Advising women with diabetes in pregnancy to express breast milk in late pregnancy (Diabetes and antenatal milk expressing [DAME]): a multi-site randomised controlled trial

### Denmark and Australia – some comparisons

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Denmark</th>
<th>Australia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population</td>
<td>5.8 million</td>
<td>25.6 million</td>
</tr>
<tr>
<td>Perinatal deaths per 1000 births</td>
<td>7.5</td>
<td>6.6 (Victoria)</td>
</tr>
<tr>
<td>Caesarean section births</td>
<td>21% (2015)</td>
<td>35% (2017)</td>
</tr>
<tr>
<td>Breastfeeding initiation</td>
<td>95%</td>
<td>96%</td>
</tr>
<tr>
<td>Breast milk feeding maintenance</td>
<td>11% (2009, exclusive bf)</td>
<td>61% (2010, any breastfeeding)</td>
</tr>
</tbody>
</table>
Types of breastfeeding studies we do

Epidemiological studies (e.g. using routinely collected data)

Randomised controlled trials: ABFAB, SILC, **DAME, RUBY**

Cohort studies: MILC, CASTLE

Case-control study: CAMEO

Cross-sectional surveys

Audits

Delphi studies

Focus groups, interviews

Case studies/series
Our breastfeeding research team

Professor Lisa Amir (General Practitioner, LC)
Professor Della Forster (midwife)
Professor Helen McLachlan (midwife)
Ms Anita Moorhead (midwife, LC, PhD candidate, DAME)
Ms Fiona McLardie-Hore (midwife, PhD candidate, RUBY)
Ms Heather Grimes (midwife, PhD candidate, RUBY)
Dr Meabh Cullinane (Research Fellow)
Dr Touran Shafiei (midwife, Research Fellow)
Dr Ranmali Rodrigo (neonatologist, PhD candidate)
Dr Helene Johns (midwife, LC)
Other higher degree candidates
Plan for today’s talks

Diabetes and Antenatal Milk Expressing (DAME)
Background and primary outcomes
Women’s views on expressing
Implications for practice, guidelines etc
Sub-study on lactogenesis

Telephone peer support for breastfeeding (RUBY)
Background and primary outcomes
Women’s views on receiving peer support
Women’s views on providing peer support

Overview of some of our other breastfeeding research (if time)
DAME research team

Della Forster
Lisa Amir
Anita Moorhead

Kerri McEgan
Gillian Opie
Sue Walker
Cath McNamara

Sue Jacobs
Amanda Aylward
Peter Davis
Rachael Ford

Susan Donath (Murdoch Childrens Research Institute)
Lisa Gold (Deakin University)
The issue – why did we do the DAME trial? (1)

Widespread practice of advising women with diabetes in pregnancy to express breast milk during pregnancy

- Infants of women with diabetes in pregnancy at increased risk of low blood glucose levels

- Women with diabetes are at higher risk of delayed onset of lactation

THEREFORE

- Infants of women with diabetes are at high risk for needing supplementation
  → if infant’s blood glucose is low and mother unable to breastfeed or provide sufficient expressed breast milk
  ...infants given infant formula or IV glucose
The issue – why did we do the DAME trial? (2)

AT THE SAME TIME...

Exclusive breastfeeding strongly encouraged for women with diabetes in pregnancy

- Infants of women with diabetes have increased risk of developing diabetes
- Infants receiving formula have higher than average risk of developing diabetes
- Breast milk stabilises infant blood glucose more effectively than formula

FOR WOMEN

- Lactation helps regulate maternal metabolic control in long term
The issue

Increasing practice of advising women with diabetes in pregnancy to express breast milk during pregnancy

- encouraged in some consumer literature

In Australia

- 60% of lactation consultants teach antenatal expressing (Chapman 2013)

- 63% of maternity services recommend antenatal expressing (Forster et al 2011)
Evidence before DAME trial: two small pilot studies

Some suggestion of harm:
- Increased neonatal admissions to SCN/NICU (Forster et al 2011, Soltani et al 2012)
- Decreased mean gestation (Soltani et al 2012)

Some suggestion of benefit:
- Less formula use during hospital stay (Forster et al 2011)

“There is no high level evidence about the potential benefits and harms of the expression and storage of breast milk during pregnancy by women with diabetes.”

Primary aim of DAME (Diabetes and Antenatal Milk Expressing)

To establish whether:

- the **practice of antenatal expressing** of colostrum from 36 weeks gestation
- for **women with diabetes in pregnancy**
- **increased the proportion of infants who require admission** to the special care nursery (SCN) or neonatal intensive care (NICU)
- **compared with** the infants of similar women receiving standard care
Secondary aims

To determine whether antenatal expressing:

- *decreased* the mean gestation at birth (*i.e. negative outcome*)

- *increased* the proportion of infants receiving *exclusive breast milk during initial hospital stay* (*i.e. positive outcome*)

- *increased* the proportion of infants receiving *exclusive breast milk at three months of age* (*i.e. positive outcome*)
We also:

Explored the views and experiences of women

Tested cost and cost-effectiveness

Collected data on other outcomes:

- fetal wellbeing associated with expressing;
- volumes of antenatal colostrum obtained;
- time to onset of lactogenesis II (milk ‘coming in’);
Methods

Two arm, multi-site, randomised controlled trial
Stratified by parity (first baby or not), diabetes type, site

<table>
<thead>
<tr>
<th>SITES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mercy Hospital for Women</td>
</tr>
<tr>
<td>Monash Medical Centre</td>
</tr>
<tr>
<td>Royal Women's Hospital</td>
</tr>
<tr>
<td>- Parkville</td>
</tr>
<tr>
<td>- Sandringham</td>
</tr>
<tr>
<td>Barwon Health</td>
</tr>
<tr>
<td>Peninsula Health</td>
</tr>
</tbody>
</table>
Inclusion criteria

Any woman:

(1) with pre-existing or gestational diabetes

(2) between 34 and 36 completed weeks gestation (i.e. up to 37+0 weeks) ...BUT only randomised from 36 weeks

(3) with a singleton pregnancy in a cephalic presentation

(4) attending a study site for pregnancy care as a public patient

(5) planning to breastfeed

(6) able to speak English
Exclusion criteria

Women with:

(1) antepartum haemorrhage or placenta praevia in current pregnancy

(2) more than one lower segment caesarean section or unknown or classical caesarean section

(3) any suspicion of fetal compromise e.g.
   - known or suspected intrauterine growth restriction
   - documented macrosomia > 97th percentile
   - polyhydramnios
   - any abnormal tests of fetal well-being

(4) a known fetal anomaly that would affect the outcome
The intervention

Women randomised to the intervention:

→ Received all standard advice and care (guided by the existing hospital protocols)

→ Taught how to hand express colostrum

→ Encouraged to express twice daily for no more than ten minutes, until being admitted to hospital
  
  ▪ unless any concerns arose that indicated intervention should cease

→ Provided with written and verbal instructions on safe storage and transportation of colostrum
Standard care

All women seen by (or could access) Diabetes Educator for management of diabetes

All women had (or could access) breastfeeding advice from midwives during pregnancy

Lactation consultants were on staff at all sites

During the trial none of the trial sites recommended that women with diabetes in pregnancy express colostrum in the antenatal period
After the birth

Women brought their frozen expressed milk with them to hospital **only to be used if required**

All babies had hypoglycaemia management using **standard guidelines** for infants of mothers with diabetes

EXCEPT babies in the trial (both standard and intervention) were requested to have only **true blood glucose measurements performed**
Sample size

Our sample size of 658 allowed for 5% loss to follow-up, i.e. providing 625 women for the primary outcome measure admission to SCN or NICU.

We wanted to be able to not miss an increase in the proportion of infants admitted to SCN or NICU in primary hospital admission following birth from estimated 17% in control group to 27% in intervention group.

This provided 85% power, 95% confidence.
Data collection

**Demographic data:**
- questionnaire at recruitment, before randomisation

**Obstetric/neonatal medical outcomes:**
- from medical record following the birth

**Other outcome data:**
- collected by telephone interview at 2 and 12 weeks postpartum

**Economic evaluation:**
- data collected from medical record and women's self-reported use of health care and resources by 12 weeks

Women in intervention arm completed an expressing diary
For more information on methods: trial protocol

BMJ Open

Obstetrics and gynaecology

Safety and efficacy of antenatal milk expressing for women with diabetes in pregnancy: protocol for a randomised controlled trial

Della A Forster1,2, Susan Jacobs2,3,4, Lisa H Amir1, Peter Davis2, Susan P Walker4,5, Kerri McEgan5, Gillian Opie4,5, Susan M Donath6, Anita M Moorhead1,2, Rachael Ford1,2, Catharine McNamara5, Amanda Aylward2, Lisa Gold7
6565 patients assessed for eligibility

3972 Excluded
1004 Obstetric risk
856 Not English-speaking
722 Fetal risk
299 > 37w at identification
161 Twins
157 Not planning to breastfeed
145 Birth before approach
122 Medical reason
33 In trial already
473 Other – private pt., moving away

381 missed (woman or research staff unavailable)

2593 eligible

2212 eligible & approached

777 recruited

635 randomised

319 allocated to intervention

316 allocated to control

1 post-randomisation exclusion
1 post-randomisation withdrawal

1 post-birth withdrawal

232 diaries returned

317 births

315 births

305 two week follow-up

297 two week follow-up

286 three month follow-up

285 three month follow-up

1 post-randomisation withdrawal

319 births

315 births

305 two week follow-up

297 two week follow-up

286 three month follow-up

285 three month follow-up
<table>
<thead>
<tr>
<th>Participant characteristics (1)</th>
<th>Intervention (n=317)</th>
<th>Control (n=315)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>Maternal age (mean (sd), n=316/315)</td>
<td>33.1</td>
<td>(4.7)</td>
</tr>
<tr>
<td>Degree or higher</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>207</td>
<td>65</td>
</tr>
<tr>
<td>Household income pre-tax ($AUS) (n=293/287)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Less than $1400/week (lowest 2 centiles)</td>
<td>126</td>
<td>40</td>
</tr>
<tr>
<td>Pension or benefit (n=315/314)</td>
<td>19</td>
<td>6</td>
</tr>
<tr>
<td>Born in Australia</td>
<td>133</td>
<td>42</td>
</tr>
<tr>
<td>English first language (n=317/314)</td>
<td>187</td>
<td>59</td>
</tr>
<tr>
<td>Smoked pre-pregnancy</td>
<td>40</td>
<td>13</td>
</tr>
<tr>
<td>Maternal BMI pre-pregnancy (n=304/298)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Underweight (&lt; 18.5)</td>
<td>10</td>
<td>3</td>
</tr>
<tr>
<td><strong>Normal range (18.5 – 24.99)</strong></td>
<td>155</td>
<td>51</td>
</tr>
<tr>
<td>Overweight (25 – 29.99)</td>
<td>71</td>
<td>23</td>
</tr>
<tr>
<td>Obese (≥ 30)</td>
<td>68</td>
<td>22</td>
</tr>
</tbody>
</table>
## Participant characteristics (2)

<table>
<thead>
<tr>
<th></th>
<th>Intervention (n=317)</th>
<th>Control (n=315)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td><strong>Type of diabetes</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type 1</td>
<td>8</td>
<td>3</td>
</tr>
<tr>
<td>Type 2</td>
<td>14</td>
<td>4</td>
</tr>
<tr>
<td>Gestational</td>
<td>295</td>
<td>93</td>
</tr>
<tr>
<td><strong>Recruitment gestation (mean (sd))</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>35.8</td>
<td>(sd 1.0)</td>
</tr>
<tr>
<td><strong>Randomisation gestation (mean (sd))</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>36.9</td>
<td>(sd 0.4)</td>
</tr>
<tr>
<td><strong>Randomisation to birth, days (mean (sd), n=314/315)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>18.1</td>
<td>(sd 7.0)</td>
</tr>
<tr>
<td><strong>First baby</strong></td>
<td>185</td>
<td>58</td>
</tr>
<tr>
<td><strong>Plan to breastfeed ≥ six months</strong></td>
<td>245</td>
<td>77</td>
</tr>
</tbody>
</table>
Ensuring fetal wellbeing

Pre-randomisation cardiotocograph (CTG) to ensure reassuring trace

Women then randomised to intervention after CTG

→ taught expressing (with CTG monitoring during this and for 20 minutes after)

→ if women had subsequent CTG we asked that they express at that time (uterus may become more sensitive to the resultant oxytocin surge with advancing gestation)

We found no evidence of fetal compromise during these expressing episodes
<table>
<thead>
<tr>
<th>Frequency of expressing</th>
<th>Antenatal expressing group only (n=316)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Never expressed after randomisation</td>
<td>19 (6%)</td>
</tr>
<tr>
<td>2–5 times</td>
<td>25 (8%)</td>
</tr>
<tr>
<td>6–19 times</td>
<td>80 (25%)</td>
</tr>
<tr>
<td>≥20 times</td>
<td>134 (42%)</td>
</tr>
<tr>
<td>Expressed, but number of times unknown*</td>
<td>49 (16%)</td>
</tr>
<tr>
<td>Unknown</td>
<td>9 (3%)</td>
</tr>
</tbody>
</table>

**Expressing outcomes**

<table>
<thead>
<tr>
<th>Expressing episodes‡</th>
<th>20.0 (1–59, 9–33)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume expressed (mL)§</td>
<td>5.5 (0–905, 0–22)</td>
</tr>
</tbody>
</table>

**Maternal blood glucose concentration after expressing**

| Mean blood sugar concentration of first three measurements† (mmol/L) | 5.6 (1.0) |

Data are n (%), median (range, IQR), or mean (SD). *Data from 3-month interview. †Only 196 women recorded all three measurements. ‡n=258. §n=241.

**Table 2: Outcomes of antenatal expressing**
Dot-plot of volumes expressed (mls) – all women (n=241)
Dot-plot of women who expressed 0 to 200 mLs (n=238)
Dot-plot of women who expressed 0 to 100 mLs
(n=230)
Dot-plot of women who expressed 0 to 50 mLs
(n=210)
Dot-plot of women who expressed 0 to 1 mLs 
(n=82)
## Birth outcomes

<table>
<thead>
<tr>
<th></th>
<th>Intervention (n=317)</th>
<th>Control (n=315)</th>
<th>RR</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gestation at birth</strong></td>
<td><strong>38.6 (1.0)</strong></td>
<td><strong>38.7 (1.0)</strong></td>
<td>-0.05</td>
<td>-0.21, 0.10</td>
</tr>
<tr>
<td>(weeks - mean, (sd), mean diff)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Onset of labour</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spontaneous</td>
<td>84 27</td>
<td>86 27</td>
<td>(chi2 p val 0.92)</td>
<td></td>
</tr>
<tr>
<td>Induced</td>
<td>189 60</td>
<td>183 58</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No labour</td>
<td>44 14</td>
<td>46 15</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Epidural /spinal for labour analgesia (if laboured)</strong> (n=272/269)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caesarean birth</td>
<td>103 33</td>
<td>93 30</td>
<td>1.10</td>
<td>0.87, 1.39</td>
</tr>
<tr>
<td>Blood loss (mls – mean (sd), mean diff) (n=316/312)</td>
<td>455.6 339.5</td>
<td>429.9 381.2</td>
<td>-25.9</td>
<td>-82.67, 30.89</td>
</tr>
</tbody>
</table>
# Neonatal outcomes (1)

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Intervention (n=314)</th>
<th>Control (n=315)</th>
<th>Adj. RR *</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n %</td>
<td>n %</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preterm (&lt; 37 weeks)</td>
<td>5 2</td>
<td>1 0.3</td>
<td>4.61</td>
<td>0.53, 39.92</td>
</tr>
<tr>
<td>Birthweight (grams - mean, (sd), mean diff)</td>
<td>3325 (420)</td>
<td>3338 (421)</td>
<td>-1.12</td>
<td>-63.03, 64.76</td>
</tr>
<tr>
<td>Birthweight &lt; 2500 grams</td>
<td>7 2</td>
<td>3 1</td>
<td>2.13</td>
<td>0.55, 8.19</td>
</tr>
<tr>
<td>Apgar &lt; 7 at 5 minutes</td>
<td>7 2</td>
<td>8 3</td>
<td>0.92</td>
<td>0.34, 2.54</td>
</tr>
</tbody>
</table>

*Adjusted for diabetes type (gestational or not), parity (first baby or not), education (degree or not), maternal age
Neonatal outcomes (2)

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Intervention (n=314)</th>
<th>Control (n=315)</th>
<th>Mean diff.</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Time until 3 consecutive BGLs ≥ 2.6 mmol/l (hours)</strong></td>
<td>12.7 (5.2)</td>
<td>13.2 (6.5)</td>
<td>-0.49</td>
<td>-1.48, 0.51</td>
</tr>
<tr>
<td><strong>Length of hospital stay (hours)</strong></td>
<td>70.9 (56.4)</td>
<td>72.1 (54.9)</td>
<td>-1.19</td>
<td>-9.99, 7.51</td>
</tr>
</tbody>
</table>
**Primary outcome – admission to SCN and/or NICU**

<table>
<thead>
<tr>
<th>Intervention (n=317)</th>
<th>Control (n=315)</th>
<th>Adj. RR*</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>n %</td>
<td>n %</td>
<td></td>
<td></td>
</tr>
<tr>
<td>46 14.5</td>
<td>44 14.0</td>
<td>1.06</td>
<td>0.66, 1.46</td>
</tr>
</tbody>
</table>

* Adjusted for diabetes type (gestational or not), parity (first baby or not), education (degree or not), maternal age

No difference in any other neonatal clinical outcome
<table>
<thead>
<tr>
<th>Reason (* Could have more than one reason so adds to more than 100%)</th>
<th>Intervention (n=45)</th>
<th>Control (n=44)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>Hypoglycaemia</td>
<td>21</td>
<td>46.7</td>
</tr>
<tr>
<td>Suspected infection</td>
<td>19</td>
<td>42.2</td>
</tr>
<tr>
<td>Respiratory distress</td>
<td>11</td>
<td>24.4</td>
</tr>
<tr>
<td>Hypothermia</td>
<td>4</td>
<td>10.1</td>
</tr>
<tr>
<td>Depression at birth requiring admission</td>
<td>3</td>
<td>6.7</td>
</tr>
<tr>
<td>Jaundice</td>
<td>3</td>
<td>6.7</td>
</tr>
<tr>
<td>Weight loss/ poor feeding</td>
<td>1</td>
<td>2.2</td>
</tr>
<tr>
<td>Preterm</td>
<td>2</td>
<td>4.4</td>
</tr>
<tr>
<td>Low birthweight or clinically wasted</td>
<td>2</td>
<td>4.4</td>
</tr>
<tr>
<td>Macrosomia (90th Centile)</td>
<td>0</td>
<td>-</td>
</tr>
<tr>
<td>Poor maternal diabetic control</td>
<td>0</td>
<td>-</td>
</tr>
<tr>
<td>Other</td>
<td>16</td>
<td>35.6</td>
</tr>
</tbody>
</table>
Treatment for hypoglycaemia
(for all babies recorded as having hypoglycaemia)

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Intervention (n=132)</th>
<th>Control (n=143)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%*</td>
</tr>
<tr>
<td>Fed with extra breastfeed</td>
<td>48</td>
<td>36.4</td>
</tr>
<tr>
<td>Fed with extra EBM</td>
<td>84</td>
<td>63.6</td>
</tr>
<tr>
<td>Fed with formula</td>
<td>60</td>
<td>45.5</td>
</tr>
<tr>
<td>IV glucose</td>
<td>14</td>
<td>10.6</td>
</tr>
<tr>
<td>Glucagon</td>
<td>0</td>
<td>-</td>
</tr>
<tr>
<td>Hydrocortisone</td>
<td>0</td>
<td>-</td>
</tr>
<tr>
<td>Diazoxide</td>
<td>0</td>
<td>-</td>
</tr>
</tbody>
</table>

* Could have more than one reason so adds to more than 100%
## Infant feeding in hospital

<table>
<thead>
<tr>
<th>Infant feeding type</th>
<th>Intervention (n=314)</th>
<th>Control (n=314)</th>
<th>Adj. RR*</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>Exclusive breast milk feeding first 24 hours (n=314/314)</td>
<td>217</td>
<td>69</td>
<td>188</td>
<td>60</td>
</tr>
<tr>
<td>Exclusive breast milk feeding birth to discharge (or to 7 days if still inpatient) (n=314/315)</td>
<td>178</td>
<td>57</td>
<td>154</td>
<td>50</td>
</tr>
</tbody>
</table>

*Adjusted for parity, diabetes type, education, age and breastfeeding intention (plan to breastfeed for six months or more vs not)
(NB: only 13 babies stayed over 7 days)
## Infant feeding at three months

<table>
<thead>
<tr>
<th>Infant feeding type</th>
<th>Intervention</th>
<th>Control</th>
<th>Adj. RR*</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>Exclusive breast milk feeding (n=284/286)</td>
<td>169</td>
<td>60</td>
<td>156</td>
<td>55</td>
</tr>
<tr>
<td>Any breast milk feeding (n=284/286)</td>
<td>235</td>
<td>83</td>
<td>233</td>
<td>82</td>
</tr>
</tbody>
</table>

*Adjusted for parity, diabetes type, education, age and breastfeeding intention (plan to breastfeeding for six months or more vs not)
Women’s comments

*You do have that sense that, is there any point in me doing this?*

[ID 1, GDM Diet, Exp x 27, 0 mls]

*S有时候我感觉有点低落，我不能表达。

[ID 2, GDM Insulin, Exp x16, 0 mls]

*Maybe the pump, would make a difference or something*

[ID 3, GDM insulin, Exp x 16, 2 ml]

*All that work to get all that milk and most of it got wasted…they were just forcing formula down his throat*

[ID 5, Type 2, Exp x 35, 34 mls]

*What is this crazy thing going on? (participant’s mother)*

[ID 3, Type 2, Exp x 11, 2 mls]

*I do get disappointed sometimes like that I might not have enough but after talking to my mum and other friends they were like you don’t have to worry, it normally comes after.*

[ID 7, GDM insulin, Exp x 25, 25 mls]
Women’s comments

I was quite proud about it [volume of milk]
[ID 4, GDM diet, Exp x 46, 57 mls]

I didn’t have any expectation that that anything might come
[ID 10, Type 1, Exp x 13, 0 mls]

I knew the technique [expressing] so it was much more easier for me [after birth]
[ID 3, Type 2, Exp x11, 2 mls]

It was gratifying like, you know, you can do it.
[ID 7, GDM Insulin, exp x25, 25mls]

I think it[ANE] is really worthwhile, especially if you are apprehensive about breastfeeding.
[ID 5, Type 2, Exp x 35, 34mls]

[?ANE again] try to start earlier to see if I can get anything out again.
[ ID 2, GDM Insulin, Exp x16, 0 mls]
Summary

70% of the women randomised to the intervention group expressed quite a number of times (mean 20 times)

Mean total volume of 24 ml but **median 5.5ml**

Outcomes:

- No difference in SCN/NICU admissions (or other infant outcomes)
- No difference in gestation at birth

Evidence of decreased formula use and increased breast milk exclusivity during primary hospital stay
A controversial trial ... A LOT of professional debate...

We were challenged (at conferences and in peer reviewed journals) that it is not ethical to trial this practice that ‘does not cause any harm’

Cox SG. An ethical dilemma: should recommending antenatal expressing and storage of colostrum continue? *Breastfeeding Review* 2010;18(3):5-7


We had many emails wanting information and trial results (including from Australia, Belgium, Canada, Finland, New Zealand, Netherlands, UK, and USA)
1998/1999 – first conversations about antenatal expressing at Mercy Hospital for Women (MHW)

2000 – started talking about pilot study at MHW

2007/2008 – recruited 43 women to pilot at MHW

2008 – first NHMRC application (breastfeeding primary outcome)

2009 – pilot paper published

2009 – second NHMRC application (breastfeeding primary outcome)

2010 – third NHMRC application (SCN/NICU admission primary outcome)

2011 – commenced recruitment

2015 – last DAME baby born in October

2017 – primary outcome paper published in Lancet
Exploring the views and experiences of women with diabetes in pregnancy in Australia who were advised to express breast milk antenatally, and implications for clinical practice

Anita Moorhead, Lisa Amir, Sharinne Crawford, Della Forster

**Not yet published, please do not share on social media**

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Aim - explore the views and experiences women in the intervention arm of the DAME trial

Anita Moorhead
DAME coordinator
PhD candidate
Previous research

Varied views and experiences from qualitative analyses:

- empowerment and security *(Brisbane, 2015)*
- confidence *(Demirci, 2019 & Brisbane, 2015)*
- embarrassment *(Brisbane, 2015)*
- pain, difficulty *(Brisbane, 2015)*
- implementation of the process and use of milk *(Demirci, 2019 & Casey, 2019)*
- perceived increased in intention to breastfeed, and benefits of expressing *(Demirci, 2019)*
- pressure to succeed, management and ownership of health *(Casey, 2019)*

Varied settings, cohorts and research designs:

- diabetes in pregnancy *(Casey, 2015)* or not *(Brisbane, 2015 & Demirci, 2019)*
- primiparous only *(Demirci, 2019)*
- cross-sectional study of acceptability of antenatal expressing (whether expressed in pregnancy or not) *(Fair, 2018)*
- volumes of breast milk not measured
- USA, Australia, UK
Methods (1)

Participants/inclusion criteria

• selected from two of the tertiary referral sites (highest recruitment of participants)

• purposive sampling for
  • diabetes type
  • parity
  • either high or low expressed milk volume in comparison to the mean of the DAME cohort (5.5mLs)
  • most recent births

When

• conducted March 2017 to January 2018

• data collection tool: interview guide developed

• interviews were semi-structured questions based on responses given at 2 week and 3 month interviews
Methods (2)

Data collection

• Face-to-face, one by ‘Zoom’ video conferencing
• Recorded on two devices
• Continued until data saturation reached
• Transcribed verbatim

Data analysis

• Read, re-read, checked for meaning
• Inductively coded into codes, categories and themes – as per Attride-Stirling, 2001 and Green, 2007
• Initially coded by AM
• Further coding with SC
• Following discussion with all the research team, agreeing to the final categories and themes


Discussion (1)

Consistent with other studies:

- Learning expressing gave some women confidence, empowerment and sense of achievement
- Some women found expressing awkward, embarrassing and painful
- Highly valued breast milk expressed regardless of volume – but wasting of milk and staff seeming to not value milk concerned women
- Diagnosis of diabetes is a shock and burden to manage especially if they have other caring responsibilities
- Breast milk is seen as ‘security’ but avoiding formula is not achieved by all
- Experienced feelings of futility when expressing no milk
Discussion (2)

New information:

- Volumes expressed were *not* directly proportional to confidence
- Cultural differences where there are traditional breastfeeding ‘experts’ within family
- Acknowledging the burden of diabetes in pregnancy for women in conjunction with potential burden of expressing
- Need for follow-up care after initial teaching of expressing before birth
So where to from here?

This is the first RCT testing this relatively widespread practice

Our results suggest there is no harm in advising women with diabetes in pregnancy who are ‘low risk’ to express breast milk from 36 weeks gestation, and evidence of benefit

These results cannot be extrapolated to high risk groups with diabetes in pregnancy nor to other high risk populations

An RCT exploring this practice in these groups is warranted if clinicians want to advise antenatal expressing to women.
Questions to consider...

What should we advise women who do not have diabetes or who have a higher risk pregnancy?

What is the impact on normal breastfeeding for women who want to express ‘just in case’?

Is there a risk that women will perceive that if they can’t express antenatally, they may not successfully breastfeed?

Is antenatal expressing appropriate for maternal and fetal conditions such as:

- poor breastfeeding history
- women with hypoplastic breasts or a history of breast surgery
- multiple birth or anticipated preterm birth
- fetal anomaly?
Implications for practice

Since completion of the DAME trial we have:

• Published primary outcome paper *(Lancet 2017)*

• Developed clinical guidelines that reflect current evidence (with multi-disciplinary input)

• Developed consumer information

• Had proactive discussions about antenatal expressing with women with diabetes in pregnancy

We are also working on further analysis and publication of the data.
Antenatal expressing for women who have diabetes during pregnancy

Key points
- Women who have diabetes during pregnancy who are at low risk of other complications can be advised to consider expressing breast milk by hand twice daily from 36 weeks of pregnancy
- Most but not all women are able to obtain milk when they express antenatally
- Antenatally expressed breast milk can be helpful in achieving exclusive breast milk feeding while in hospital. Breastfeeding and EBM is always the best food for babies before considering the use of infant formula
- Consumer fact sheet is embedded in this clinical guideline

1. Purpose
This clinical guideline provides advice for staff when recommending antenatal breast milk expressing for women with diabetes during pregnancy who are planning to give birth at The Women’s.

There is strong evidence of the short and long term health benefits of exclusive breastfeeding for all women who have diabetes and their babies [1, 2], however infants of women with diabetes during pregnancy are more likely to be given infant formula or glucose due to increased risk of infant hypoglycaemia.[3] Women with diabetes during pregnancy are at increased risk of delay in lactogenesis II (known as secretory activation) [6] and breastfeeding difficulties [4,5]. In some circumstances the woman may not be able to provide sufficient breastfeeding or expressed breast milk for her baby if infant hypoglycaemia occurs. Expressing breast milk antenatally may provide sufficient breast milk that can be used in addition to usual breastfeeding and freshly expressed breast milk to assist with hypoglycaemia management and may also lead to the reduction of infant formula use.

A recent study of low risk women with predominantly gestational diabetes during pregnancy (DAME trial) found that expressing from 36 weeks of pregnancy showed no harm (increase in premature birth or infant admission to special care nursery) and some benefit (an increase in the percentage of women exclusively breast feeding during their hospital stay). While the median volume of milk expressed was 5mls (total) 25% of women expressed nothing or less than one ml. [7] A smaller number of women in the study had pre-existing diabetes (Type 1 and 2) but due to smaller numbers of these women it is uncertain if all the results would apply equally for all diabetes types.

This guideline is related to the Breastfeeding policy at http://intranet.thewomens.org.au/BreastfeedingPolicy

2. Definitions
- Antenatal expressing – expressing breast milk by hand
- Antenatal colostrum is also called antenatal breast milk – in this document the term antenatal breast milk will be used

3. Responsibilities
Maternity staff – to be able to advise women with diabetes during pregnancy about antenatal expressing
Neonatal staff – to be aware of the possibility of antenatal milk being available to supplement breastfeeding in the postnatal period
Lactation consultant (LC) to provide breastfeeding advice to midwives, other staff and pregnant women

4. Guidelines
Antenatal expressing algorithm

- Woman has diabetes during pregnancy, is at least 36 weeks pregnant and intending to breastfeed

**Are there any concerns regarding?**
- Fetal growth or well-being, or a fetal anomaly (that affects fetal well-being),
- Fetal movements at 36 weeks
- Placental problems - e.g. insufficiency, praevia, acretal, percreta, increta
- Significant maternal comorbidities associated with pre-existing diabetes
- Pre-eclampsia, maternal hypertension and proteinuria with associated fetal concerns

**Has there been?**
- Previous classical CS or more than one LUSCS
- Bleeding in 2nd half of pregnancy
- Illicit drug use in pregnancy
- Severe maternal obstetric/medical issues that would affect fetal wellbeing
- Poly/oligohydramnios < 5% or > 95%
- Anticoagulation therapy > 36w

**If woman does not have diabetes or is not low risk and is still considering antenatal expressing discuss precautions and give fact sheet only**

Refer woman to midwifery teams for expressing instructions - advise expressing no more 5 minutes from each breast twice a day

Give woman expressing starter pack (kept in cupboard, clean store room, pregnancy clinics) - a plastic bag which contains an information sheet, syringes + caps.

Provide sheet of maternal UR labels for labelling milk. Instruct to record date and time of expressing on label and to use a fresh syringe each 24hrs.

- Discuss bringing frozen milk (if any) stored with an ice pack in a small esky to hospital at time of birth. Frozen milk will be stored in freezer in 4E milk room until needed after birth.
- Discuss best practice for initiating breastfeeding after birth especially for the woman with diabetes during pregnancy e.g. early and frequent skin-to-skin feeds and response to infant feeding cues, and management of hypoglycaemia if associated with antenatal expressing or breastfeeding
- Check woman’s expressing technique, need for more syringes or any questions she may have about expressing at subsequent appointments

Advise hospital attendance if: Regular contractions
Bright vaginal bleeding (not show)
Decreased fetal movement

Advise cessation of expressing if: Contraction with expressing
Frequent contractions (> 5 in 10 mins)
Prolonged contraction (> 1 min. during or ≤ 30’ after...
Appendix 2

Consumer Fact sheet: Antenatal breast milk expressing for women with diabetes during pregnancy

Antenatal breast milk expressing for women with diabetes during pregnancy

Why might I express breast milk (colostrum) before my baby is born?
Babies of mothers who have diabetes during pregnancy sometimes have low blood sugar levels soon after birth. Expressing breast milk from about 36 weeks of pregnancy might be a way to produce and store some milk to use if needed when your baby is born.

Should all women with diabetes during pregnancy express breast milk before birth?
Breastfeeding is highly recommended for you and your baby's health and breast milk blood sugar levels after birth. Because some pregnancies are more complicated we are only advising women with diabetes during pregnancy who are at low risk of complications to consider expressing while pregnant. Talk with your midwife or doctor to see if expressing breast milk during pregnancy is right for you.

When would I start expressing?
Express from 36 weeks of pregnancy after discussion with your midwife or doctor.
Expressing pack

Breastfeeding service volunteer (Maria), Anita Moorhead, and ward clerk (Tamzin). Packs for women made up by volunteer and ward clerk.
Antenatal breast milk expressing for women with diabetes during pregnancy

Why might I express breast milk (colostrum) before my baby is born?
Babies of mothers who have diabetes during pregnancy sometimes have low blood sugar levels soon after birth. Expressing breast milk from about 36 weeks of pregnancy might be a way to produce and store some milk to use if needed when your baby is born.

Should all women with diabetes during pregnancy express breast milk before birth?
For most women, expressing breast milk before birth is not necessary. However, if you are concerned about your baby’s health, you may wish to express milk. Your healthcare provider can help you decide if expressing milk is right for you.

For more information, or a copy of the guideline and fact sheet, contact Anita Moorhead. Email address: anita.moorhead@thewomens.org.au
Conclusions
Although this review has found evidence of an association between women experiencing diabetes during pregnancy and delayed onset of lactation, the presence of many potential confounding factors needs to be acknowledged.

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RESEARCH MIDWIVES AND ASSISTANTS AND VOLUNTEERS:

STAFF AT RECRUITMENT SITES

DATA MONITORING COMMITTEE: Caroline Crowther, Caroline Homer, Kate Lee

SAFETY COMMITTEE: Rodney Hunt, Fiona Cullinane, Mary Anne Biro
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Please contact:

Professor Della Forster- Principal Investigator
D.forster@Latrobe.edu.au