or appointments described as being chaotic.
  - No dietician or lack of consultant involvement.
- Documentation
  - Poor diabetic history taking.
  - Failure to document management plans.
  - Lack of blood sugar recordings intrapartum.
  - Failure to document post partum care.
- Diabetes Clinical management
  - No diabetes care in the first trimester.
  - Lack or insufficient retinal screening - failure to follow up retinopathy.
  - Lack or insufficient monitoring of diabetes (insufficient HbA1c testing).
  - Inappropriate insulin regimes (use of glargine, insufficient insulin relating to high BMs).
  - Clinical findings not addressed, e.g. ketonuria.

- Obstetric Clinical management
  - Failure to obtain and follow up results.
  - Fetal anomalies missed.
  - Fetal monitoring either lack of or felt to be reduced (delay/absence of growth scans) failure to recognise fetal distress.
  - Suboptimal management of hypoglycaemia - failure to recognise, hypertension, cholestasis.
  - No sliding scale or not adjusted accordingly.
  - Experience of medical staff/Midwives questionable.
  - Inappropriate practice: in use of antibiotics, steroids, ARM, prolonged trial of labour, delivery mode, and timing.
  - Use of metformin whilst breastfeeding.
  - No breast feeding advice.
  - Deviations from protocols.

Concerns relating to patient and/or family circumstances

The main issues identified by the assessors related to the woman's approach to her condition and the pregnancy were centred on the following aspects;

- Poor attendance at pre-pregnancy clinics.
- Poor glycaemic control due to inadequate BM testing, omitting/non-compliance with changes to insulin regimes.
- Lack of understanding regarding the seriousness of their medical condition and the effects of pregnancy.
- Late booking/presentation for antenatal care.
- Non-English speaking.

Those women with type 1 diabetes may be in the transition between paediatric and adult diabetic services and/or have received little input with regards to pregnancy planning and may have a reduced awareness of how to access pre-conception services.

They often are empowered to self manage their condition whilst juggling lifestyle issues, annual check-ups and contact numbers so they can access both primary and secondary care. Some may find that diabetes has been an intrusion or a hindrance on their lifestyle and obtaining additional health service provision may be of secondary concern. Unresolved psychological issues where freedom of choice has not been a perceived option for them may impact the planning of a pregnancy where they feel the need to be in control in what would appear a normal choice.

To obtain optimal glycaemic control and minimise the risk of diabetes related conditions pre-pregnancy involves the woman to be either planning a pregnancy and/or is motivated and actively seeking advice rather than just self managing. Women planning pregnancies do not always consider the rationale of pre-conception services.

Women with type 2 are discussed in more detail in Chapter 5.

The panel assessed separately deficiencies in communication between health professionals and the woman. Again this highlighted poor understanding on the part of the woman as to the importance of tight glycaemic control or why medical/insulin regimes needed to be altered. This is particularly discussed further in Chapter 5, in women with type 2. If English is not the first language difficulties present when family members are the only source of communication and their own be questionable understanding can affect the ability to convey the information being expressed.

4.6 Summary of Panel Enquiries

The confidential panel enquiry has provided a detailed, thorough analysis of the details and care afforded to selected cases ending in good or adverse pregnancy outcomes. This level of detail, derived from patient notes or other relevant documentation, has allowed the panel to make judgements about care given and to highlight areas of optimal or suboptimal care.

The cases and controls were matched in terms of maternal ethnicity, socio-demographics, parity, and diabetic/medical complications before and during the pregnancy. This included assessing variables from folic acid usage, hospital attendance to hypoglycaemic events. However, there were significant differences found between the cases and controls in particular areas:

- Uptake of pre-pregnancy counselling.
- Suboptimal glycaemic control in the pre-pregnancy and first trimester periods.
- Incidence of maternal mental health problems.

Cases had lower usage of folic acid, higher levels of "*poor*" glycaemic control, and an increased incidence of mental health problems. In addition, in the separate analysis of stillbirths and neonatal deaths, a similar picture of suboptimal glycaemic control prior to pregnancy and in the first/third trimesters was evident. A possible new association in this small number of cases with a previous history of premature delivery is intriguing and should act as a "*marker*" for the identification of those pregnancies that may be at an increased risk of late perinatal loss.

Panel assessments of care provided did not show a clear difference in any of the broad areas of care examined between cases and controls. This is perhaps surprising given that there was a clear difference in the panel CESDI grading of cases/controls, with 72% of cases allocated a CESDI 2/3 grading. Maternity units and health care professionals must look at the number of comments related to communication issues between them and the woman or between different health professionals, the generally poor management in setting and adhering to glycaemic targets and the lack of senior involvement in planning and managing labour and delivery. All of these areas and others could be tackled at an individual, Trust, and regional level to improve care provided. Examples of initiatives in this line are highlighted at the end of this report.

Engaging women before pregnancy, motivating them to the importance of tight glycaemic control and general pre-pregnancy care, involving them in all the steps of management prior to and during a pregnancy and ensuring good, effective communication at all levels should be striven for. The panel CE shows that this is very far from the norm and that pregnancy outcomes are unlikely to improve in this group of patients until wholesale changes to achieve this are brought about.

Chapter 5 Type 2 Diabetes

5.1 Outcomes and Demographics

There were 149 pregnancies complicated with maternal type 2 diabetes, 34 of which were assessed within the confidential panel enquiry (see Chapter 4).

In this chapter, we will analyse in more detail the outcomes and care provided to these women before and throughout pregnancy. In order to do this the cohort group of 149 as been divided as follows:

- **Good outcomes** in type 2 group=116 pregnancies resulting in a neonate alive at 28 days alive with no congenital anomaly.
- **Poor outcomes** in type 2 group=33 pregnancies resulting in pregnancy loss/Perinatal death or a neonate alive at 28 days with a congenital anomaly.

Outcomes from type 2 Diabetic Pregnancies

The major congenital malformation rate for type 2 diabetic pregnancies is 88.2/1,000 births. The perinatal mortality rate is 52.6/1,000 births. More details regarding these figures are to be found in section 3.6.

Table 5.1.1 *Outcomes of all type 2 diabetic pregnancies cohort*

Cohort	Early fetal loss <20/40	Late fetal Loss ≥20-23^{+6}	Stillbirth	Neonatal Death	Alive at 28 days	Total
Poor outcomes	13	1	8	2	9	33
Congenital anomalies	1	0	1	1	9	12
Good outcomes	0	0	0	0	116	116
Total						149

In addition the subset of 34 type 2 cases subjected to the confidential enquiry have provided, in some areas, scope for more detailed analysis of care. These are described as panel enquiry **controls** (18) and **cases** (16) as per Chapter 4.

Type 2 Demographics

The cohort of type 2 diabetic pregnancies comprised of 64 women of European descent (43%) and 85 women of non-European descent (42.3% Asian and 14.7% other ethnic group). There was equal representation of Europeans (42%) and non-Europeans (58%) within each pregnancy outcome group. More detailed ethnic breakdown is given in Table 5.1.3.

Figure 5.1.2 shows the two pregnancy groups (GO - Good Outcome, PO - Poor Outcome) broken down by ethnicity and by the Index of Multiple Deprivation (IMD) score. There were no significant differences when comparing these parameters with equal proportions of European and non-European mothers in each pregnancy outcome group. In addition, there were no demographic differences when comparing maternal age at delivery, age of onset of diabetes and/or duration of diabetes (Table 5.1.3).

Overall, half of those women experiencing a poor pregnancy outcome were located in IMD 5.

Figure 5.1.2 *Outcomes of all type 2 diabetic pregnancies in relation to area of deprivation and ethnicity*

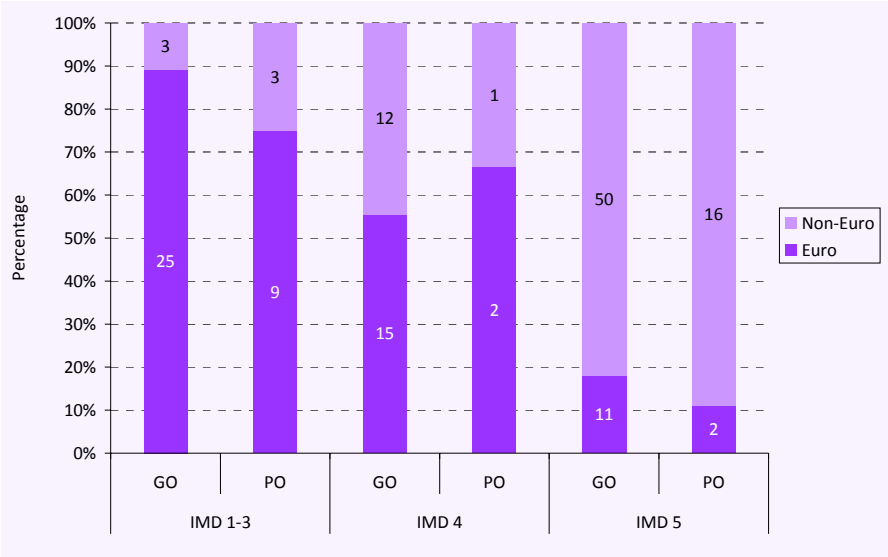


Table 5.1.3 *Diabetes characteristics for all type 2 pregnancies*

Cohort	Good Outcome (n=116)	Poor outcome (n=33)	Significance (t-test)
TOTAL			
Maternal age at delivery	32.5 yrs	31.1 yrs	p=0.23
Age of diabetes onset	28.0 yrs	25.8 yrs	p=0.47
Duration of diabetes	4.5 yrs	5.3 yrs	p=0.15
EUROPEAN			
Maternal age at delivery	33.3 yrs	31.2 yrs	p=0.23
Age of diabetes onset	29.3 yrs	26.0 yrs	p=0.53
Duration of diabetes	4.1 yrs	5.2 yrs	p=0.27
NON-EUROPEAN			
Maternal age at delivery	31.8 yrs	31.1 yrs	p=0.33
Age of diabetes onset	27.0 yrs	26.0 yrs	p=0.36
Duration of diabetes	4.8 yrs	5.3 yrs	p=0.39

5.2 Diabetes Care Before and in Pregnancy

Table 5.2.1 *Type 2 diabetes Cohort*

Case		European	Non-European	Total
PRE-PREGNANCY COUNSELLING				
Good outcomes	Yes	14	15	29
	No	37	50	87
Subtotal		51	65	116
Poor outcomes	Yes	3	4	7
	No	10	16	26
Subtotal		13	20	33
Total		64	85	149
ON INSULIN PRE-PREGNANCY				
Good outcomes	Yes	15	17	32
	No	36	48*	84
Subtotal		51	65	116
Poor outcomes	Yes	7	9	16
	No	6	11*	17
Subtotal		13	20	33
Total		64	85	149
RETINAL ASSESSMENT IN PREGNANCY				
Good outcomes	Yes	40	58	98
	No	11†	7*	18
Subtotal		51	65	116
Poor outcomes	Yes	9	16	25
	No	4†	4*	8
Subtotal		13	20	33
Total		64	85*	149
FETAL MONITORING IN LABOUR				
Good outcomes	Yes	19	39	58
	No	3	3	6
Subtotal		22	42	64
Poor outcomes	Yes	2	1	3
	No	0	3	3
Subtotal		2	4	6
Total		24	46	70

* includes one case as being not documented
† includes three cases as being not recorded).

In the whole of the type 2 cohort, 36 women received pre-pregnancy counselling. This equated to 25% of those women with a good pregnancy outcome and 20% of those with a poor outcome (p=0.8 NS). European women were more likely to have had pre-pregnancy counselling than non-European women (27% v 22%), although this was a non-significant difference. The majority of type 2 women accessed pre-pregnancy counselling within an adult diabetes clinic (50%). 17% of women received this counselling either in a formal pre-pregnancy clinic or with their GP. There was no significant difference between pregnancy outcome groups as to the location of pre-pregnancy counselling, although 71% of the poor outcome group were documented as being seen in an adult diabetic clinic. This may indicate

poorer diabetic control necessitating secondary hospital-based care and resulting in a poorer pregnancy outcome.

The use of pre-pregnancy folic acid was again not significantly different between the two outcome groups (36% v 21%, p=0.16 NS). There was no difference between European and non-European groups.

Only 32% of all type 2 diabetic women were taking insulin prior to the pregnancy but this was statistically more likely in those women with a poor pregnancy outcome (48.5% v 27.6%, p=0.04).

The rates of detailed retinal assessment for both groups were very similar to the overall West Midlands cohort with 83% of type 2 diabetic women having had this assessment in pregnancy. There was no significant difference in comparing pregnancy outcomes groups for retinal assessment in pregnancy. It can be noted that only 69% of Europeans in the poor outcome group were assessed during pregnancy.

5.3 Glycaemic Control

Table 5.3.1 *Type 2 Cohort - Comparison of pregnancy outcomes and mean HbA1c (SD Values) during Pregnancy*

HbA1c values	Poor outcomes* n=33			Good outcomes† n=116			p value§
	[n]	Mean	(SD)	[n]	Mean	(SD)	
TOTAL COHORT							
Pre-pregnancy	[10]	9.0%	(3.0)	[39]	7.2%	(2.2)	N sig 0.13
10 week	[24]	7.7%	(1.4)	[87]	6.7%	(1.4)	Sig <0.01
20 week	[18]	6.4%	(1.2)	[103]	6.1%	(1.2)	N sig 0.31
34 week	[12]	6.8%	(1.2)	[104]	6.2%	(1.0)	Sig 0.05
EUROPEAN							
Pre-pregnancy	[6]	7.4%	(2.2)	[24]	7.1%	(1.7)	N sig 0.92
10 week	[8]	7.1%	(0.6)	[37]	6.6%	(1.3)	N sig 0.20
20 week	[7]	5.9%	(0.8)	[43]	5.8%	(1.0)	N sig 0.66
34 week	[6]	6.3%	(1.0)	[45]	6.1%	(1.0)	N sig 0.66
NON-EUROPEAN							
Pre-pregnancy	[4]	11.4%	(2.5)	[15]	7.4%	(2.9)	Sig 0.02
10 week	[16]	8.0%	(1.2)	[50]	6.7%	(1.5)	Sig <0.01
20 week	[11]	6.7%	(1.4)	[60]	6.3%	(1.2)	N sig 0.33
34 week	[6]	7.3%	(1.2)	[59]	6.2%	(1.1)	Sig 0.02

* poor outcomes= all pregnancies resulting in loss/perinatal death or a neonate alive at 28 days with a congenital anomaly.
† good outcomes= all pregnancies resulting in a neonate alive at 28 days alive with no congenital anomaly
§ p value used - Mann Witney or T-test as appropriate

Table 5.3.1 compares mean HbA1c values recorded throughout pregnancy for both outcomes groups. A significantly higher mean HbA1c was found in the first and third trimesters in those pregnancies resulting in poor outcomes compared to the good outcome group. When broadly broken down by ethnicity there was no difference found in the European population for glycaemic control between the two groups throughout pregnancy (Figure 5.3.2a) However in the non-European population significantly greater HbA1c values were identified in the poor outcome group pre-pregnancy and in the first and third trimester (Figure 5.3.2.b).

As in the main cohort study pre-pregnancy glycaemic control was found to be suboptimal (>7.0%) in all the type 2 groups with a significant difference found in the small non-European group (n=4) who went on to have a poor pregnancy outcome (mean HbA1c 11.4%).

Figure 5.3.2a *Mean HbA1c values in the European type 2 pregnancies*

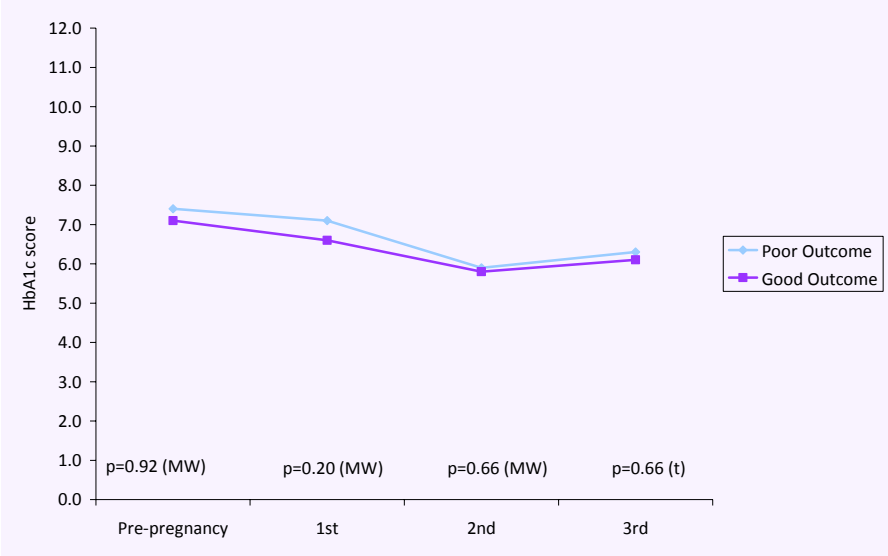
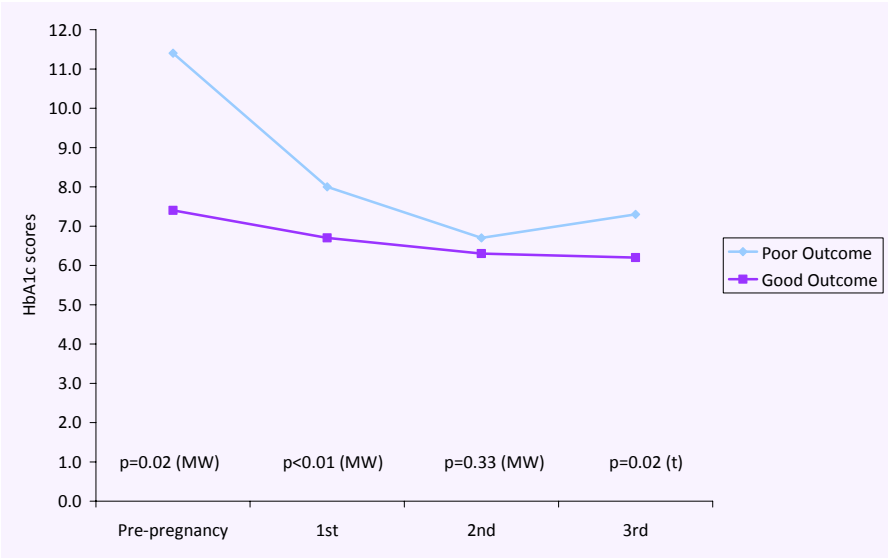
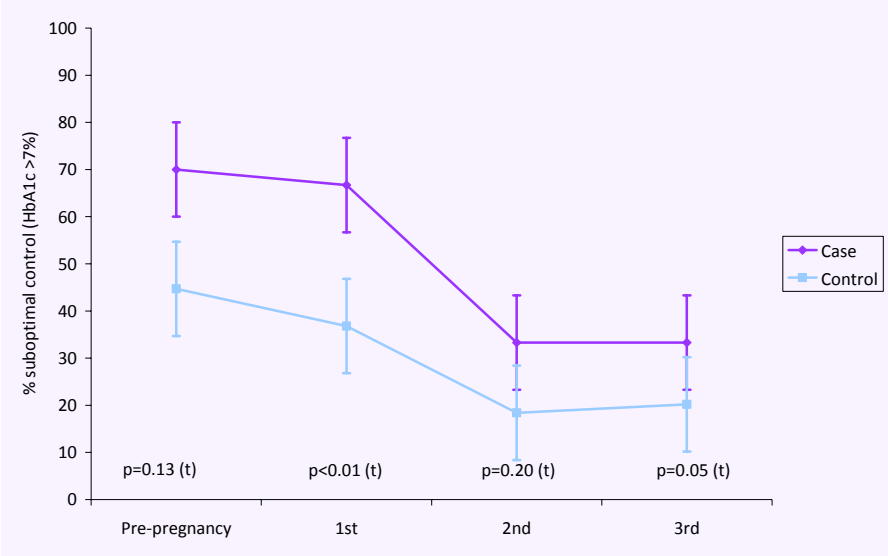


Figure 5.3.2b *Mean HbA1c values in Non- European type 2 Pregnancies*



Glycaemic control was also evaluated by defining levels of suboptimal control pre-pregnancy and within in each trimester as a mean HbA1c as >7.0% (as in the confidential Panel Enquiry) Figure 5.5.3 shows greater levels of suboptimal glycaemic control in the poor pregnancy outcome group compared to the good outcome group, at all stages before and during the pregnancy. This level of difference reached statistical significance in the first and third trimesters (students t-test analysis).

Figure 5.3.3 *Suboptimal Glycaemic control (of all who had test) in the type 2 Cohort*



5.4 Treatment/Insulin Regimes in Pregnancy

Data from the 34 type 2 pregnancies included in the Confidential panel enquiry have been examined to undertake a detailed assessment of treatment regimes used prior to and during pregnancy. 11 women (32%) were of European ethnicity and 23 (68%) non-European.

Table 5.4.1 summarises these data for each individual case or control. Types of insulin used and regimes are included to illustrate changes that occurred in pregnancy.

Pre-pregnancy

Pre-pregnancy 47% (16/34) of type 2 women were managed with oral hypoglycaemic agents (OHA) and 18% with diet alone (6/34). Those taking OHAs were equally distributed between European (46%) and non-European (48%) women. 24% of women (8/34) were using insulin prior to pregnancy, 3 of whom changed onto an insulin regime specifically in preparation for pregnancy.

3 women were using a combination of OHA and subcutaneous insulin. Metformin was the most commonly prescribed OHA (14/34, 41%) with 4 women also using a sulphonylurea and two women using Gliclazide only.

Treatments Agents in Pregnancy

At a first hospital appointment in pregnancy 56% (19/34) were commenced on insulin and their OHAs stopped. 58% (11/19) commenced insulin in the first trimester, 37% in the second and only one in the third trimester at 35 weeks. The majority of these women were non-European (14/19). In total 61% of non-European women commenced insulin during the pregnancy.

One woman continued using an OHA and insulin was administered at night only. 3 (9%) women remained just on diet control throughout pregnancy and did not require additional treatment.

The majority of women were seen in the first trimester (79%) for a first hospital appointment with a range of 4.5-12.3 weeks gestation.

During analysis of the treatment/insulin regimes increases in insulin dosages have not been counted as changes to treatment as insulin requirements are known to increase as pregnancy progresses. Changes to regimes were documented as the starting or stopping of an agent or the adoption of a different insulin regime/agent (e.g. from basal bolus regime to a twice daily mixed insulin regime).

20% (7/34) of type 2 women remained on the same treatment regime prior to and throughout pregnancy (2 on diet, 5 using insulin). 80% of type 2 women (27/34) changed onto a different treatment regime in pregnancy. In total 31 women were treated with insulin during pregnancy (91%) - half being prescribed a basal bolus regime and half a mixed insulin twice daily regime. Of these 19 (61%) were maintained on the same regime throughout - 5 from pre-pregnancy and 14 from booking to delivery. 12 women (39%) changed insulin regimes as the pregnancy progressed - 7 changed onto a basal bolus regime whilst 5 altered the frequency of prescribed insulin.

Postnatally 17 women (50%) reverted back to their pre-pregnancy treatment regime. 16 women (47%) remained on insulin during the early postnatal period. There was no correlation between the postnatal regime recommended and the overall pregnancy outcome.

These 34 cases represent those analysed by the Panel Enquiry. In the National CEMACH dataset, there were no data pertaining to start of insulin treatment in type 2 women in pregnancy or the treatment regimes employed. It is interesting to note that both one third of the type 2 panel group (11/34) and the WM cohort (48/149) were using insulin prior to pregnancy. It is therefore reasonable to presume that in the WM cohort 84 of the 149 type 2 women (56%) would have needed to commence insulin either at booking or at a first hospital appointment.

Table 5.4.1 *Type 2 Cohort - treatment regimes throughout pregnancy*

case	pre-pregnancy agent *changed from OHA to insulin (3)	1st hosp appt (wks)	time insulin commenced	agent/regime adopted @ booking	pre-delivery insulin regime increase/adjustments not stated	post delivery regime	pregnancy outcomes	ethnicity
1	Gliclazide	6	at booking	Mixtard 30 bd	no change	insulin regime	control	European
2	diet	19	at booking	Actrapid tds & Insulatard od	no change	insulin regime	case-LB-CA	non-European
3	metformin	6	7	Mixtard 30 bd	no change	OHA - metformin	control	European
4	metformin	8	35	novomix 30 bd	no change	OHA - metformin	control	non-European
5	Insulatard od	9	pre-pregnancy	Mixtard 30 bd	Actrapid & Insulatard qds	insulin regime	case-LB-CA	European
6	Humulin M3*	10	pre-pregnancy	Humulin M3 bd	no change	poor documentation	case-SB	non-European
7	diet	14	15	Humulin M3 bd	no change	insulin ->7/52 pn diet alone	control	non-European
8	metformin	8	9	Humulin M3 bd	Humulin s tds & Humulin I bd	OHA - metformin	case-SB	non-European
9	diet	10	16	Humalog bd & Humulin I bd	no change	diet	control	non-European
10	diet	12	diet	diet	diet	diet	control	European
11	Humulin M3*	9	pre-pregnancy	Humulin M3 bd	Humulin s tds & Humulin I bd	insulin regime	control	European
12	Gliclazide & acarbose	6	at booking	Actrapid tds & Insulatard od	Humulin s tds & Humulin I od	insulin regime	case-NND-CA	non-European
13	metformin	15	20	Actrapid tds & Insulatard od	Actrapid tds & Insulatard bd	OHA - metformin	case-LB-CA	European
14	metformin	15	pre-booking	Mixtard 50 bd	Actrapid tds & Insulatard bd	OHA - metformin	case-LB-CA	non-European
15	lack of documentation	12	pre-booking	Humalog tds & Insulatard od	Humalog tds & Insulatard bd	insulin regime	control	European
16	Humalog & Humulin I*	9	pre-pregnancy	Humalog & Humulin I	Humalog tds & Humulin I bd	insulin regime	case-EFL-CA	European
17	Actrapid tds & Insulatard od*	5	pre-pregnancy	Actrapid tds & Insulatard od	no change	insulin regime	case-NND	non-European
18	Novorapid & Insulatard	6	pre-pregnancy	Novorapid tds & Insulatard od	no change	insulin regime	control	European
19	Mixtard	6	pre-pregnancy	Mixtard 30 bd	Humalog tds	OHA - metformin	case-SB-CA	non-European
20	metformin & glimepiride	8	9	Mixtard 30 bd	Actrapid qds	insulin regime	case-SB	European
21	metformin & Actrapid tds	11	pre-pregnancy	Actrapid tds & Insulatard od	no change	insulin regime - breastfed	control	non-European
22	metformin & glimepiride	11	pre-booking	Mixtard 50 bd	no change	OHA	case-LFL	non-European
23	diet	20	at booking	Mixtard 50 bd	no change	diet - GTT arranged	control	non-European
24	metformin	7	12	Humulin M3 bd	no change	OHA -metformin	control	non-European
25	diet	8	diet	diet	diet	diet	control	non-European
26	metformin	10	pre-booking	Insuman basal & rapid bd	no change	insulin regime - breastfed	case-SB	non-European
27	metformin & Actrapid tds Insulatard od	5	pre-pregnancy	Actrapid tds & Insulatard od	no change	insulin regime	case-SB	non-European
28	metformin	15	17	Humalog bd & Insulatard bd	Humalog tds & Insulatard bd	diet (metformin 6/52 p/n)	control	non-European
29	metformin, pioglitzone, Humalog tds Humulin I nocte	5	pre-pregnancy	Humalog tds & Humulin I od	no change	insulin regime	control	non-European
30	metformin	5	diet	diet	diet	diet - GTT	control	European
31	Mixtard 30	10	pre-pregnancy	Mixtard 30 bd	no change	insulin regime	control	non-European
32	metformin & rosiglitazone	15	pre-booking	Actrapid tds & Insulatard od	no change	OHA	case-LB-CA	non-European
33	metformin & Gliclazide	9	at booking	Humalog bd & Humulin I bd	Humalog tds & Humulin bd	OHA - metformin	control	non-European
34	metformin & Gliclazide	10	12	metformin & Insulatard nocte	no change	OHA - metformin	case-SB	non-European

Table 5.4.2 *Type 2 Cohort - summary table of treatment regimes throughout pregnancy*

case	pre-pregnancy treatment regime		1st hosp appt		time insulin commenced		agent/regime adopted @ Booking		post delivery regime		pregnancy outcomes		ethnicity	
	Insulin	(8)	1st trim	(27)	Insulin pre-pregnancy	(11)	On Insulin from pre-preg	(11)	Diet	(6)	Control	(18)	Euro	(11)
	OHA & Insulin	(3)	2nd trim	(7)	Insulin pre-booking	(5)	OHA & Insulin	(1)	OHA	(11)	Case	(16)	non-Euro	(23)
	OHA	(16)	3rd trim	(0)	Insulin at booking	(5)	Commenced Insulin	(19)	Insulin	(16)	LB/CA	(5)		
	Diet	(6)			Insulin later in pregnancy	(10)	Diet	(3)	Documentation poor	(1)	SB	(8)		
	Poor documentation	(1)			Diet	(3)					SB/CA	(1)		
	Total	**34**									EFL/CA	(1)		
											LFL	(1)		
											NND	(1)		
											NND/CA	(1)		
											CA	(8)		

5.5 Diabetic Complications

Diabetic complications were assessed as part of the CE in 34 type 2 pregnancies (16 cases, 18 controls).

Recurrent hypoglycaemia was documented in 9 (26.5%) women with type 2 diabetes compared to 28 (65%) women with type 1 disease. None of the type 2 women required additional help from a second person in managing the hypoglycaemic episode although documentation was scarce and it may be that careers/health professionals did not sufficiently detail each hypoglycaemic episode.

Retinopathy was documented as being present in 4 women. There were 2 new diagnoses of diabetic retinopathy during pregnancy in the type 2 group. Two women had pre-existing retinopathy changes prior to pregnancy, one of which was subsequently referred to an Ophthalmologist because of identifiable deterioration.

All women were monitored for signs of nephropathy during the pregnancy, however there were no documented cases of new or established diabetic nephropathy in this group.

Table 5.5.1 lists the established complications attributed to diabetes and any medical/surgical conditions documented in this group in the 12 months prior to the pregnancy. The non-European group required more treatment within the 12 months preceding the pregnancy although this was not significantly different compared to the European group (83% v 73%). Pre-existing hypertension was found in two women prior to pregnancy and in one woman there was established retinopathy. The European type 2 women had no pre-existing diabetic complications. Asthma again was the most common additional medical condition, however depression/mental health problems and PCOS were found only in the non-European group.

Table 5.5.1 *Diabetic and medical/surgical complications*

Complication	Type 2		
	European (n=11)	Non-European (n=23)	All women (n=34)
Diabetic			
Hypertension	0	2	2
Retinopathy	0	1	1
Medical/Surgical			
Asthma	3	4	7
Depression/mental health	0	4	4
Hypertension	1	3	4
PCOS	0	3	3
Others	4	5	9

5.6 Mode of Delivery

Table 5.6.1 *Mode of delivery in the type 2 cohort after 24 weeks Gestation*

Mode of delivery	European n=58 (%)		non-European n=77 (%)		Total n=135 (%)	
SVD	12	(21)	33	(43)	45	(33)
Forceps	2	(3)	2	(3)	4	(3)
Emergency CS	15	(26)	26	(34)	41	(30)
Elective CS	29	(50)	16	(21)	45	(33)

In the type 2 cohort 36% of women had a vaginal delivery with similar proportions having an emergency or planned caesarian section.

Non-European type 2 women were more than twice as likely to achieve a vaginal delivery and conversely European women were than more than twice as likely to opt for an elective caesarian section.

There was no significant difference between the delivery details of women with good or poor pregnancy outcomes. In both groups two thirds of women delivered by caesarian section, although in the good outcome group most of these were by planned operation whereas in the poor outcome group most (40%) were performed as an emergency procedure.

5.7 Postnatal Care

CE Panel assessments for postnatal maternal care included the documentation of a diabetic management plan, the provision of contraceptive advice to the mother prior to discharge and a follow-up appointment for diabetic review being booked prior to discharge. In the group of 34 type 2 pregnancies assessed by the panel, 65% of women had a postnatal diabetic plan recorded, but this was much less clear in the group of women choosing to breast feed where only 20% had a specific plan documented. 44% of women had documented contraceptive advice given before leaving hospital and 82% of women had a specific diabetic review booked.

Details regarding admissions to NNU and neonatal complications are presented in section 3.8.

Breastfeeding rates for the type 2 cohort were analysed having excluded the poor pregnancy outcome group. Overall 33% (38/116) of this group breast fed from delivery. This compares to 46% of the West Midlands type 1 cohort. Non-European type 2 women were much less likely to breast feed from delivery (25 v 43%) but more likely to use mixed feeding methods (20 v 4%) compared to the European group. Half of type 2 women solely used formula milk as their feeding method of choice (no difference between European and non-European).

Table 5.7.1 *Method of feeding from delivery in the good outcome cohort*

Mode of feeding	European n=51 (%)		non-European n=65 (%)		Total n=116 (%)	
Breast	22	(43)	16	(25)	38	(34)
Formula	26	(51)	34	(52)	60	(52)
Mixed	2	(4)	13	(20)	15	(13)
Not documented	1				1	
Don't know			2		2	

As with the WM cohort, increasing numbers of mothers switched to formula milk only by 28 days postpartum (71%). This was more likely to occur in European mothers with more non-European mothers (22%) using mixed feeding methods.

Table 5.7.2 *Method of feeding at 28 days in the good outcome cohort*

Mode of feeding	European n=51 (%)		non-European n=65 (%)		Total n=116 (%)	
Breast	6	(12)	6	(9)	12	(10)
Formula	38	(75)	44	(68)	82	(71)
Mixed	6	(12)	14	(22)	20	(17)
Other			1		1	
Don't know	1				1	

5.8 Panel Enquiry Comments

Tables on the following pages detail the panels comments from the confidential enquiries in relation to type 2 pregnancies. Individual comments have been displayed by ethnicity (European v non-European) and pregnancy outcome (cases v controls) having been categorised into the different enquiry codes from a health service provision viewpoint as well as from a woman focused/family related position.

There were 34 pregnancies assessed by panel, 11 (32%) women were of European descent and 23 (68%) non-European.

The following paragraphs are brief summaries of the detailed charts on the following pages and should be read in conjunction with them.

Pre-pregnancy (Table 5.8.1)

In the European group, issues relating to pre-pregnancy (glycaemic control and other areas of care) were few but related totally to poor attendance, smoking, and obesity. The opposite was true in the non-European group where comments made by the panel focused on issues mainly surrounding provision of health services.

Antepartum Glycaemic Control (Table 5.8.2)

There were no issues in the European group relating to the professional health management of glycaemic control. In one case the woman's own actions contributed to suboptimal care (non-attendance, obesity and no monitoring until the second trimester).

There were several comments in relation to health service provision in the non-European women particularly in the case group (Communication and clinical practice).

Diabetes and Maternity Care in Pregnancy (Table 5.8.3)

A large majority of issues in this section relate to care in the non-European group and concern health professional involvement both in cases and in controls. There were fewer issues relating to non-compliance/none attendance during pregnancy. By contrast in the European group, the issues pertain to the woman's actions more frequently (though the overall comments are much fewer).

Glycaemic Control and Maternity Care during Labour

During labour issues related to glycaemic control solely focused on the use of sliding scale insulin/appropriate insulin regimes. The majority of comments in both population groups related to obstetric management of labour and particularly the level of expertise of clinicians managing the woman in labour. Lack of senior involvement was again recognised as a major issue. Some of these comments are highlighted in Box 5.8.1.

Box 5.8.1 Panel comments type 2 diabetes

Inappropriate expertise level of obstetrician and anaesthetist

Mode & timing of delivery unsuitable

Poor level of fetal monitoring (2) *Delay in commencing sliding scale of insulin (4)*

Deviation from glycaemic protocol

Conflicting delivery plans *No consultant involvement in delivery*

Not actively managed in labour *minimal care in labour*

Postnatal Diabetes Care (Table 5.8.4)

There was only issue in the European group relating to the professional health management in the area of postnatal diabetes care. In the non-European group, there were a number of health management issues pertaining to both the control and case groups most noted in areas of clinical practice and communication. The majority of these related to management of maternal diabetes post-natally.

The tables in this section illustrate the number and variety of panel comments related to poor practice or factors, which may contribute to poor outcomes. There are significantly more registered comments for non-European women compared to the European group and a large proportion of these concerned communication and clinical practice issues. Poor communication due to language differences or the use of interpreters between non-European women (mainly Asian and African) and carers did occur but was only one of a number of areas highlighted in this category including poor communication between different health professionals, lack of adequate counselling or discussion on issues such as the timing of delivery. There were no communication issues noted in the European women.

Clinical practice issues in non-European women were varied in the area of maternity and diabetes care and pre-pregnancy care, which relates to both primary and secondary health care. Specific highlighted issues concerned poor/inappropriate glycaemic control and target setting, wrong dose of folic acid being prescribed, lack of senior input into management and the failure to recognise risk factors in the pregnancy.

These issues of care were not seen in the European group. Within the group assessed by panel, there were twice as many women of non-European ethnicity than European. Although this must be borne in mind when assessing the comments recorded it does not explain the great disparity in the types and numbers of comments made by the panel in regards to these two broad ethnic groups.

Issues relating to the patient/her family were less common but present equally in European and non-European groups. For Europeans these centred on patient DNA and smoking rates whereas in non-Europeans most patient issues were related to poor compliance or not following recommended advice.

When comparing comments for cases against controls in each category of care there were very similar types and numbers of issues recorded. The two areas showing a clear difference were related to maternity care in Europeans during labour and delivery and in the non-European group concerning glycaemic control prior to delivery. This would seem to indicate that, on the numbers of type 2 pregnancies assessed, issues of poor care occur equally in pregnancies resulting in both good and poor outcomes and that professional care provided is not the leading factor in the overall outcome.

Table 5.8.1 *Pre-Pregnancy Comments (glycaemic control and other aspects of PPC)*

European n=11				Non-European n=23			
Health Service Provision		**Patient/Family issues**		**Health Service Provision**		**Patient/Family issues**	
Control n=7	None	Woman's actions	smoking (2) obesity not addressed missed pre-pregnancy clinics	**Control n=11**	Communication	Woman's actions	poor control prior to conception
					did not transfer to hospital pre-conception clinic v poor communication (2) poor use of interpreters		
					Clinical practice		
					referred to wrong consultant incorrect dose of folic acid inappropriate hypertension treatment no folic acid (3)		
					Documentation		
					no information prior to pregnancy little information		
Case n=4	None	Woman's DNA	poor attendance no attendance	**Case n=12**	Communication	Woman's actions	no presentation until 12/40 unplanned
					pregnant before assessed & unsure pre-preg folic acid advised poor communication & post operative advice no counselling communication inadequate	PO -lifestyle factors	no folic acid, metformin not stopped
					Clinical practice	Woman active choice	ignored pre-conception advice
					very poor glycaemic control pre-conception no advice given not sent for earlier assessment poor GP care no folic acid on ace inhibitor		
					Documentation		
					HbA1c 7.4-7.6% - no clear plan made HbA1c over 8		

Table 5.8.2 *Pregnancy Comments (glycaemic control prior to delivery)*

European n=11				Non-European n=23			
	Health Service Provision	**Patient/Family issues**			**Health Service Provision**	**Patient/Family issues**	
Control n=7	None	None		**Control n=11**	Communication	Woman's actions	woman not testing, or taking diabetes seriously
					Documentation		insufficient information
Case n=4	None	Woman's DNA	non-attendance no monitoring until 15/40	**Case n=12**	Communication	Woman's actions	no home monitoring records (2) didn't hit HbA1c targets late booking
		Woman's actions	obesity		Clinical practice	PO-lifestyle factors	non-English speaking not interested in weight loss
							poor advice regarding insulin unusual insulin regime fructosamine difficult to interpret limited HbA1c monitoring (2) didn't see dietician until 26/40 no dietician

Table 5.8.3 *Pregnancy Diabetes and Maternity Care*

European n=11					Non-European n=23				
	Health Service Provision		**Patient/Family issues**			**Health Service Provision**		**Patient/Family issues**	
Control n=7	DIABETES Clinical practice	inadequate eye checks	Woman's DNA	DNA'd appts	**Control n=11**	DIABETES Communication	was not seen until late	Woman's DNA	did not attend
	Documentation	little documentation of diabetes care until 29/40 no information in notes	Woman's actions	multiple DNAs		Clinical practice	no diabetic input in 1st trim. retinopathy found - no action incorrect folic acid dose, late eye screening no fundal assessment noted no retinal screening, no 24 hr urine collection poor diabetic advice no evidence of coherent service	Woman's actions	not compliant did not attend (2)
	MATERNITY Clinical practice	no evidence of "*big baby*" described in notes no indication given of thought processes behind LSCS	None			MATERNITY Communication	no discussion of timing of delivery no involvement of psychiatrist no communication	None	
						Clinical practice	no consultant involvement no recognition of high risk patient suboptimal management hypertension no action when proteinuric few urinalyses odd management of cholestasis no advice re shingles - no dermatology review no anticipation of labour difficulties poor fetal assessment no growth scans		

European n=11					Non-European n=23				
	Health Service Provision		Patient/Family issues			Health Service Provision		Patient/Family issues	
Case n=4	DIABETES None		Woman's actions	v late booking no folic acid poor attender	**Case n=12**	DIABETES Communication	chaotic early appt late booking, continued metformin	Woman's actions	late presentation
						Clinical practice	failure to refer to ophthalmologist no dietician/dietary advice no retinal assessment		
						Documentation	no documented retinal screening		
						Resources	HbA1c not measured in lab which could deal with haemoglobinopathy		
	MATERNITY Clinical practice	lack of more intensive monitoring in 3rd trim	Woman's actions	poor attendance until monitoring of eyes		MATERNITY Communication	no smoking cessation advice long gaps between appts. some confusion over early appts	None	
						Clinical practice	very late induction evidence of poor growth - poor management insufficient fetal monitoring infrequent urinalysis no detailed anomaly scan no fetal growth scans 28, 34/40 inappropriate use of steroids		
						Resources	male interpreter		

Table 5.8.4 *Postnatal Diabetes Care*

European n=11				Non-European n=23			
	Health Service Provision		**Patient/Family issues**		**Health Service Provision**		**Patient/Family issues**
Control n=7	Clinical practice	failure to document any care concerning diabetes postpartum	None	**Control n=11**	Communication	no advice for breastfeeding diabetic management unclear	None
					Clinical practice	metformin & breastfeeding, unlikely to manage on diet alone, should have started on insulin no advice regarding diabetes control	
Case n=4	None		None	**Case n=12**	Communication	postnatal insulin not sorted prior to delivery no advice given prior to discharge	Woman's actions — DNA follow up appt
					Clinical practice	inappropriate request for postpartum GTT	
					Documentation	unclear documentation of what advice was given	

5.9 Summary

This chapter has looked at the care provided, treatments used, and pregnancy outcomes solely in the type 2 diabetes group. This group is over-represented in the WM, making up 36% of pregnancies complicated by pre-gestational diabetes. Women with type 2 diabetes are more likely to be older, to be of a higher parity, have a higher BMI, and to be of a non-European ethnic group (chiefly Pakistani). For these reasons the issues that affect this group are very different and require careful consideration.

Pregnancy outcomes in women with type 2 diabetes, as nationally, are the same as for those with type 1 diabetes. This is reflected in the high CMR and PNMR that has been documented. We have tried to identify those factors that may be implicated in these poor outcomes. There was no difference in ethnic, diabetes, or demographic characteristics in type 2 women whose pregnancies result in a good or poor outcome.

Only 24% of women embarked on a pregnancy after pre-pregnancy counselling. Even after attending healthcare services prior to pregnancy, many women (good and poor outcome groups alike) were not taking the recommended dose of folic acid (5 mgs). Non-European women commenced pregnancy poorly prepared with impaired glycaemic control, significantly higher than their European counterparts.

As in Chapter 3 (WM cohort) and Chapter 4 (WM Confidential Enquiry) poor glycaemic control was the main factor identified in association with a poor pregnancy outcome. Poor glycaemic control (HbA1c>7%) in the first and third trimesters is significantly associated with a fetal/neonatal loss or major congenital anomaly both in all type 2 women and, more specifically, in non-European women.

Type 2 diabetes was treated in the majority prior to pregnancy either with an OHA or by diet. Those women taking insulin before pregnancy were significantly more likely to suffer a poor pregnancy outcome. This may be due to a longer history of unstable glycaemic control necessitating insulin therapy compared to those on OHAs/diet.

Over 50% of women needed to start on insulin at their first antenatal booking visit together with monitoring of their blood sugars more regularly. During this first visit, a lot of information needs to be conveyed to and absorbed by women and family members. This is especially challenging for those where English is not their first language. Altering diet, starting insulin injections and increasing home blood glucose monitoring all require in-depth discussion and explanation in clinic. This is one of the key roles of the multidisciplinary clinic. Women with type 2 diabetes require additional education, support, and time from those providing antenatal services as they adapt not only to the condition of pregnancy but the need to modify lifestyle factors and familiarize themselves to treatment changes. The use of female interpreters and developing new and innovative ways to pass on this education and support are needed. Overcoming communication issues between clinicians and these women/families as well as having an understanding of different cultural and family expectations in the type 2 diabetes group are important in being able to achieve compliance with treatment and attendance at clinic. The benefits of solely breastfeeding the neonate is one key message that needs to be promoted in this group where cultural and family standards have produced a scenario where mixed or formula feeding is now preferentially chosen.

34 women (cases and controls) were selected for the confidential enquiry analysis. Diabetic complications prior to pregnancy were rare but panel assessors found that the cases generally appeared to be "*healthier*" than those in the control group, i.e. had less diabetic/medical/surgical complications. It may be that these women had less contact with health services prior to pregnancy and were more likely to self manage their own diabetes with sometimes little or no regular medical input.

Deficiencies in clinical practice and communication between clinicians and women but also between different allied health professionals were highlighted much more commonly in the non-European population. This was particularly evident concerning glycaemic management and planning/management of labour and delivery. A recognition by clinicians that ethnicity seems to make a huge difference to the care provided is required and should be tackled along with the communication issues that go with it. By contrast in the European group, issues due to the woman's/family actions were more evident and this is related to social demographics, patient expectations and a lack of education concerning possible complications in the pregnancy. However, this detailed analysis failed to

show an increased prevalence of deficiencies in care (from whichever source) in those pregnancies resulting in a poor outcome compared to those ending in a good outcome. It is therefore likely that there are more important determinants of outcome than the quality of antenatal/intrapartum care provided. The level of glycaemic control before and throughout pregnancy, as in the main WM cohort, seems to be this overriding determinant.

Chapter 6 Summary of Key Findings and Recommendations

The West Midlands Diabetes in Pregnancy study has aimed to provide accurate data on maternal and pregnancy outcomes for type 1 and 2 diabetic women in pregnancy. The basis for performing the cohort analysis and the detailed panel enquiry was to inform women and health professionals about the risks posed in pregnancy and to start to point the way to how, regionally, positive changes can be made to improve outcomes and reduce the risks towards those faced by the non-diabetic, healthy maternal population.

This chapter aims to:

1 **Summarise the key findings relating to both the Cohort and Panel Enquiry analyses.**

2 **Make recommendations - both clinical and organisational - that can be adopted within the West Midlands to improve clinical care and pregnancy outcomes.**

Key Finding 1 - Type 2 diabetes - different needs

The West Midlands has a significantly higher incidence of type 2 diabetes in pregnancy than the national average. These women are predominantly from ethnic minorities, older, multiparous and live in the most deprived areas.

This study provides evidence of the high prevalence of type 2 diabetes in our local population (36% of all pregnancies in cohort) and of the demographic make-up of these women. This study shows they were less likely to attend pre-pregnancy counselling, have had a pre-pregnancy glycaemic measurement or taken folic acid than type 1 diabetic women. Women with type 2 diabetes from ethnic minorities have a perinatal mortality rate 2.5 times greater than European, predominantly type 1 diabetic women and this figure reflects the findings above. In this group, suboptimal glycaemic control before pregnancy and in the first and third trimesters is associated with adverse pregnancy outcomes.

Women with type 2 diabetes are generally commenced on insulin in the first trimester and increased glycaemic testing is recommended. This presents a significant change in management to the woman and workload within the multidisciplinary clinic setting.

Recommendation: Issues relating to accessing health care before and in early pregnancy and education informing this group of the importance of pre-pregnancy counselling and glycaemic control needs to be addressed across the region in order to try and start improving pregnancy outcomes for these women.

Key Finding 2 - Pregnancy Outcomes/Healthy Babies

Babies from women with pre-gestational diabetes in the West Midlands have significantly higher rates of congenital malformation and perinatal mortality compared with diabetic women elsewhere in the UK or the background local maternity population.

This study analysing the West Midlands region and coming out of the nationally collected CEMACH data is the largest and most authoritative study of pregnancy outcomes in women with type 1 and type 2 diabetes living in the West Midlands. It shows high congenital malformation and perinatal mortality rates (82.1/1,000 births and 45.6/1,000 births respectively). It confirms that we are a long way from achieving the aims of the St Vincent's Declaration and normalising pregnancy outcomes in this population. The risk of congenital malformation is highest in European type 2 women although, overall, there was no significant difference in malformation rates for type 1 or type 2 diabetic women.

In addition, these women have a 4-5 fold greater risk of suffering a perinatal loss than non-diabetic mothers in WM. This risk is highest in the non-European population. Maternal ethnicity and a history of previous premature delivery should be seen as significant risk factors for subsequent perinatal loss.

Recommendation: Pregnancy outcomes can only improve if diabetic and obstetric clinical care both during the pregnancy and, crucially, pre-pregnancy improves. Optimal glycaemic control pre- and antenatally and reasoned obstetric management in late pregnancy and intrapartum are the keys (see below).

Key Finding 3 - Pre-conception Care

In the West Midlands, as nationally, women were poorly prepared for pregnancy:

only 41% took folic acid before conception,

only 28% had documented pre-pregnancy counselling, and

only 41% had a measure of glycaemic control performed before conception.

The importance of well-organised, accessible pre-pregnancy counselling has been highlighted in this study. Uptake of pre-pregnancy counselling is currently low (28%) and this is reflected in the following ways:-

- Low usage of folic acid pre- and periconceptually.
- Low levels of glycaemic testing and even lower attainment of optimal glycaemic control before pregnancy (13% prigs).
- High congenital malformation and perinatal mortality rates.
- Association between poor glycaemic control pre-pregnancy and in the first trimester and poor pregnancy outcomes.

The key to improving pregnancy outcomes and in particular to reducing congenital anomaly rates in this population is in obtaining tight glycaemic control before conception and throughout the first trimester. New and innovative ways of spreading the message of pre-pregnancy care must be implemented to start to rectify this situation.

Recommendation: regionally the set up of pre-pregnancy counselling clinics needs to be challenged by each maternity unit and by PCTs in the following ways.

- Primary and secondary care professionals need to work together to ensure women in all areas of the region have access to a multidisciplinary pre-pregnancy clinic or service.
- GPs and practice nurses should provide pre-pregnancy information yearly to diabetic patients at their annual review including written information with contact addresses and telephone numbers for their local pre-pregnancy clinic. Targets and incentives for this to occur should be recognised and set by regional authorities and PCTs.
- A partnership between primary and secondary care needs to be established to provide a community-based education package (meetings, literature, visual/aural information). This should target women for whom attending a hospital clinic proves difficult and thereafter enable them to access health services. Diabetic women need to understand the importance of pre-pregnancy preparation and the local provision for this.
- Those working in antenatal diabetes care should ensure that pre-pregnancy services are organised to a high standard.
- Pharmacy services/Surestart/Community groups locally should be approached regarding giving information on pre-pregnancy services to women generally as well as those attending for diabetic prescriptions.
- Hospital diabetic and obstetric services should make budgetary allowance and fund investment in pre-pregnancy care.

Key Finding 4 - Clinical Care and Standards

In assessing clinical standards of care in pregnancy and labour the West Midlands was in line with care given nationally.

In the majority of clinical standards of care assessed WM was found to provide equivalent or better care than nationally. This included standards assessing the use of ultrasound scans for pregnancy dating and fetal growth assessment, retinal screening and the use if IV dextrose and insulin in labour. Clinical standards assessing glycaemic control in pregnancy showed that more glycaemic testing occurred and more women (both type 1 and 2) achieved optimal glycaemic control at all stages of pregnancy than nationally. However, this still meant that more than 50% of women had not achieved optimal control by the end of the first trimester.

Standards relating to the administration of prophylactic antenatal steroids and the use of glucagons in pregnancy were not well achieved in WM. The issues relating to these two standards need to be examined more fully to inform local practice.

Recommendation: there remains scope for improvement in all the clinical standards assessed in the report. Regional guidelines, which can advise on practice rather than individual Unit guidelines, will help with adherence to standards and recommend methods of "best practice" (see below).

Key Finding 5 - Optimising Glycaemic control

This report adds to the body of evidence indicating that maternal hyperglycaemia/poor glycaemic control is strongly associated with adverse pregnancy outcomes - major fetal malformations and/or perinatal death.

Several different analyses of maternal glycaemic control with pregnancy outcome are contained within this report. The cohort study (Chapter 3) shows the low level of mothers entering pregnancy with a level of control acknowledged to reduce the risk of congenital anomalies (only 13% had HbA1c<7%). The CE analysis has shown a significant association between suboptimal glycaemic control and adverse outcomes both in the case-control study and in comparison with the whole WM cohort (poor outcomes v good outcomes). This association is most marked pre-pregnancy and in the first and third trimesters.

Recommendation: All health professionals involved in looking after women aged 16-45 with pre-gestational diabetes should be actively involved in promoting the message of tight glycaemic control before and during pregnancy. Women must be encouraged to attend pre-pregnancy planning especially to optimise their glycaemic status. Maintaining good control throughout pregnancy through effective target setting, close monitoring and good communication and advice is vital and is one of the chief tasks of the multidisciplinary antenatal clinic.

Key Finding 6 - Fetal monitoring

Pregnancy in type 1 and 2 diabetic women in WM are affected by high congenital malformation and stillbirth rates.

This study confirms that major congenital malformations occur twice as commonly within WM compared to the rest of the UK pre-gestational diabetic population and that fetal congenital heart disease and CNS malformations account for more than half of these malformations. There is variation in the CMR by ethnicity and location of care within the WM. The antenatal detection rate was 60%.

Recommendation: all type 1 and 2 diabetic women have a detailed anomaly and cardiac scan performed by a trained professional (RCR/RCOG accreditation or equivalent) at 20-22 weeks gestation to exclude a major CA. Imaging the cardiac outflow tracts is required to exclude major vessel anomalies, such as Transposition of Great arteries.

Stillbirth in the latter half of third trimester is a known risk in diabetic pregnancies. Additional risk factors for perinatal loss have been identified from this study and discussed previously (Chapter 4.4). From detailed case-control analysis, stillbirth was seen to occur more commonly in those women with infrequent hospital appointments or little/no fetal monitoring after 34 weeks gestation.

Recommendation: All local antenatal diabetes services should have an agreed protocol for antenatal monitoring of the fetus after 34 weeks gestation. There is no clear indication as to the optimal method of fetal monitoring, however regional guidelines can make recommendations on this based on the available evidence. All women should be aware of an increased risk of stillbirth and methods of monitoring for this.

Key Finding 7 - High Preterm Delivery and Caesarean section rate

There is a preterm delivery rate of 32% and a caesarean section rate of 72% within the region for pre-gestational diabetic women. This reflects national figures.

West Midlands figures for mode of delivery, gestation at delivery and induction of labour are in line with those nationally for 2002-03. Type 2 diabetic women are more likely to deliver vaginally following spontaneous or induced labour however even then the majority of type 2 women still deliver by caesarean section (60%). The most common gestation period for an induction of labour to be carried out was 38^{+0}-38^{+6} days. This was significantly more likely to happen in the West Midlands than nationally.

*Recommendation: Obstetricians and Midwives need to consider IOL on an individual basis, providing the woman with the most accurate evidence of risks to her and her baby. This study supports NICE guidance recommending IOL at 38-40 weeks gestation. Avoiding "*routine*" IOL at 38 weeks will allow more women to labour spontaneously.*

Key Finding 8 - Large babies/complications of labour

Over half of birthweights were over the 90th customised centile with the majority being over the 95th centile.

The incidence of shoulder dystocia was the same as nationally (7.4%) but this still represents a two-fold increase compared to the general maternity population. Shoulder dystocia was more common in babies born with a birthweight greater than the 99th customised centile.

Type 1 and type 2 diabetic women gave birth to larger babies than the general maternity population. This occurred in both the European and non-European groups, whilst the latter group were also more likely to have growth restricted babies below the 10^{th} customised centile. Complications of delivery such as shoulder dystocia and Erb's palsy also occurred more commonly in this population.

Recommendation: those health professionals involved in antenatal care and attending these women in labour need to be aware of these increased risks. Senior obstetric involvement in discussing/planning delivery with the mother in a dedicated antenatal diabetes clinic and when labour/induction deviates from the norm on delivery suite is vital to avoid the recognised complications of birth trauma and intrapartum asphyxia/stillbirth.

Key Finding 9 - Neonatal Care

60% of babies born in WM were admitted to a neonatal unit.

One in five term babies and one quarter of all babies born were admitted for special care often as "*routine/observation only*". This occurred more commonly in babies born to type 1 diabetic mothers.

Healthy babies should be kept with their mothers and each maternity unit should have staff and arrangements to enable this and to avoid unnecessary NNU admission.

Each maternity unit and its NNU needs to respond to the data relating to admissions to NNU, inappropriate separation of mother and baby and methods of neonatal glycaemic testing. 20-33% of all admissions to NNU could be avoided by stopping "*routine*" observation-only admissions, using optimal tests for the detection of hypoglycaemia and avoiding performing these tests too early following delivery. This would reduce neonatal expenditure on this group of neonates and free up cot space within each NNU.

Changes in working arrangements, staff, and the set up of postnatal wards may be required.

Recommendation: healthy babies from diabetic women should stay with their mother. Individual maternity units should make arrangements such as transitional care wards to minimise separations only to those babies needing active neonatal care.

Key Finding 10 - Breastfeeding

The West Midlands cohort had a lower rate of breastfeeding than nationally and formula milk was more popular both as an intended and an actual feeding method.

Breast milk has very definite physiological advantages to newborn babies from diabetic mothers and is the food of choice in both term and preterm babies, babies with their mother and those separated when the baby needs neonatal support. There needs to be greater awareness of the importance of breastfeeding both in diabetic women and in health professionals looking after her and her baby who should be promoting this message in different ways. This is particularly important in non-European type 2 diabetic women where formula and mixed feeding methods have become much more common.

Recommendation: education and the benefits of breastfeeding should be stressed in the antenatal period and a definite plan of care for the postnatal period made which encompasses early breastfeeding. Barriers to breastfeeding such as maternal drugs and baby separation/not having arrangements for expressed milk to be given to babies on NNU should be tackled and broken down within each maternity unit regionally.

Key Finding 11 - Communication between Health Professionals

Poor clinical care was found to result from breakdowns in communication between health professionals or following inappropriate choices in clinical practice. This was seen as one of a number of contributory factors to the levels of suboptimal care commented upon within the confidential enquiry analysis.

The CE demonstrated that failures in communication between health professionals and the woman or between themselves regularly occurred in both the confidential enquiry cases and controls. This was a recurring theme in the three areas of:

- glycaemic management and target setting,
- diabetic care other than glycaemic,
- maternity care: planning/management of labour and delivery.

These themes were dealt with within Chapters 4 and 5.

Recommendation: Health professionals working with diabetic women in pregnancy should always work together as part of a multidisciplinary team within one clinic setting. Each maternity unit must ensure that such a clinic exists and that the members of the antenatal diabetes team regularly meet to discuss management protocols, cases, improvements to care etc…. All staff, particularly medical staff working on delivery suite, should recognise that these women are at high risk of pregnancy and delivery complications and that advice from medical, obstetric and anaesthetic senior staff charged with antenatal diabetes care should always be sought when applicable.

Key Finding 12 - Guidelines

The Confidential Panel enquiry revealed major differences in the management of diabetic women in pregnancy.

The Confidential Panel Enquiry, which examined in detail the quality of clinical care provided and looked at individual unit protocols, found that there were discrepancies in management especially in the areas of:

- Glycaemic control/targets
- Investigation of diabetic complications
- Timing and mode of delivery
- Monitoring for fetal wellbeing
- Steroid administration antenatally
- Use of glucagons in pregnancy

Recent WM Diabetes in Pregnancy Perinatal Forums have indicated the benefits of adopting a region-wide approach to diabetic care in pregnancy. A regional group has been formed to provide guidelines for care that can be implemented across all maternity units in WM (see "*Current Regional Developments*"). These guidelines, although broad, have encompassed points of good practice from different units and give advice on difficult aspects of management and guidance on areas of controversy. In addition, specific patient hand-held notes for DIP have been produced to facilitate good communication, documentation and the flow of information for women and their carers. These two initiatives are being promoted regionally and nationally as a way of significantly reducing suboptimal clinical care.

Appendix A Contributors to the WM Diabetes Enquiry

Panel Assessors		
Aresh Anwar	Consultant Physician	Walsgrave
Dawn Bailey	Midwife	Stafford
Chandrika Balachandra	Consultant Obstetrician	Walsall Manor
Nighat Bhatti	Consultant Obstetrician	City
Peter Biggs	Consultant Physician	Walsgrave
Helen Buckley	Midwife	Good Hope
Julie Carrick	Midwife	Solihull
Nicki Chatterton	Diabetes Nurse Specialist	Selly Oak
Sally Clifford	Diabetes Specialist Nurse	Heartlands
Phil Coates	Consultant Physician	Stafford
Jane Dale	Consultant Physician	Russells Hall
Louise Farrell	Consultant Obstetrician	Walsgrave
Lynn Foster	Midwife	Stafford
Karen Gale	Diabetes Specialist Nurse	Queens, Burton
Harry Gee	Consultant Obstetrician	Birmingham Women's
Lyn Gilbert	Diabetes Specialist Nurse	Kidderminster
Wendy Goodwin	Diabetes Specialist Nurse	Walsgrave
Linda Granner	Midwife	City
Urmilla Griffiths	Diabetes Specialist Nurse	Good Hope
Wasim Hanif	Consultant Physician	Selly Oak
Fahmy Hanna	Consultant Physician	North Staffordshire
Rosie Hemming	Midwife	Birmingham Women's
Carol Hill	Diabetes Specialist Nurse	Stafford
Ann Hollins	Midwife	Worcester Royal
Emma Innes	Diabetes Specialist Nurse	Worcester Royal
Simon Jenkinson	Consultant Obstetrician	New Cross
Sharon Jones	Consultant Physician	Good Hope
Maggie Kennerley	Midwife	Royal Shrewsbury
Helen Kesterton	Midwife	Queens, Burton
Sarah Lockett	Midwife	Royal Shrewsbury
Geraldine Masson	Consultant Obstetrician	North Staffs
Suzy Matts	Consultant Obstetrician	George Eliot
Lorna Meer	Consultant Obstetrician	Russells Hall
Jan Meggy	Consultant Obstetrician	Worcester Royal
Anne Mellor	Midwife	Stafford
Eleen Minto	Midwife	Sandwell
Julie Mountford	Midwife	George Eliot
Judy Nicholas	Midwife	Hereford County
Helen O'Leary	Diabetes Specialist Nurse	City
Annie Parker	Midwife	Royal Shrewsbury
Karen Powell	Consultant Obstetrician	Stafford
David Redford	Consultant Obstetrician	Royal Shrewsbury
Sue Rodgers	Diabetes Specialist Nurse	Worcester Royal
Theresa Smyth	Diabetes Specialist Nurse	Selly Oak

Ken Taylor	Consultant Physician	Birmingham Women's
Sue Thomas	Midwife	Walsgrave
Val Tristram	Midwife	Kidderminster
Jackie Webb	Diabetes Specialist Nurse	Heartlands
Jonathan Webber	Consultant Physician	Selly Oak
Lisa Williams	Diabetes Specialist Nurse	Selly Oak
	Midwife Unit Coordinators	
Lynn Shepherd		Alexandra
Sally Clifford		Birmingham Heartlands
Rosie Hemming		Birmingham Women's
Linda Granner Lavinia Henry		City Hospital
Julie Mountford		George Eliot
Helen Buckley		Good Hope
Judy Nicholas		Hereford County
Val Tristram		Kidderminster
Jenny Maddock		New Cross
A P Rooney Karen Sterling		North Staffordshire
Maggie McKeown		Queens, Burton
Maggie Kennerley Annie Parker		Royal Shrewsbury
Eleen Minto		Sandwell
Julie Carrick		Solihull
Sally Freeman Carmen McCourt		Stafford
Janet Holgate Shelley Homer		Walsall Manor
Sue Thomas		Walsgrave
Mel Crockett Ella Fentiman		Warwick
Ann Hollins		Worcester
Anne Baker		Wordsley

In addition we would like to express our thanks to all those who assisted in preparing the case notes for the confidential enquiries.

Appendix B West Midlands Maternity Units

All 20 maternity units within the West Midlands participated in this study. The table below shows the numbers of women who participated in the study in relation to hospital of booking.

Hospital	Number booked
Alexandra Hospital	10
Birmingham Heartlands Hospital	48
Birmingham Women's Hospital	46
City Hospital	23
George Eliot Hospital	14
Good Hope Hospital	20
Hereford County Hospital	10
Kidderminster Hospital	5
Manor Hospital, Walsall	24
New Cross Hospital	10
North Staffordshire Maternity Hospital	36
Queens Hospital	22
Royal Shrewsbury Hospital	27
Sandwell District General Hospital	14
Solihull Hospital	13
Stafford Hospital	6
Walsgrave Hospital	28
Warwick Hospital	11
Worcester Royal Infirmary	14
Wordsley Hospital	33
Out of region*	4

* pregnancies which were transferred in to the region

Appendix C Standards of Care

Standard: A pre-conception clinic should be run jointly by the adult diabetes service and the maternity service for women with diabetes wishing to become pregnant. [Diabetes NSF - illustrative service models; www.publications.doh.gov.uk/nsf/diabetes/ch2/servicemodels/pregnancy.htm].

Standard: Women with diabetes have an increased risk of neural tube defects and should be offered pre-pregnancy folic acid supplements, continuing up to 12 weeks of gestation. [CEMACH Diabetes Multidisciplinary Resource Group - standard derived from SIGN Guideline No. 9].

Standard: All women with diabetes should be promptly referred for a first trimester scan to enable accurate dating of the pregnancy. They should all be offered a detailed anomaly scan between 18 and 22 weeks and serial ultrasound scans during the third trimester to monitor fetal growth. [Diabetes NSF Intervention details; www.publications.doh.gov.uk/nsf/diabetes/ch2/interventions/pregnancy.htm].

Standard: If delivery is indicated before 34 weeks, administration of corticosteroids should be considered to prevent neonatal respiratory distress syndrome. [Diabetes NSF Intervention details; www.publications.doh.gov.uk/nsf/diabetes/ch2/interventions/pregnancy.htm].

Standard: Women should be encouraged and supported to monitor their blood glucose levels regularly and to adjust their insulin dosage, in order to maintain their blood glucose levels within the normal (non-diabetic) range. The aim should be for the woman to maintain her HbA1c below 7%. [Diabetes NSF Intervention details; www.publications.doh.gov.uk/nsf/diabetes/ch2/interventions/pregnancy.htm].

Standard: Hypoglycaemia should be discussed and glucagon made available with clear instructions on its use. [CEMACH Diabetes Multidisciplinary Resource Group - standard derived from SIGN Guideline No. 9].

Standard: A full retinal assessment should be undertaken in all women with pre-existing diabetes during the first trimester or at booking if this is later. [Diabetes NSF Intervention details; www.publications.doh.gov.uk/nsf/diabetes/ch2/interventions/pregnancy.htm].

Standard: Labour and delivery should be undertaken in a maternity unit with facilities for the resuscitation and stabilisation of babies and with personnel skilled in advanced resuscitation immediately available on a 24-hour basis. [Diabetes NSF Intervention details; www.publications.doh.gov.uk/nsf/diabetes/ch2/interventions/pregnancy.htm].

Standard: The mode and timing of delivery should be determined on an individual basis, aiming to realise a spontaneous vaginal delivery by no later than 40 weeks of gestation is if possible. [CEMACH Diabetes Multidisciplinary Resource Group - standard derived from SIGN Guideline No. 9].

Standard: Continuous electronic fetal monitoring should be offered to all women with diabetes during labour and fetal blood sampling should be available if indicated. [Diabetes NSF Intervention details; www.publications.doh.gov.uk/nsf/diabetes/ch2/interventions/pregnancy.htm].

Standard: Intravenous dextrose and insulin should be administered during labour and delivery following an agreed multidisciplinary protocol. [CEMACH Diabetes Multidisciplinary Resource Group - standard derived from SIGN Guideline No. 9].

Standard: All babies should remain with their mothers during the neonatal period unless there is a specific medical indication for admission to a neonatal intensive care unit. [Diabetes NSF Intervention details; www.publications.doh.gov.uk/nsf/diabetes/ch2/interventions/pregnancy.htm].

Standard: Babies born to women with diabetes should be fed as soon as possible after birth and all should receive their first feed within 4 hours of birth, unless contraindicated for medical reasons. [Diabetes NSF Intervention details; www.publications.doh.gov.uk/nsf/diabetes/ch2/interventions/pregnancy.htm].

Standard: Breastfeeding is recommended but all mothers should be supported in the feeding method of their choice. [CEMACH Diabetes Multidisciplinary Resource Group - standard derived from SIGN Guideline No. 9].

Standard: Babies of mothers with diabetes should have a test of blood glucose concentration by 4-6 hours of age, before a feed. [Diabetes NSF Intervention details; www.publications.doh.gov.uk/nsf/diabetes/ch2/interventions/pregnancy.htm].

Standard: The diagnosis of hypoglycaemia should be made using a ward-based glucose electrode or laboratory method and not by reagent strip testing. [CEMACH Diabetes Multidisciplinary Resource Group - standard derived from SIGN Guideline No. 9].

Standard: Interventions for the management of hypoglycaemia should be guided by blood glucose level and clinical assessment. [CEMACH Diabetes Multidisciplinary Resource Group - standard derived from SIGN Guideline No. 9].

Appendix D Major Fetal Congenital Anomalies

anomaly group	ICD10	anomaly description	anomaly detected	diabetes type
cardiac	Q20.4 Q20.3	double inlet left ventricle with transposition of great arteries	antenatal	type 2
cardiac	Q21.0 Q25.0	patent ductus arteriosus & ventricular septal defect	postnatal	type 2
cardiac	Q20.3 Q21.0	transposition of great arteries with ventricular septal defect	postnatal	type 2
cardiac	Q24.8	asymmetric septal hypertrophy	postnatal	type 1
cardiac	Q23.4	hypoplastic left heart	antenatal	type 1
cardiac	Q23.4	hypoplastic left heart	antenatal	type 2
cardiac	Q21.0	ventricular septal defect	postnatal	type 2
cardiac	Q23.4	hypoplastic left heart syndrome	antenatal	type 1
cardiac	Q22.6	hypoplastic right ventricle	antenatal	type 1
cardiac	Q24.9	severe cardiac problems	postnatal	type 2
cardiac	Q20.3 Q20.4	transposition of great vessels with ventricular septal defect	antenatal	type 1
cardiac & limb/musculoskeletal	Q21.0 Q25.42 Q25.5 Q66.8 Q72.4	multiple congenital anomalies; cardiac/limb/other	antenatal	type 1
respiratory	Q33.0	congenital cystic lung	postnatal	type 1
limb/musculoskeletal	Q79.0	congenital diaphragmatic hernia	postnatal	type 1
limb/musculoskeletal	Q66.0	talipes equinovarus	postnatal	type 1
limb/musculoskeletal	Q66.8	bilateral talipes	antenatal	type 1
limb/musculoskeletal	Q77.1	thanatophoric dysplasia	antenatal	type 1
limb/musculoskeletal	Q66.8 Q77.9 Q67.8	short long bones (possible genetic syndrome)	antenatal	Type 2
central nervous system	Q00.0	exencephaly	postnatal	type 1
central nervous system	Q00.0	anencephaly	antenatal	type 1
central nervous system	Q03.9	hydrocephalus	antenatal	type 1
central nervous system	Q02#	microcephalic	postnatal	type 2
central nervous system	Q05.2	hydrocephalus and lumbar spina bifida	antenatal	type 2
central nervous system	Q03.9	hydrocephaly	antenatal	type 1
cleft lip (with or without palate)	Q37.9	cleft lip and palate	antenatal	type 2
urogenital system	Q61.40	left multicystic dysplastic kidney	antenatal	type 1
urogenital system	Q63.9	abnormal left kidney (unspecified)	postnatal	type 2
urogenital system	Q54.9	hypospadias	postnatal	type 2
genetics and micro deletions	Q87.04	facial dysmorphic syndrome	postnatal	type 1
genetics and micro deletions	Q87.20	syndrome involving limb anomalies	antenatal	type 1
chromosomal	Q90.0	Down's syndrome	antenatal (amnio centesis)	type 1
chromosomal	Q90.2	Down's syndrome	antenatal	type 1

West Midlands Confidential Enquiry into Diabetic Pregnancy

Diabetes Enquiry Proforma

Do NOT keep any duplicates or copies of this form
Do NOT enter any names or signatures

Enquiry reference number ☐

Panel members

Tick box or enter number if several members from one speciality

Obstetric ☐	Neonatology ☐	Diabetologist ☐
Midwifery ☐	Neonatal nursing ☐	Diabetic nurse specialist ☐

Other (specify) _____

_____

This is a modified version of the original CEMACH Diabetes Enquiry Proforma 2004

Guidance for completing the proforma

Please read before proceeding to complete this assessment

Panel guidance

Some questions in the enquiry pro forma include guidance (in italics) for the panel assessors. The purpose of this guidance is to aid consistent definitions and is not intended to be prescriptive. This is particularly relevant when evaluating glycaemic control as it is recognised that the panel may have access to information at enquiry which is at variance with the guidance provided. In this situation it is expected that the panel will make a decision based on all the information available rather than on the guidance only

Terminations and intrauterine death

Only the relevant sections need be completed. We have a record of both the pregnancy outcome and gestation so all subsequent questions can be automatically coded as not applicable in analysis.

'No' and 'Not documented' options

Only use the 'no' option where it is documented in the notes that something has not been done or is not present. We are aware that the nature of note keeping makes the 'no' option redundant in many questions but we need to record the information in this way for consistency in analysis. Use the 'not documented' option in all other situations.

Coding

The intention with the diabetes enquiry pro forma is that where glycaemic control, clinical care or the woman's approach to managing her diabetes is thought to be poor or adequate, the qualitative issues that informed this decision should be précised in the accompanying free text space. However in order to assist us with analysis of the data at a later stage there is also a basic coding system in operation. This means that wherever possible the free text should be categorised into main and supplementary codes by the panel as below. It is not essential to provide supplementary codes so please only complete if appropriate. We are aware that the codes are simplistic and that cases reviewed at panel are often complex with multiple issues, but the intention is only to assist in analysis and the detail of the free text will always be studied.

Broadly there are two categories of codes, those relating to the woman and her diabetes and those relating to the provision of health services.

A prefix **P** denotes that the issues discussed relate directly to the patient and/or family issues and the codes are:

PD	Duration or severity of diabetes
PO	Other complicating medical or social and/or lifestyle factors which may hinder optimal management e.g. management-intensive medical conditions such as thrombophilia or cardiac disease, and social factors such as housing problems or lack of family support
PC	Woman actively chose not to follow the medical advice given e.g. refusal to undergo induction of labour until 42+ weeks of gestation
PA	Woman.s actions detracted from optimal management e.g. infrequent home blood glucose monitoring, not following dietary instructions
PN	Woman did not attend appointments e.g. failure to attend for clinic visits or ultrasound scans

A prefix **H** denotes that the issues discussed relate to the provision of health services and the codes are:

HP	Clinical practice e.g. no timely discussion of timing and mode of delivery
HC	Communication. This could be a failure of communication between professionals caring for the woman e.g. inadequate discussion between obstetrician and physician or a failure of communication between professionals and the woman e.g. interpreting services were not adequate despite difficulties with English
HR	Resources including staffing e.g. no dietician in the antenatal clinic, lack of midwifery staff on labour ward, problems with accessing timely fetal surveillance such as growth scans
HN	Insufficient information

Pre-pregnancy care Please complete with reference to the pre-pregnancy proforma

1. Does the panel think the woman's glycaemic control was optimal, adequate or poor prior to conception?

Panel guidance: HbA1c < 7% optimal; 7 to 8% adequate; > 8% poor, but please consider all available information including home blood glucose testing results and episodes of hypoglycaemia when making an essessment

☐ Optimal
☐ Adequate
☐ Poor
☐ Insufficient information in notes

If poor or adequate, please summarise key issues and code accordingly:

_____
_____
_____
_____
_____
_____

☐☐ Main code
☐☐ Supplementary codes
☐☐
☐☐

2. Does the panel think pre-pregnancy care, other then glycaemic control, was optimal, adequate or poor?

Panel guidance: please consider the assessment and treatment of complications, advice given, folic acid and other information contained in the pre-pregnancy proforma. Optimal indicates that there are no issues with care, including dosage, that need documenting; adequate indicates that there are some issues

☐ Optimal
☐ Adequate
☐ Poor
☐ Insufficient information in notes

If poor or adequate, please summarise key issues and code accordingly:

_____
_____
_____
_____
_____
_____

☐☐ Main code
☐☐ Supplementary codes
☐☐
☐☐

a) If folic acid used, what dosage? ☐ None ☐ 400 mcg ☐ 4-5 mg ☐ Multivitamin ☐ Dose not specified

Pregnancy care up to delivery

3. Was the current pregnancy planned? ☐ Yes ☐ No ☐ Not documented

4. Was this woman a primagravida? ☐ Yes ☐ No ☐ Not documented

a) If NO, please indicate if any previous pregnancy ended in a congenital malformation. ☐ Yes ☐ No ☐ Not documented

5. If this woman has type 2 diabetes, **did she have gestational diabetes in a previous pregnancy?** ☐ Yes ☐ No ☐ Not documented ☐ Not applicable

6. What was the date of the first contact with a health professional this pregnancy? (DD/MM/YY) ☐☐/☐☐/☐☐

7. What was the date of the first hospital appointment this pregnancy? (DD/MM/YY) ☐☐/☐☐/☐☐

8. Please indicate which professionals were involved in the antenatal care of this woman.

☐ Diabetes nurse specialist
☐ Physician ☐ Midwife with special interest in diabetes
☐ Dietician ☐ Obstetrician with special interest in diabetes

9. Was antenatal care carried out in a dedicated multidisciplinary combined clinic? ☐ Yes ☐ No ☐ Not documented

Panel guidance: a clinic where the relevant professionals are present at the same time.

10. Was a retinal assessment performed in the first trimester or at booking, if later? ☐ Yes ☐ No ☐ Not documented

a) If YES, was this through dilated pupils? ☐ Yes ☐ No ☐ Not documented

11. Was retinopathy present? ☐ Yes ☐ No ☐ Not documented

If YES, please answer a) and b).

a) Please indicate type: ☐ Pre-existing, no change ☐ Pre-existing, deteriorating ☐ New finding

b) Was this woman referred to an opthalmologist? ☐ Yes ☐ No ☐ Not documented

Pregnancy care up to delivery (continued)

12. Was folic acid taken in the first trimester? ☐ Yes ☐ No ☐ Not documented

If YES, please answer a) and b).

a) Please specify dose of folic acid: ☐ 400 mcg ☐ 4-5 mg ☐ Multivitamin ☐ Dose not specified

b) Please indicate when folic acid started (completed weeks) ☐☐

13. Was this woman monitored for signs of nephropathy? ☐ Yes ☐ No ☐ Not documented

14. Did this woman have diabetic nephropathy? ☐ Yes ☐ No ☐ Not documented

If YES, please answer a) and b).

a) Please indicate type: ☐ Incipient with microalbuminuria ☐ Established with persistent dip stick positive proteinuria and/or serum creatinine >130

b) Was renal function monitored adequately? ☐ Yes ☐ No ☐ Not documented
Panel guidance: at least every trimester by 24 hour urinary protein estimation in women with microalbuminuria. At least monthly monitoring of urine and blood in women with macro-proteinuria

15. Were there recurrent episodes of hypoglycaemia during pregnancy? ☐ Yes ☐ No ☐ Not documented

16. Did any episode of hypoglycaemia require help from another person? ☐ Yes ☐ No ☐ Not documented

17. Were there any pre-existing diabetic complications that required treatment during the last year? ☐ Yes ☐ No ☐ Not documented

If YES, please describe:

_____

_____

_____

18. Were there any other medical or surgical complications that required treatment during the last year? ☐ Yes ☐ No ☐ Not documented

If YES, please describe:

_____

_____

_____

19. Was a target range set for blood glucose control during the first trimester (prior to 13 weeks)? ☐ Yes ☐ No ☐ Not documented
Panel guidance: if not documented in the notes but included in the hospital protocol, please complete as 'Yes'.

a) If YES, was this target range communicated to the woman? ☐ Yes ☐ No ☐ Not documented

20. Was a target range set for blood glucose control thereafter (from 13 weeks up to labour and delivery)? ☐ Yes ☐ No ☐ Not documented
Panel guidance: if not documented in the notes but included in the hospital protocol, please complete as 'Yes'.

a) If YES, was this target range communicated to the woman? ☐ Yes ☐ No ☐ Not documented

21. Does the panel think the woman's glycaemic control was optimal, adequate or poor?
Panel guidance: HbA1c < 7% optimal; 7 to 8% adequate; > 8% poor.

a) In the first trimester (prior to 13 weeks) ☐ Optimal ☐ Adequate ☐ Poor ☐ Insufficient information in notes

If poor or adequate, please summarise key issues and code accordingly:

_____

_____

_____

_____

_____

☐☐ Main code

☐☐ Supplementary codes

☐☐

☐☐

Pregnancy care up to delivery (continued)

21. (continued)

b) Thereafter (from 13 weeks up to labour and delivery)

☐ Optimal ☐ Adequate ☐ Poor
☐ Insufficient information in notes

If poor or adequate, please summarise key issues and code accordingly:

_____
_____
_____
_____
_____

☐☐ Main code
☐☐ Supplementary codes
☐☐
☐☐

22. Does the panel think the diabetic care of the mother during pregnancy, other than glycaemic control, was optimal, adequate or poor?

Panel guidance: Please consider retinal and renal screening and the management of any complications. Optimal indicates that there are no issues with care that need documenting; adequate indicates that there are some issues.

☐ Optimal
☐ Adequate
☐ Poor
☐ Insufficient information in notes

If poor or adequate, please summarise key issues and code accordingly:

_____
_____
_____
_____
_____
_____

☐☐ Main code
☐☐ Supplementary codes
☐☐
☐☐

NOTE to panel: Please discuss question 24 BEFORE question 23

23. Does the panel think the maternity care of the mother during pregnancy (up until delivery) was optimal, adequate or poor?

☐ Optimal
☐ Adequate
☐ Poor
☐ Insufficient information in notes

If poor or adequate, please summarise key issues and code accordingly:

_____
_____
_____
_____
_____
_____

☐☐ Main code
☐☐ Supplementary codes
☐☐
☐☐

Fetal assessment before labour

24. Was there antenatal evidence of:

a) Fetal growth restriction or poor growth velocity? ☐ Yes ☐ No ☐ Not documented

b) Fetal size greater than 90th centile? ☐ Yes ☐ No ☐ Not documented

c) If YES to EITHER a) or b), does the panel think the subsequent monitoring of fetal well being was optimal, adequate or poor? ☐ Optimal ☐ Adequate ☐ Poor ☐ Insufficient information in notes
Panel guidance: optimal indicates there are no issues with care that need documenting; adequate indicates that there are some issues.

If poor or adequate, please summarise key issues and code accordingly:

_____
_____
_____
_____
_____
_____

☐☐ Main code
☐☐ Supplementary codes
☐☐
☐☐

Labour and delivery (continued)

25. What was the date of delivery? (DD/MM/YY) ☐☐/☐☐/☐☐

26. Was this delivery less than 36^{+0} weeks? ☐ Yes ☐ No ☐ Not documented ☐ Not applicable

If YES:

a) Were any corticosteroids given? ☐ Yes ☐ No ☐ Not documented

b) If corticosteroids WERE NOT given, please give reason, if documented:

_____

_____

_____

c) If corticosteroids WERE given, were any of the following undertaken:

i. Increased checking of blood glucose? ☐ Yes ☐ No ☐ Not documented

ii. Change in subcutaneous insulin regime? ☐ Yes ☐ No ☐ Not documented

iii. Intravenous dextrose and insulin? ☐ Yes ☐ No ☐ Not documented

d) Was any medication given to delay the onset of preterm labour? ☐ Yes ☐ No ☐ Not documented

27. Was the mode and timing of delivery discussed with the woman? ☐ Yes ☐ No ☐ Not documented ☐ Not applicable

a) If YES, at what gestation was this first discussed (completed weeks)? ☐☐

28. Was the mode and timing of delivery appropriate?

a) mode ☐ Yes ☐ No ☐ Not documented ☐ Not applicable

b) timing ☐ Yes ☐ No ☐ Not documented

29. Were intravenous dextrose and insulin administered during labour and delivery? ☐ Yes ☐ No ☐ Not documented ☐ Not applicable

If NO, give any documented reason:

_____

_____

30. Was a target range set for blood glucose control during labour and delivery? ☐ Yes ☐ No ☐ Not documented ☐ Not applicable

Panel guidance: if not documented in the notes but included in the hospital protocol, please complete as YES.

31. *Complete this section for VAGINAL deliveries or EMERGENCY caesarean sections ONLY*

Does the panel think the management of the woman's blood glucose control was optimal, adequate or poor during labour and delivery?

Panel guidance: 3.5 - 8 mmols/l optimal; 8 - 9 adequate; >9 poor.

☐ Optimal
☐ Adequate
☐ Poor
☐ Insufficient information in notes

If poor or adequate, please summarise key issues and code accordingly:

_____

_____

_____

_____

_____

_____

☐☐ Main code
☐☐ Supplementary codes
☐☐
☐☐

32. *Complete this section for ELECTIVE caesarean sections ONLY*

Does the panel think the management of the woman's blood glucose control was optimal, adequate or poor during delivery?

Panel guidance: 3.5 - 8 mmols/l optimal; 8 - 9 adequate; >9 poor.

☐ Optimal
☐ Adequate
☐ Poor
☐ Insufficient information in notes

... continued

Labour and delivery (continued)

32. (continued)

If poor or adequate, please summarise key issues and code accordingly:

_____
_____
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_____
_____

☐☐ Main code
☐☐ Supplementary codes
☐☐
☐☐

33. Does the panel think that maternity care during labour and delivery was optimal, adequate or poor ?

Panel guidance: Optimal indicates that there are no issues with care that need documenting; adequate indicates that there are some issues.

☐ Optimal
☐ Adequate
☐ Poor
☐ Insufficient information in notes

If poor or adequate, please summarise key issues and code accordingly:

_____
_____
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_____

☐☐ Main code
☐☐ Supplementary codes
☐☐
☐☐

Postnatal care of mother

34. Was there a plan for post-delivery diabetic management while still in hospital (including glycaemic control if breast feeding)? ☐ Yes ☐ No ☐ Not documented ☐ Not applicable

a) If breast feeding, was there advice given with regard to glycaemic control? ☐ Yes ☐ No ☐ Not documented ☐ Not applicable

35. Was contraceptive advice given prior to discharge from hospital? ☐ Yes ☐ No ☐ Not documented ☐ Not applicable

36. Was there a follow-up appointment for diabetic management arranged prior to discharge from hospital? ☐ Yes ☐ No ☐ Not documented ☐ Not applicable

37. Does the panel think that postnatal diabetic care and advice was optimal, adequate or poor?

Panel guidance: optimal indicates that there are no issues with care that need documenting; adequate indicates that there are some issues.

☐ Optimal
☐ Adequate
☐ Poor
☐ Insufficient information in notes

If poor or adequate, please summarise key issues and code accordingly:

_____
_____
_____
_____
_____
_____

☐☐ Main code
☐☐ Supplementary codes
☐☐
☐☐

Neonatal care

38. Was the baby separated from its mother after delivery? ☐ Yes ☐ No ☐ Not documented ☐ Not applicable

If YES, please give the reason for this

_____
_____
_____

Neonatal care (continued)

39. Was there an intended method of feeding in notes? ☐ Yes ☐ No ☐ Not documented ☐ Not applicable

a) What was the method of feeding? ☐ No selection ☐ Not recorded ☐ Breast ☐ Bottle ☐ Breast & bottle ☐ Other

40. Was low reagent stick measurement (<2.6mmol/l) checked by laboratory examination? ☐ Yes ☐ No ☐ Not documented ☐ Not applicable

Please give method:

_____

_____

_____

41. Was supplemental milk or glucose given in the first 24 hours after delivery? ☐ Yes ☐ No ☐ Not documented ☐ Not applicable

Pathology

42. Was placental pathology carried out? ☐ Yes ☐ No ☐ Not documented

If YES, please indicate whether any of the following were found.

a) Cord oedema ☐ Yes ☐ No ☐ Not documented

b) Villious oedema ☐ Yes ☐ No ☐ Not documented

c) Villious immaturity ☐ Yes ☐ No ☐ Not documented

Please specify any further relevant finding:

_____

_____

_____

_____

Congenital malformation Complete if baby HAS congenital malformation ☐ Not applicable

43. When was the congenital malformation first detected? ☐ antenatally ..... ☐☐ gestation (completed weeks) ☐ postnatally

44. Was the congenital malformation confirmed? ☐ Yes ☐ No ☐ Not documented

If YES, please give method of confirmation.

_____

_____

_____

Post mortem Complete if baby DIED ☐ Not applicable

45. Was a post mortem offered? ☐ Yes ☐ No ☐ Not documented

46. Was a post mortem carried out? ☐ Yes ☐ No ☐ Not documented

a) If NO, please give reason?

_____

_____

_____

b) If YES, was PM performed by a perinatal pathologist? ☐ Yes ☐ No ☐ Not documented

Post mortem (continued)

47. Was the post mortem report available at panel? ☐ Yes ☐ No ☐ Not documented

If YES, please indicate whether any of the following were found.

a) Pancreas: Islet cell hyperplasia ☐ Yes ☐ No ☐ Not documented

Eosinophilic pancreatitis ☐ Yes ☐ No ☐ Not documented

b) Heart: Cardiomegaly/fibre disarray ☐ Yes ☐ No ☐ Not documented

c) Kidneys: Vascular thrombosis ☐ Yes ☐ No ☐ Not documented

Please specify any further relevant finding:

_____

_____

_____

_____

Now, please go to Summary section on the following page.

Summary

48. Does the panel think that the overall diabetes care was optimal, adequate or poor?

Panel guidance: This is a summary of glycaemic control and other aspects of diabetic care from preconception through to the postnatal period. Detailed issues should be documented earlier in the proforma.

- ☐ Optimal
- ☐ Adequate
- ☐ Poor
- ☐ Insufficient information in notes

49. Does the panel think that the overall maternity care was optimal, adequate or poor?

Panel guidance: This is a summary of maternity care throughout pregnancy. Detailed issues should be documented earlier in the proforma.

- ☐ Optimal
- ☐ Adequate
- ☐ Poor
- ☐ Insufficient information in notes

50. Does the panel think that the woman's approach to managing her diabetes was optimal, adequate or poor:

Panel guidance: optimal indicates that there are no issues with care that need documenting; adequate indicates that there are some issues.

a) In the preconception period?
Panel guidance: optimal indicates that there are no issues with care that need documenting; adequate indicates that there are some issues

- ☐ Optimal
- ☐ Adequate
- ☐ Poor
- ☐ Insufficient information in notes

If poor or adequate, please summarise key issues and code accordingly:

_____
_____
_____
_____
_____
_____

- ☐☐ Main code
- ☐☐ Supplementary codes
- ☐☐
- ☐☐

b) During pregnancy?
Panel guidance: optimal indicates that there are no issues with care that need documenting; adequate indicates that there are some issues

- ☐ Optimal
- ☐ Adequate
- ☐ Poor
- ☐ Insufficient information in notes

If poor or adequate, please summarise key issues and code accordingly:

_____
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_____
_____
_____
_____

- ☐☐ Main code
- ☐☐ Supplementary codes
- ☐☐
- ☐☐

51. Does the panel think that there were any deficiencies in communication between the different professionals involved in the woman's care?

☐ Yes ☐ No ☐ Not possible to infer from notes

If YES, please summarise key issues detailing disciplines involved and grades.

_____
_____
_____
_____

52. Does the panel think that there were any deficiencies in communication between professionals and the woman?

☐ Yes ☐ No ☐ Not possible to infer from notes

If YES, please summarise key issues detailing disciplines involved and grades.

_____
_____
_____
_____

Summary (continued)

53. Does the panel think that there were any deficiencies in the standard of notes?

Panel guidance: please comment on whether this is to do with structure of notes or quality of note-keeping.

a) Obstetric notes ☐ Yes ☐ No

If YES, please comment:

b) Diabetes notes ☐ Yes ☐ No

If YES, please comment:

54. Does the panel think that there were any deficiencies in the hospital protocols? ☐ Yes ☐ No ☐ Not available at panel meeting

If YES, please comment:

55. Please add any additional relevant information or comments not captured elsewhere on the proforma.

56. Please list any examples of good practice that you think should be shared.

Summary (continued)

For completion by Panel Chair and Regional Manager after enquiry

57. Please note any positive or negative issues relating to the 3 areas defined below. This will help to evaluate the panel enquiry process and make improvements for further enquiry work.

a) Panel process:

b) Panel member(s) involvement in the assessment meeting:

c) Clinical issues noted during panel enquiry (eg inconsistency of existing definitions, variance in practice, ...):

Appendix F Confidential Panel Enquiry Comments

Below are listed comments and key issues related to individual cases within the West Midlands Confidential Panel Enquiry. These comments are quotations taken directly from the panel enquiries.

1 Diabetes care of the mother during pregnancy (other than glycaemic control)

27 mothers in both the case and control groups were deemed to have received "*optimal*" diabetes care up during pregnancy. It was the opinion of the panels that 48 cases received adequate or poor care and the key issues are highlighted in Table 1a (Case group) and in Table 1b (Control group). In two sets of notes allocated as "*cases*" there was insufficient information for the panel to attribute a code clearly.

Table 1a *Diabetic care in the **case group** of the mothers during pregnancy*
List of key issues, summarised during panel enquiries where care was found to less than optimal (adequate/poor)

Case (n=23)	Key issues
Issues relating to provision of health services	• chaotic early appointment • organisation of care • no retinal assessment, did not see a dietician • no retinal screening • no retinal screening • late booking, continued metformin, good care thereafter retinopathy screening poor, ketones at clinic not addressed • didn't check proteinuria 24 hour urine soon enough • failure to refer to maculopathy to Ophthalmologist, late presentation, HbA1c not measured in a lab which could deal with haemoglobinopathy • inadequate eye screening, little past history of diabetes, duration etc, • no action on possible severe retinopathy, no retinal screening at booking, • no dietician • not multidisciplinary clinic, no dietician, no eye check, renal function not assessed • poor input form professionals, no retinopathy screening • blank n=2
Issues relating to patient/family	• didn't pursue renal function, poor compliance • own actions, dietician attended late • patient unhappy with close monitoring, no HbA1c after 24 weeks • eye appt - DNA • very late booking & no folic acid • blank n=1

Table 1b *Diabetic care in the **control group** of the mothers during pregnancy*
List of key issues, summarised during panel enquiries where care was found to less than optimal (adequate/poor)

Control (n=25)	Key issues
Issues relating to provision of health services	• was not seen until late, did not attend • fundoscopy, retinopathy found, no action • inadequate documentation of retinopathy, lack of formal nephropathy screening • inadequate eye checks • inappropriate use of glargine at week 11, poor screening of albuminuria • incorrect folic acid dose, late eye screening • insufficient eye care, hypoglycaemia • little documentation diabetes care until 29 weeks, DNA'd appts, attended clinic but refused to be seen • no dietician, retinal screening poor • no follow up of retinopathy after 15 weeks, few urine tests • no fundal assessment noted • no information in notes • no retinal screening, no 24 hr urine collection • no screening of fundi until 16 weeks • one documented fundoscopy at 20/40 • poor dietetic advice • query dilated, query no further retinal check • no retinal screening until 23 weeks • blank n=4
Issues relating to patient/family	• lack of dietician, injection sited noted late, late presentation • one documented fundoscopy at 20 weeks • woman not compliant, no evidence of coherent service

2 Maternity care of the mother during pregnancy (up until delivery)

39 Cases and controls were deemed to have received "*optimal*" maternity care up until delivery. It was the opinion of the panels that 38 cases received adequate or poor care, key issues as highlighted in Table 2a (Case group) and in Table 2b (Control group).

Table 2a *Maternity care in the **case group** of the mothers during pregnancy*
List of key issues, summarised during panel enquiries where care was found to less than optimal (adequate/poor)

Case (n=23)	Key issues
Issues relating to provision of health services	• confusion re echo results, no definite management plan • smoked during pregnancy, long gaps without supervision, very late induction • perhaps delivery delayed, IOL should have been at 38 weeks • regular mid-t scan, no detailed scan, scans at 28,34, no detailed anomaly scan, no growth scans after 34/40 • no follow up of persistent proteinuria until 32 weeks, present from 22 weeks • anomaly scan did not detect problems (only done by a sonographer), poor CTG interpretation • patient not given choice • deviating from own protocol • delay in scan - after evidence of poor growth • infrequent urinalysis • treatment of UTI was suboptimal, given co amoxiclav when no sensitivity given to this antibiotic, last UTI not treated but only take 5 days before delivery • lack of more intensive monitoring in late trimester 3 • plan made at 11/40 not to see until after 20/40, no referral to diabetic team until 25/40, fetal abnormalities missed, • some confusion over early appointments, inappropriate use of steroids e for feticide, risk of hysterectomy not discussed, no Haematologist involved • increase in size, hydramnios and no CTGs • steroids & monitoring, ?inappropriate steroids, failure to recognise DKA • male interpreter! • blank n=4
Issues relating to patient/family	• poor attendance until monitoring of eyes • poor patient compliance

Table 2b *Maternity care in the **control group** of the mothers during pregnancy*
List of key issues, summarised during panel enquiries where care was found to less than optimal (adequate/poor)

Control (n=15)	Key issues
Issues relating to provision of health services	• lack of documentation of discussion, lack of documentation by obstetrician • no timing delivery, no involvement of psychiatrist re schizophrenia, no adequate fetal assessment scan, no action when proteinuric, suboptimal management hypertension • inappropriate use of Dopplers to monitor, little mention of discussion of fetal movements • little follow up of possible cholestasis • can't see any consultant involvement or recognition of high risk patient • few urinalyses, odd management of cholestasis, no advice re shingles, never had dermatology review, no anticipation of fact that known to be impossible to examine vaginally - should have planned ahead, • poor communication, no growth scans • no evidence of "*big baby*" described in the notes, no indication given for thought processes behind LSCS • poor fetal assessment • was due to be sent home without investigation when she was developing pet, poor clinical assessment • sent home with pyrexia & UTI, insulin stopped, magnesium sulphate levels not done, slow to give steroids • availability of cots • blank n=2
Issues relating to patient/family	• blank n=1

3 Maternity Care during Labour and Delivery

47 Cases and controls were deemed to have received "*optimal*" maternity care during labour and delivery. It was the opinion of the panels that 27 cases received adequate or poor care, key issues as highlighted in Table 3a (Case group) and in Table 3b (Control group). In two sets of notes allocated as "*cases*" there was insufficient information for the panel to attribute a code clearly.

Table 3a *Maternity care in the **case group** of the mothers during labour and delivery*
List of key issues, summarised during panel enquiries where care was found to less than optimal (adequate/poor)

Case (n=13)	Key issues
Issues relating to provision of health services	• prolonged trial of labour, poorly managed, no early use of Syntocinon • conflicting delivery plans • doubt over glucose measurement • antibiotics - strep, no documentation for trial of scar, did not follow wishes of mother, experience of Midwife & registrar not clear • no CTG, poor diabetic control and not sterilised • inappropriate use of steroids, no discussion re mode of delivery • mifepristone not immediately available • panel view LSCS decision perhaps inappropriate • no consultant involvement in delivery • inappropriate arm and ventouse not appropriate • high risk patient, should have been advised to attend labour ward immediately • blank n=2

Table 3b *Maternity care in the **control group** of the mothers during labour and delivery*
List of key issues, summarised during panel enquiries where care was found to less than optimal (adequate/poor)

Control (n=14)	Key issues
Issues relating to provision of health services	• no appropriate communication with patient • haven't documented blood glucose control - probably poor • left with little care in labour • didn't control BP pre-theatre, no ve done, slow to get her to theatre with abruption & increased BP • should of started Syntocinon-Earlier, sectioned her too soon, didn't increase Syntocinon fast enough, monitoring poor (husband) • should have had arm earlier, too much prostin • inappropriate grade (reg) for caesarian and anaesthetic. inappropriate skin closure, mode and timing doubtful on evidence given • CTG prior to delivery failed & no further action • no definition of baby's head prior to assisted delivery • not actively managed in labour • not clear that LSCS was required • ventouse slipped, delayed epidural • concerns re induction of labour process, especially about transfers • slow to respond to pathological CTG

List of Abbreviations

CA	Congenital Anomaly
CE	Confidential Enquiry
CEFM	Continuous Electronic Fetal Monitoring
CEMACH	Confidential Enquiry into Maternal and Child Health
CESDI	Confidential Enquiry into Stillbirths and Deaths in Infancy
CMR	Congenital Malformation Rate
CNS	Central Nervous System
CS	Caesarean Section
CTG	Cardiotocograph
DCCT	Diabetes Control and Complications Trial
DEP	Diabetes Enquiry Proforma
DiP	Diabetes in Pregnancy
DiPAG	Diabetes in Pregnancy Advisory Group
DKA	Diabetic Ketoacidosis
DSN	Diabetes Specialist Nurse
EDD	Expected Delivery Date
ENND	Early Neonatal Death
EUROCAT	European Surveillance of Congenital Anomalies
GO	Good Outcome
GP	General Practitioner
HbA1c	Glycated Haemoglobin
HDU	High Dependency Unit
ICD10	International Classification of Diseases, revision 10
IMD	Index of Multiple Deprivation 2004
IOL	Induction of Labour
ITU	Intensive Care Unit
IV	Intravenous
NND	Neonatal Death
NNU	Neonatal Unit
OHA	Oral Hypoglycaemic Agents
OR	Odds Ratio
PCOS	Polycystic Ovarian Syndrome
PCTs	Primary Care Trusts
PMR	Perinatal Mortality Rate
RR	Relative Risk

References

1 CEMACH. Pregnancy in women with type 1 and type 2 diabetes in 2002–2003. 2005.

2 Hotu S, Carter B, Watson PD, Curtfield WS, Cundy T. Increasing prevalence of type 2 diabetes in adolescents. J Paediatr Child Health 2004;40(4):201-204.

3 Department of Health. National Service Framework for Diabetes (England) standards. London: The Stationary Office; 2001.

4 Casson IF, Clarke CA, Howard CV, McKendrick O, Pennycook S, Pharoah PO et al. Outcomes of pregnancy in insulin dependent diabetic women: results of a five year population cohort study. BMJ 1997;315:275-278.

5 Hawthorne G, Robson S, Ryall EA, Sen D, Roberts SH, Ward Platt MP. Prospective population based survey of outcome of pregnancy in diabetic women: results of the Northern Diabetic Pregnancy Audit. BMJ 1994;315:279-281.

6 Brydon P, Smith T, Proffitt M, Gee H, Holder R, Dunne F. Pregnancy outcome in women with type 2 diabetes needs to be addressed. International J Clinical Practice. 2000:54;418-419.

7 Dunne F, Brydon P, Smith K, Gee H. Pregnancy in women with type 2 diabetes: 12 years outcome data 1990-2002. Diabetic Medicine 2003;20:734-738.

8 Ray JG, Singh G, Burrows RF. Evidence for suboptimal use of periconceptional folic acid supplements globally. BJOG 2004;111:399-408.

9 Evers IM, Ter Braak EWMT, de Valk HW, van der Schoot B, Janssen N, Visser GHA. Risk indicators predictive for severe hypoglycaemia during the first trimester of type 1 diabetic pregnancy. Diabetes Care 2002;25(3):554-559.

10 Lewis G, Drife J, editors. Why mothers die 1997-1999. The fifth report of the confidential enquiries into maternal deaths in the United Kingdom. London: RCOG Press; 2001.

11 Lewis G, editor. Why mothers die 2000-2002: The sixth report of the confidential enquiries into maternal death in the United Kingdom. London: RCOG Press; 2004.

12 Jardine Brown C, Dawson A, Dodds R, Gamsu H, Gillmer M, Hall M et al. Report of the pregnancy and neonatal care group. Diabetic Med 1996:13:S43-53.

13 Penney GC, Pearson D. A national audit to monitor and promote the uptake of clinical guidelines on the management of diabetes in pregnancy. Br J Clin Governance 2000;5(1):28-34.

14 Marshall SM, Barth JH. Standardisation of HbA1c measurements: a consensus statement. Diabetic Med 2000;17:5-6.

15 CEMACH. Pregnancy in women with type 1 and type 2 diabetes in 2002–2003. 2005: Table 5.2 page 23.

16 Evers IM, de Valk HW, Visser GH. Risk of complications of pregnancy in women with type 1 diabetes: nationwide prospective study in the Netherlands. BMJ 2004;328:915-918.

17 Department of Health. NHS Maternity Statistics, England 2002-2003, Statistical Bulletin 2004/10.

18 Department of Health. National Service Framework for Diabetes (England) standards. London: The Stationary Office; 2001.

19 West Midlands Perinatal Mortality (Update March 2006).

20 European registration of congenital anomalies. EUROCAT Report 8: Surveillance of congenital anomalies in Europe 1980-1999. Belfast: University of Ulster; 2002.

21 Office for national Statistics. Key Population and vital statistics 2002.

22 Chaudhry T, Ghani AM, Mehrali TH, Taylor RS, Brydon PA, Gee H, Barnett AH, Dunne FP. A comparison of foetal and labour outcomes in Caucasian and Afro-Caribbean women with diabetes in pregnancy. Int J Clin Pract. 2004 Oct; 58(10):932-6.

23 Penney GC, Mair G, Pearson DW. Scottish Diabetes in Pregnancy Group. Outcomes of pregnancy in women with type 1 diabetes in Scotland: a national population-based study. BJOG 2003;110:315-318.

24 Evers IM, de Valk HW, Visser GH. Risk of complications of pregnancy in women with type 1 diabetes: nationwide prospective study in the Netherlands. BMJ 2004;328:915-918.

25 Clausen TD, Mathiesen E, Ekbom P, Hellmuth E, Mandrup-Poulsen T, Damm P. Poor pregnancy outcome in women with type 2 diabetes. Diabetes Care 2005;28:323-328.

26 Evers IM, de Valk HW, Visser GH. Risk of complications of pregnancy in women with type 1 diabetes: nationwide prospective study in the Netherlands. BMJ 2004;328:915-918.

27 Rennie JN, Robertson NRC. Textbook of Neonatology. 4th ed. Edinburgh: Churchill Livingstone; 2005.

28 Johnstone FD, Myerscough PR. Shoulder dystocia. Br J Obstet Gynaecol 1998;105:809-810.

29 Gardosi J, Mongelli M, Wilcox M, Chang A. An adjustable fetal weight standard. Ultrasound Obstet. Gynaecol. 6 (1995) 168-174.

30 Nesbitt TS, Gilbert WM, Herrhen B. Shoulder dystocia and associated risk factors with macrosomic infants born in California. Am J Obstet Gynaecol 1998;179:476-480.

31 McFarlane A, Mugford M. Birth Counts: Statistics of pregnancy and Childbirth. 2nd Edition Oxford: National Perinatal Epidemiology Unit; 2000.

32 Forsythe P. New practices in the transitional care centre improve outcomes for babies and their families. J Perinatol 1998;18:S13-17.

33 Laing I, Ducker T, Leaf A, Newmarch P. Designing a neonatal Unit. Report for the British Association of Perinatal Medicine. London: BAPM; 2004.

34 Hawdon JM, Ward Platt MP, Aynsley-Green A. Patterns of metabolic adaptation for preterm and term infants in the first neonatal week. Arch Dis Child 1992;67:357-365.

35 Williams AF. Hypoglycaemia of the Newborn. Review of the literature. CHD/97.1. Geneva: World Health Organization; 1997.

36 16 Hamlyn B, Brooker S, Oleinikovo K, Wands S. Infant feeding survey. The Stationery Office, London, 2002.

37 Cornblath M, Schwartz R, Aynsley-Green A. Lloyd JK. Hypoglycaemia in infancy: the need for a rational definition. A Ciba Foundation discussion meeting. Paediatrics 1990;85:834-837.

38 Deshpande S, Ward Platt M. The investigation and management of neonatal hypoglycaemia. Semin Fetal Neonatal Med 2005;10:351-361.

39 CEMACH Diabetes in Pregnancy: How do we care? Findings of a national enquiry. February 2007.

Diabetes in Pregnancy: addressing the challenge in the West Midlands
Perinatal Institute, 2010 www.pi.nhs.uk/diabetes/publications/report2010.pdf

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