

Title: Obstetric and perinatal outcomes for women with pre-existing diabetes in rural compared to metropolitan settings in Victoria, Australia.

Running title: Rural vs metro diabetes in pregnancy outcomes

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Abstract:

Background: Pre-existing diabetes in pregnancy is associated with an increased risk of complications. Likewise, living in rural, regional and remote Victoria, Australia is also associated with poorer health outcomes. There is a gap in the literature with regards to whether Victorian women with pre-existing diabetes experience a greater risk of adverse pregnancy outcomes compared to their metropolitan counterparts.

Aim: Our objective is to compare obstetric and perinatal outcomes for women with pre-existing diabetes delivering in rural versus metropolitan hospitals in Victoria, Australia.

Materials and Methods: Retrospective population-based study using routinely collected state-based data of singleton births to women with type 1 and type 2 diabetes who delivered in metropolitan (n=3,233) and rural hospitals (n = 693) in Victoria, Australia between 2006 – 2015. Pearson's chi-square test, Fisher's exact test and Mann-Whitney U test were used to compare obstetric and perinatal outcomes between metropolitan and rural locations.

Results: Delivery in a rural hospital was associated with higher rates of stillbirth (2.3% vs 1.1%,  $p=0.027$ ), macrosomia (25.9% vs 16.9%,  $p<0.001$ ), shoulder dystocia (8.4% vs 3.5%,  $p<0.001$ ) and admission to the neonatal intensive care unit/special care nursery (73.2% vs 59.3%,  $p<0.001$ ). Smoking (18.0% vs 8.9%,  $p<0.001$ ), overweight/obesity ( $p=0.047$ ) and socioeconomic disadvantage ( $p<0.001$ ) were more common in rural women.

Conclusions: Women with pre-existing diabetes who deliver in rural hospitals experience a greater risk of adverse perinatal outcomes and present with increased maternal risk factors.

These results suggest a need to improve care for women with pre-existing diabetes in rural Victoria.

## Introduction

In 1989, the St Vincent's Declaration established international targets for the health of people living with diabetes, including a five year goal to achieve equivalent pregnancy outcomes for women with and without diabetes<sup>1</sup>. However, almost 30 years later, pre-existing diabetes continues to be associated with an increased frequency of obstetric and perinatal complications<sup>2-4</sup>.

In the Australian obstetric population there is a disparity in maternal and perinatal health between rural and metropolitan settings<sup>5-7</sup>. Women living in rural and remote communities face a greater risk of maternal death, and their babies a disproportionate risk of neonatal death, which in part reflects the increased proportion of Indigenous mothers<sup>6-7</sup>. It is not known whether a rural-metropolitan divide is present for women with pre-existing diabetes in

Victoria. Our aim was to compare metropolitan and rural cohorts of women with type 1 and type 2 diabetes in pregnancy delivering in Victoria, Australia. We hypothesised that women delivering in rural hospitals have an increased burden of complications and maternal risk factors.

## Materials and Methods

### Study design, data source and study population

This is a retrospective population-based cohort study. De-identified data of every birth in Victoria between 2006 and 2015 were accessed from the Victorian Perinatal Data Collection (VPDC). The VPDC routinely collects information on all births on behalf of the Consultative Council on Obstetric and Paediatric Mortality and Morbidity (CCOPMM). All births of  $\geq 20$  weeks' gestation, or with a birthweight of  $\geq 400$  grams if gestation is unknown, in Victoria are notified to the VPDC and data entry is completed by trained midwives. Obstetric diagnoses, such as pre-eclampsia, were defined by the business rules of the VPDC<sup>8</sup>. All hospitals with greater than 100 births annually were included as defined by the VPDC.

Singleton births to women with pre-existing diabetes were included. Pre-existing diabetes was defined as either type 1 diabetes or type 2 diabetes diagnosed prior to pregnancy. These births were identified using ICD-10AM codes corresponding to type 1 diabetes (O240), type 2 diabetes (O2419) or unclassified pre-existing diabetes (O243). Multiple births, women with gestational diabetes (GDM) and terminations of pregnancy were excluded. Data entries were also excluded if the women had been categorised as having both pre-existing diabetes and GDM.

### Ethics

Ethics approval was granted by the Mercy Health Human Research Ethics Committee (R16/56).

### Maternal characteristics

Maternal characteristics included diabetes status, age, parity, previous caesarean section (C/S), body mass index (BMI), country of birth, smoking status at the beginning of pregnancy and socioeconomic status (SES). BMI, smoking status and SES were available from 2009 onwards. Socioeconomic status was measured according to the Socio-Economic Indices for Areas (SEIFA) quintiles.

#### Primary outcomes

The primary outcomes were stillbirth and neonatal death. Stillbirth was defined as an infant born after 20 weeks gestation (or birthweight >400 grams if unknown gestation) who did not show any signs of life after birth. Neonatal death referred to the death of a liveborn infant within 28 days of birth, of at least 20 weeks gestation (or birthweight >400 grams if unknown gestation). Perinatal death was defined as the combined total of all stillbirths and neonatal deaths.

Maternal outcomes included induction of labour (IOL), elective C/S, emergency C/S, instrumental delivery, pre-eclampsia, intensive care unit/high dependency unit (ICU/HDU) admission and post – partum haemorrhage (PPH). PPH was defined as estimated blood loss greater than 500 millilitres. Perinatal outcomes included gestational age, preterm delivery prior to 37+0 weeks gestation, very preterm delivery prior to 34+0 weeks, birth weight, small for gestational age birthweight < 10th centile for age (SGA), large for gestational age birthweight > 90th centile for age and > 95th centile for age (LGA), macrosomia (birthweight >4000 g regardless of gestation), shoulder dystocia, Apgar score less than 7 at 5 minutes and admission to the special care nursery/neonatal intensive care unit (SCN/NICU).

#### Exposure

Location of delivery was the exposure of interest and was categorised as rural or metropolitan based on the Department of Health and Human Services map of local government areas (Figure 1)<sup>9</sup>.

#### Statistics

STATA version 14.0 (StataCorp, College Station, TX, USA) was used to analyse the data. Numbers and percentages were used to describe categorical variables. Median and interquartile range (IQR) are given for continuous variables. Fisher's exact test was used for

infrequent outcomes. All other categorical data were compared using Pearson's chi-square test. Continuous data were compared using Mann – Whitney U test. Raw data is presented and no statistical adjustments were made. Statistical significance was defined as a p value <0.05.

## Results

Data was accessed for 737529 births in Victoria from 1 January 2006 to 31 December 2015. Women with pre-existing diabetes represented 4101 of these pregnancies, with a prevalence of 0.56%. Singleton births accounted for 3926 of these deliveries. Excluded from our study cohort were 845 women classified as having both pre-existing diabetes and GDM. Rural births accounted for 17.7% of deliveries to women with pre-existing diabetes (Table 1).

Maternal characteristics are described in Table 1. Women delivering in rural hospitals were younger ( $p<0.001$ ) and more likely to be overweight/obese ( $p = 0.047$ ). Furthermore, rural women experienced a greater burden of socioeconomic disadvantage ( $p<0.001$ ), and were more likely to be classified as a smoker at the beginning of pregnancy ( $p<0.001$ ).

Obstetric and perinatal outcomes are described in Table 2. There were 68 perinatal deaths in total, 53 of these were stillbirths and the remaining 15 were neonatal deaths (Table 2). The incidence of stillbirth was significantly higher in rural compared to metropolitan hospitals (2.3% vs 1.1%,  $p=0.027$ ) (Table 2). Median gestational age for stillbirth in the rural group was 33.5 weeks (IQR 24 - 37.5) compared to 30.0 weeks (IQR 22.5 – 35.5) in the metropolitan group ( $p=0.28$ ). There was no statistically significant difference in the incidence of neonatal death in metropolitan compared to rural settings (0.4% vs 0.1%,  $p=0.49$ ) (Table 2). The 15 neonatal deaths included one in a rural hospital, at 22 weeks gestation, and the remaining 14 in metropolitan hospitals. Of the 14 neonatal deaths in metropolitan hospitals, only three occurred in babies born after 28 weeks gestation.

Babies born to women delivering in a rural hospital were larger than those born in metropolitan hospitals. Both LGA ( $p<0.001$ ) and macrosomia ( $p<0.001$ ) were significantly increased in rural settings (Table 2). Delivery in a rural hospital was associated with a higher risk of shoulder dystocia compared to in a metropolitan hospital (8.4% vs. 3.5%,  $p<0.001$ ) (Table 2). Babies born in rural hospitals were more likely to require admission to the SCN/NICU (73.2% vs 59.3%,  $p<0.001$ ) (Table 2).

## Discussion

This study is the first to investigate metropolitan and rural cohorts of women with pre-existing diabetes delivering in Victoria. The prevalence of pre-existing diabetes in our study, 0.56%, was similar to a previously reported 0.47% in Victoria from 1999 – 2008<sup>10</sup>. We found women with pre-existing diabetes who delivered in a rural hospital experience increased maternal risk factors and perinatal complications.

Previous work by Shand et al (2008) found delivery in a small rural hospital in New South Wales for women with pre-existing and gestational diabetes to be protective against having an infant with major morbidity/mortality, suggesting appropriate referral processes were in place to ensure higher risk women delivered in tertiary or large district hospitals<sup>3</sup>. Our study presented outcomes for all metropolitan hospitals, including tertiary centres, and all rural hospitals, including both small rural and large regional referral centres. In contrast to the findings by Shand et al, our study demonstrated delivery in a rural setting to be associated with poorer outcomes, notably a significantly higher risk of stillbirth<sup>3</sup>.

The majority of neonatal deaths were in very preterm babies and occurred among women who delivered in metropolitan hospitals. It is usual practice in Victoria to transfer women antenatally to a hospital with higher capability, in the metropolitan area, if preterm birth is planned or imminent. It is possible that some of these women may have been transferred antenatally from a rural location to a higher capability metropolitan hospital, however we do not have information on the planned place of birth<sup>3, 11, 12</sup>. In contrast, women who experience a stillbirth will not be transferred antenatally and therefore these women would remain in a rural hospital to deliver<sup>12</sup>. This finding suggests that appropriate inter-hospital transfer is taking place in the setting of threatened preterm labour or reasons for iatrogenic prematurity.

Babies born in rural hospitals were larger. Higher birth weights may reflect poorer maternal glycaemic control in rural settings, however, this data is not routinely collected<sup>13</sup>. The higher risk of shoulder dystocia in the rural cohort is likely contributed to by larger birth weights<sup>14</sup>.

Rural infants were more likely to be admitted to the SCN/NICU, however, this may reflect poorer outcomes at birth or differing hospital policies<sup>4</sup>.

Rural mothers were more likely to smoke, be overweight/obese, and experience socioeconomic disadvantage, findings consistent with previous studies comparing metropolitan and rural populations in Australia<sup>12</sup>. These maternal characteristics are associated with adverse pregnancy outcomes<sup>5, 15</sup>. We chose not to adjust our findings for maternal demographics, including smoking, BMI and SES, because we wanted to reflect the realities of the needs of the women in their pregnancy, including diabetes, and other factors that contribute to higher risk pregnancies. Adjusting the findings for maternal demographics may provide theoretical information regarding the care of diabetes in pregnancy in rural settings, but is not helpful in real world terms for the clinicians providing the multidisciplinary bundle of care required for these high needs women.

Previous findings of poorer health for women in rural Australia acknowledge that the disparity is reflective of both patient demographics and reduced access to appropriate care<sup>6, 12</sup>. Reducing maternal risk factors is important but difficult to achieve, especially given the majority of women with diabetes do not receive pre-pregnancy counselling<sup>2</sup>. Our findings thus suggest a need for increased focus on the provision of high-quality multidisciplinary care for rural women with diabetes, including pre-pregnancy care. Findings borne out of the Confidential Enquiry into Maternal and Child Health (CEMACH) and subsequent National Institute for Health and Care Excellence (NICE) recommendations have highlighted the need for joint diabetes and antenatal clinic accessibility that provide specialist endocrine, obstetric, dietician and diabetes nurse educator expertise, and access to pre-pregnancy care<sup>16-17</sup>. Reduced availability of these services is likely to be one of the major discrepancies for women in rural areas<sup>6-7, 12, 18-20</sup>. Increasing access to specialist care is not a simple task or a solution that will likely be achieved in the short-term<sup>20-22</sup>. In the meantime, investment in initiatives such as telehealth appears to be one avenue for improved outcomes<sup>20</sup>.

Limitations of our study include the inability to account for the clustering effect of women within hospitals or that a woman may be represented more than once in our cohort. Important markers of diabetic control such as HbA1c and diabetes duration were not available. SES, BMI and smoking status were not available prior to 2009. Women who received antenatal care in rural Victoria may have transferred to a metropolitan centre, and these women are

likely to be higher risk and may have experienced a complication prior to transfer, contributing to the rate of adverse outcomes recorded in metropolitan settings<sup>3, 11,12</sup>.

Strengths of our study include that our rural cohort of women with diabetes is the largest studied in Australia<sup>3, 23</sup>. We are the first to investigate outcomes for women with pre-existing diabetes state-wide in Victoria and births across a ten year period were included. This is routinely collected data, so there is less likely to be reporting bias as clinicians recording the births had no involvement in our study. A validation study demonstrated high levels of accuracy for the VPDC data<sup>24</sup>.

In conclusion, this study demonstrates that women with pre-existing diabetes delivering in rural compared to metropolitan hospitals in Victoria experience increased maternal risk factors and adverse perinatal outcomes. Sadly, stillbirth is twice as frequent for women with diabetes living in rural Victoria. This rural-metropolitan divide is likely multifactorial, reflecting both maternal characteristics and the availability of specialist care outside metropolitan areas. These findings suggest a need to improve access to specialist care for rural women.

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## Tables

Table 1. Maternal characteristics according to location of delivery

Data are presented as n (%). NC: not calculated, C/S: caesarean section.

†Unclassified refers to women reported to have either type 1 or type 2 pre-existing diabetes.

‡P value was not calculated for diabetes status given the high proportion of unclassified entries.

§Not reported for deliveries prior to 2009. For 2009 – 2015, data was unavailable in 449 metropolitan and 9 rural deliveries.

¶Data unavailable in 2 metropolitan deliveries.

||Not reported for deliveries prior to 2009. For 2009 – 2015, data was unavailable in 62 metropolitan and 4 rural deliveries.

††Not reported for deliveries prior to 2009. For 2009 – 2015, data was unavailable in 238 metropolitan and 106 rural deliveries.

	<b>Metropolitan</b> n = 3233/3926 (82.3%)	<b>Rural</b> n = 693/3926 (17.7%)	<b>P-value</b>
<b>Diabetes status<sup>†</sup></b>			NC <sup>‡</sup>
<b>Type 1</b>	1145/3233 (35.4%)	272/693 (39.2%)	
<b>Type 2</b>	811/3233 (25.1%)	104/693 (15.0%)	
<b>Unclassified</b>	1277/3233 (39.5%)	317/693 (45.7%)	
<b>Age (years)</b>			<0.001
<20	19/3233 (0.6%)	13/693 (1.9%)	
20-24	172/3233 (5.3%)	79/693 (11.4%)	
25-29	669/3233 (20.7%)	168/693 (24.2%)	
30-34	1170/3233 (36.2%)	241/693 (34.8%)	
35-39	912/3233 (28.2%)	146/693 (21.1%)	
40-44	271/3233 (8.4%)	46/693 (6.6%)	
45+	20/3233 (0.6%)	0/693 (0.0%)	
<b>Parity</b>			0.001
<b>Primiparous</b>	1336/3233 (41.3%)	240/693 (34.6%)	
<b>Multiparous</b>	1897/3233 (58.7%)	453/693 (65.4%)	
<b>Previous C/S</b>	1001/1897 (52.8%)	242/453 (53.4%)	0.80
<b>BMI (kg/m<sup>2</sup>)<sup>§</sup></b>			0.047
≤25	610/1889 (32.3%)	113/428 (26.4%)	
25 – 30	534/1889 (28.3%)	125/428 (29.2%)	
>30	745/1889 (39.4%)	190/428 (44.4%)	
<b>Country of birth<sup>¶</sup></b>			<0.001
<b>Australia</b>	2076/3231 (64.2%)	633/693 (91.3%)	
<b>Not Australia</b>	1155/3231 (35.8%)	60/693 (8.7%)	
<b>Smoking status<sup>  </sup></b>			<0.001
<b>Smoker</b>	202/2276 (8.9%)	78/433 (18.0%)	
<b>Non – smoker</b>	2074/2276 (91.1%)	355/433 (82.0%)	
<b>Socioeconomic status quintile<sup>††</sup></b>			<0.001
<b>1 (most disadvantaged)</b>	464/2100 (22.1%)	121/331 (36.6%)	
<b>2</b>	410/2100 (19.5%)	94/331 (28.4%)	

3	442/2100 (21.1%)	61/331 (18.4%)	
4	424/2100 (20.2%)	38/331 (11.5%)	
5 (least disadvantaged)	360/2100 (17.1%)	17/331 (5.1%)	

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Table 2. Maternal and perinatal outcomes according to location of delivery

Data are presented as n (%) or median (IQR). C/S: caesarean section, LGA: large for gestational age, SGA: small for gestational age, NICU: neonatal intensive care unit, SCN: special care nursery, PPH: post-partum haemorrhage, ICU: intensive care unit, HDU: high dependency unit.

†P value calculated using Fisher's exact test.

‡Data unavailable in 2 metropolitan deliveries.

§Data unavailable in 1 rural and 4 metropolitan deliveries.

¶Data unavailable in 1 rural and 5 metropolitan deliveries.

||Data unavailable in 1 rural and 3 metropolitan deliveries.

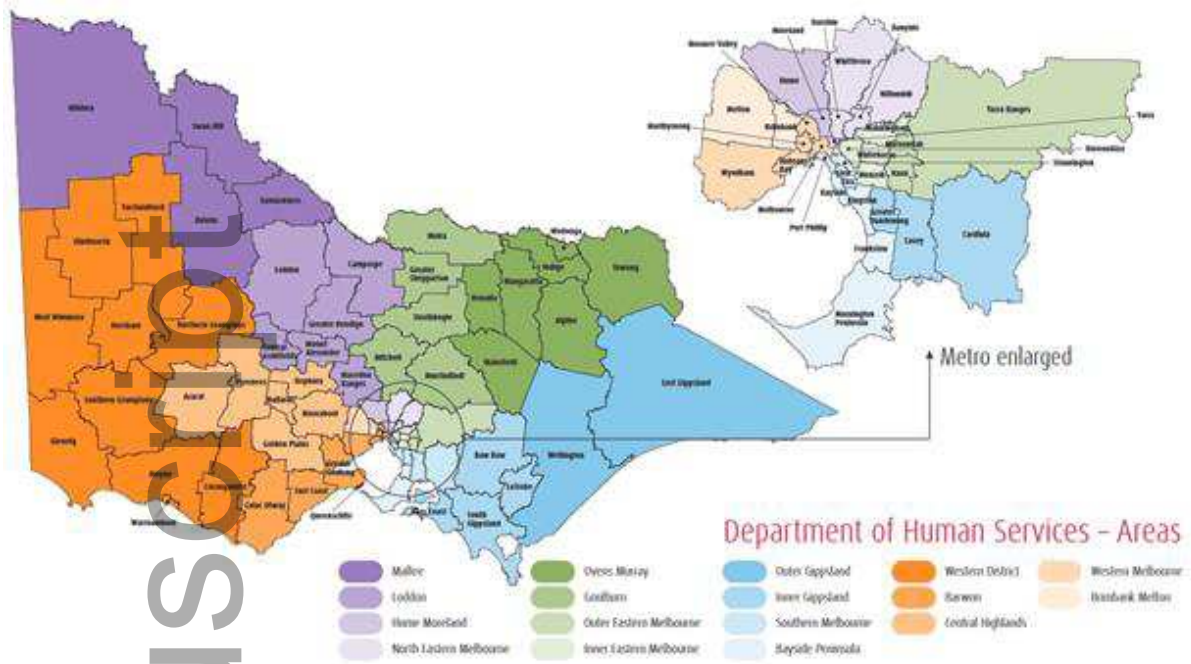
††Data unavailable in 24 rural and 33 metropolitan deliveries.

‡‡Data unavailable in 1 rural and 1 metropolitan delivery.

## Figures

Figure 1. Department of Human Services map of local government areas (9)

	<b>Metropolitan 3233/3926 (82.3%)</b>	<b>Rural 693/3926 (17.7%)</b>	<b>P-value</b>
<b>Stillbirth<sup>†</sup></b>	37/3233 (1.1%)	16/693 (2.3%)	0.03
<b>Neonatal death<sup>†</sup></b>	14/3233 (0.4%)	1/693 (0.1%)	0.49
<b>Gestational age (weeks)<sup>‡</sup></b>	38.0 (36.0 - 38.0)	37.0 (37.0 – 38.0)	0.19
<b>Preterm delivery<sup>‡</sup></b>	820/3231 (25.4%)	171/693 (24.7%)	0.70
<b>Very preterm delivery<sup>‡</sup></b>	252/3231 (7.8%)	26/693 (3.8%)	<0.001
<b>Mode of delivery</b>			
<b>Unassisted vaginal delivery</b>	892/3233 (27.6%)	194/693 (28.0%)	0.83
<b>Instrumental delivery</b>	312/3233 (9.7%)	68/693 (9.8%)	0.90
<b>Elective C/S</b>	1082/3233 (33.5%)	265/693 (38.2%)	0.02
<b>Emergency C/S</b>	947/3233 (29.3%)	166/693 (24.0%)	0.005
<b>Total C/S</b>	2029/3233 (62.8%)	431/693 (62.2%)	0.78
<b>Induction</b>	1150/2151 (53.5%)	239/428 (55.8%)	0.37
<b>Birth weight (grams)<sup>§</sup></b>	3390 (2974 – 3810)	3542 (3094 – 4043)	<0.001
<b>LGA&gt;90<sup>th</sup> centile<sup>¶</sup></b>	1083/3228 (33.6%)	304/692 (43.9%)	<0.001
<b>LGA &gt;95<sup>th</sup> centile<sup>¶</sup></b>	766/3228 (23.7%)	246/692 (35.5%)	<0.001
<b>SGA<sup>¶</sup></b>	186/3228 (5.8%)	25/692 (3.6%)	0.02
<b>Macrosomia<sup>§</sup></b>	544/3229 (16.9%)	179/692 (25.9%)	<0.001
<b>Shoulder dystocia</b>	76/2151 (3.5%)	36/428 (8.4%)	<0.001
<b>Apgar score &lt;7 at 5 mins<sup>  </sup></b>	162/3230 (5.0%)	37/692 (5.3%)	0.72
<b>NICU/SCN admission<sup>††</sup></b>	1897/3200 (59.3%)	490/669 (73.2%)	<0.001
<b>PPH</b>	857/3233 (26.5%)	206/693 (29.7%)	0.08
<b>Pre-eclampsia</b>	228/3233 (7.1%)	48/693 (6.9%)	0.91
<b>Maternal ICU/HDU admission<sup>††</sup></b>	123/3232 (3.8%)	26/692 (3.8%)	0.95



Enlarged area on the image represents metropolitan Victoria, elsewhere is classified as rural