

**Antenatal colostrum harvesting
for pregnant women with
diabetes in preparation
for breastfeeding**

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**Declaration Concerning Thesis Presented for
The Degree of Master of Midwifery**

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solemnly and sincerely declare, in relation to the thesis/dissertation entitled:

Antenatal Colostrum Harvesting for Diabetes in Pregnancy

(a) That this work was done by me, personally

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(b) The material has not previously been accepted in whole, or in part, for any other degree or diploma

Signature:.....

Date: 3rd December, 2011

Abstract

Purpose: During recent years the breastfeeding support offered to women with diabetes mellitus has been changing. In many hospitals women with diabetes have been recommended to express their colostrum antenatally for use in the newborn period in order to minimise the administration of cows' milk formula and promote full or exclusive breastfeeding. To date these changes have not been supported by research but rather anecdotal evidence. This pilot study is the beginning steps to providing some research based evidence around this practice. The purpose of this pilot study is to firstly explore the possibility that antenatal colostrum harvesting is achievable for women with diabetes in pregnancy. Secondly to examine the feasibility of mothers and core midwifery staff using banked colostrum in the hospital setting as part of the care of babies with hypoglycaemia. The tools and processes used in this pilot study are assessed for their suitability for use in a larger study powered to provide statistically significant results.

Method: Ten participants were recruited from Christchurch Women's Hospital Maternity Outpatients Department. Participants were taught colostrum expression techniques and then asked to record episodes and volumes of antenatal colostrum harvesting from 34 weeks gestation. Birth and postnatal data was collected from hospital records. Breastfeeding information was collected from a telephone interview between eight and ten days postpartum, and women completed a participant satisfaction survey, at two weeks postpartum. These data were analysed quantitatively and common themes were extracted from the satisfaction survey comments.

Results: No statistical tests were applied to this data as it was a small pilot study with no control group. This pilot study demonstrated that these women were able to harvest, store and transport their colostrum safely for use in the hospital setting. The results were less compelling with respect to the hospital processes around using the colostrum for hypoglycaemic infants. However some of the study participants supplemented their babies with their banked colostrum indicating that it was accessible.

Conclusion: The tools and processes were used successfully in this pilot study suggesting it would be feasible to conduct a larger study to determine whether or not antenatal colostrum harvesting and banking facilitates exclusive or full breastfeeding for women with diabetes. Further study is need in this area to provide evidence for an existing practice which may have positive outcomes for mothers with diabetes and their babies.



Lily Jane Edward
(First grandchild to Catherine & Kees Rietveld)

Photographer: Catherine Rietveld

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I wish to acknowledge that the breastfeeding experiences of those reading this thesis will be varied. The information you are about to read about breastfeeding and colostrum harvesting is an academic study and is presented objectively. It is not intended to be judgemental or critical of any reader's personal experiences with breastfeeding.

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Glossary of Terms

Artificial feeding	The infant has had no breastmilk but has had alternative liquid such as infant formula with or without solid food in the past 48 hours.
Beta Cells	Insulin producing cells within the cluster of pancreatic endocrine cells called Islets of Langerhans.
Breastfeeding – Exclusive	The infant has never, to the mother’s knowledge, had any water, formula or other liquid or solid food. Only breastmilk, from the breast or expressed, and prescribed medicines* have been given from birth. *Prescribed as per the Medicines Act 1981.
Breastfeeding – Fully	The infant has taken breastmilk only, no other liquids or solids except a minimal amount of water or prescribed medicines, in the past 48 hours.
Breastfeeding – Partial	The infant has taken some breastmilk and some infant formula or other solid food in the past 48 hours.
Colostrum	The first secretion from the breast and can be observed during the second trimester.
Diabetes	Throughout this thesis wherever the word diabetes is used it implies all forms of diabetes mellitus.
Diabetes Mellitus – Type 1	A disease of the pancreas in which the body’s immune system has destroyed the beta cells that produce insulin.
Diabetes Mellitus – Type 2	A condition, usually aggravated by obesity, in which the beta cells of the pancreas produce insulin but the

body is unable to use it effectively because the cells of the body are resistant to the action of insulin.

Diabetes Mellitus - Gestational	Glucose intolerance which is first diagnosed during pregnancy and resolves after birth although it is associated with an increased risk of developing Type 2 diabetes mellitus later in life.
Expressing	The action of extracting colostrum from the breast either by hand or with a breast pump.
Hyperinsulinaemia	High levels of blood insulin.
Hypoglycaemia	Low levels of blood glucose.
Insulin	A protein hormone secreted by the beta cells of the pancreas. It functions to regulate the metabolism of carbohydrates and fats principally the conversion of glucose to glycogen, lowering the circulating blood glucose level.
Islets of Langerhans	Clusters of pancreatic endocrine cells including beta cells which produce insulin.
Lactation	The process of milk production from the breast or mammary gland.
Lactogenesis I	The stage of human breast development which is characterised by the proliferation and maturation of the breast tissue in preparation for milk synthesis. Colostrum may exude during this phase.
Lactogenesis II	The secretory phase of human breast development which occurs 30 – 40 hours post-partum and requires the withdrawal of progesterone and the presence of

insulin, oxytocin, prolactin and hydrocortisone. This phase heralds the onset of copious milk production.

Lead Maternity Carer (LMC)	The health professional, usually a registered midwife but could be a general practitioner or obstetrician, who takes full responsibility for the pregnancy, labour, birth and post natal care of a woman and her baby.
Multiparous	Women who have previously given birth to one or more babies.
Normoglycaemic	A blood glucose level in the normal range.
Nulliparous	Women who have not yet given birth to a baby.

Chapter Overview

Chapter 1 - Context and significance

In the first chapter the historical context and significance of research into antenatal colostrum harvesting is explored.

Chapter 2 - Literature Review

This chapter reviews the literature which informs and underpins the research into antenatal colostrum harvesting for pregnant women with Type 1 diabetes mellitus (Type 1 DM), Type 2 diabetes mellitus (Type 2 DM) or gestational diabetes mellitus (GDM). It highlights the lack of current research into the area of antenatal colostrum harvesting.

Chapter 3 – Methodology

Chapter three provides a rationale for utilising a pilot study for this research into antenatal colostrum harvesting. It also explains the methodology, data collection and analysis.

Chapter 4 – Results

In chapter four the results of this study are presented.

Chapter 5 - Discussion & Conclusion

The final chapter discusses the results in the context of the published literature and looks at the limitations and achievements of this study. It poses questions which could provide the impetus for further research which may inform midwifery and medical practice with respect to the care of breastfeeding women and babies affected by diabetes.

Chapter One – Context and Significance

1.1 Introduction

Pivotal to the continuation of the human species over several millennia has been the ability of the women to breastfeed successfully (World Alliance for Breastfeeding Action, 2006). *Homo sapiens* or human beings are mammals. The Oxford Dictionary definition of the animal class of mammals is “having mammae [breasts] for nourishment of the young” (1976). Human beings are the only species in the family of over four thousand mammals who require breastfeeding education and support. Part of the reason for this exception could be that all mammals, except humans, who are raising their young in their natural habitat, have no alternative but to suckle their young (Deshmukh, 2002). All mammalian females produce colostrum as the initial nourishment for the newborn and the situation is no different for the human female. Colostrum is the species specific, antibody rich, first food consumed by all mammals. Colostrum begins to be produced by the human breast in the second trimester. Secretory Immunoglobulin A (SIgA), which is a predominant antibody in colostrum, provides protection against pathogenic invasion across the mucous membranes of the respiratory and gastro-intestinal tract (Baumslag & Michels, 1995; Hanson, 2004). Breastfeeding may be considered a fundamental human right (Ball, 2010). However there may be challenges to breastfeeding for babies born to women with diabetes mellitus (Type 1 DM, Type 2 DM, or gestational DM) who frequently experience hypoglycaemia.

Currently at Christchurch Women’s Hospital (CWH), in accordance with the Canterbury District Health Board’s written policy for the management of neonatal hypoglycaemia, infants born to mothers with Type 1 DM, Type 2 DM or GDM are very likely to receive cows’ milk supplements as a treatment for hypoglycaemia (Austin, 2008). This is at odds with Step Six of the World Health Organisations “Ten Steps to Successful Breastfeeding” which states: “Give newborn infants no food or drink other than breast milk, unless medically indicated” (World Health Organisation, 2009).

Anecdotal evidence collected from a number of Canterbury, New Zealand women with diabetes who have voluntarily collected their colostrum suggests that antenatal colostrum harvesting may increase the amount of colostrum that a mother has available at birth. It also suggests that it might have decreased the need for babies born to mothers with diabetes to receive supplementary feeding with cows’ milk formula or other breastmilk substitutes. This is supported by a 2009 study which analysed the effect of antenatal breast expression and found that antenatal expression of breastmilk [colostrum] led to an

increased amount of milk available at birth and an increase in exclusive breastfeeding (Singh, Chouhan & Sidhu, 2009).

The aim of this study is to firstly explore the possibility that antenatal colostrum harvesting is achievable for women with DM in pregnancy. Secondly to examine the feasibility of mothers and core midwifery staff using banked colostrum in the hospital setting as part of the care of babies with hypoglycaemia.

1.2 Context and Significance of Conducting this Research

In 2007, Lindsay Irons, Midwife Diabetes Educator at Christchurch Women's Hospital gave me an article to read. The article, written by Sue Cox, an Australian lactation consultant, is entitled "Expressing and storing colostrum antenatally for use in the newborn period" published in "Breast Feeding Review" (Cox, 2006). After reading the article, Lindsay and I discussed exploring the concept of antenatal colostrum harvesting for women with diabetes in pregnancy. The first part of my journey as a researcher was to produce the brochure "Diabetes Mellitus in Pregnancy & Colostrum Harvesting in Preparation for Breastfeeding" (Appendix 1). I started sharing my ideas with pregnant women who had diabetes and found that a number of these women were able to express and store their colostrum. Most of their babies were cared for without needing cows' milk formula supplementation. This anecdotal evidence led to the current proposal to conduct formal research into this topic.

1.3 Rationale Underpinning Antenatal Colostrum Harvesting Research

The philosophy which underpins this research into antenatal colostrum harvesting is the widely accepted tenet that human milk is the optimal first food for all newborn babies (Hanson, 2004; World Health Organisation, 2009). Exclusive or full breastfeeding is accepted widely by a range of health professionals as the gold standard for infant nutrition for the first six months life (World Health Organisation, 2001; 2009). It is suggested that every effort should be made, by health professionals who care for mothers and babies, to enable the newborn baby to breastfeed early irrespective of the mode of birth (Duijts, Jaddoe, Hoffman & Moll, 2010; Singh et al., 2009).

The New Zealand Ministry of Health definitions of breastfeeding were developed in 1999 and provide clear and consistent definitions of breastfeeding (Coubrough, 1999). They are used in the Canterbury District Health Board policies and documents and for this reason they have been used in this study. Exclusively breastfed infants have by definition never been administered any water, formula or other liquid or solid food, only breastmilk, from the breast or expressed and prescribed medicines have been given from birth

(Coubrough, 1999). Fully breastfed infants have been fed breastmilk only, no other liquids or solids except a minimal amount of water or prescribed medicines, in the previous 48 hours (Coubrough, 1999). It is suggested that babies born to mothers with Type 1 DM, Type 2 DM or GDM are entitled to that same level of protection but are frequently denied the opportunity to be exclusively or fully breastfed (Taylor, Kacmar, Nothnagle & Lawrence, 2005). This is because these babies often develop hypoglycaemia which is corrected with supplementary feeds of cows' milk formula when insufficient colostrum is available.

Antenatal colostrum harvesting may provide a mechanism for an appropriate intervention for mothers and babies faced with breastfeeding challenges as a result of diabetes. Supplementing hypoglycaemic babies with freshly expressed or banked colostrum may avert the need to expose vulnerable babies to cows' milk formula. It is probable that harvested colostrum is a more appropriate supplement for babies who are clinically hypoglycaemic than cows' milk formula (Oscroft, 2001; Riordan, 2005). Encouraging antenatal colostrum harvesting and banking among women with diabetes has the potential to facilitate exclusive or full breastfeeding. Women and babies who are not facing health challenges, such as diabetes are physiologically equipped for breastfeeding without the need of any supplementary feeding (Hartwell, 2001). Antenatal colostrum harvesting is an intervention strategy which is only intended to be employed by mothers who are anticipating breastfeeding complications as may be the case for women with diabetes.

1.4 What is Already Written about Antenatal Colostrum Harvesting?

In 2006, Paul and his research team proposed that consideration needed to be given to the development of practical strategies which would facilitate successful breastfeeding and reduce maternal and neonatal morbidity amongst vulnerable populations (Paul, Lehman, Hollenbeak, & Maisels, 2006). Babies born to mothers with diabetes would be one such vulnerable group. Jackson, (2004) also considered that the naturally available protective factors conferred during breastfeeding should be taken more seriously with further research warranted in the development of Type 1 DM and the suggested links with the ingestion of cows' milk. Jackson states that "if the future of diabetes care is prevention, then further investigation into the possibility that breastfeeding has a preventative action is urgently required" (Jackson, 2004, p.164).

Delay in the onset of lactation has been noted to be a common occurrence in mothers with diabetes and this delay can be an impediment to successful breastfeeding for this group of mothers (Arthur, Kent & Hartmann, 1994; Arthur, Smith & Hartmann, 1989;

Chapman & Perez-Escamilla, 1999; Hartmann & Cregan, 2001). Hutt, (1989) recommended that further research should be conducted into ways to optimise lactation when the initiation of breastfeeding is impeded. Despite this recommendation there has been little research into the topic.

In the light of the concerns that have been raised by research regarding the delayed onset of lactogenesis in women with diabetes (Arthur et al., 1989; Arthur et al., 1994; Chapman & Perez-Escamilla, 1999; Hartmann & Cregan, 2001; Hutt, 1989; Jackson, 2004; Paul et al., 2006), it seemed that a study into antenatal colostrum harvesting, colostrum banking and colostrum supplementation for the vulnerable group of neonates influenced by diabetes, may lead to a useful intervention strategy. Thus the aim of this study was to pilot a study to determine the acceptability of antenatal colostrum harvesting and banking to women and the feasibility of administering it to hypoglycaemic babies in the hospital setting.

1.5 The Potential Risks and Benefits of Colostrum Harvesting

There is a currently inadequate documented knowledge about practical and safe ways to support, protect and promote breastfeeding among women with diabetes. Antenatal colostrum harvesting and colostrum banking may be a simple solution to a complex issue. Research is warranted which explores the potential benefits or otherwise of antenatal colostrum harvesting and colostrum banking.

In conclusion, there is sufficient compelling evidence with respect to the benefits of receiving colostrum and being exclusively or fully breastfed. However, for many reasons, babies born to mothers with DM may experience hypoglycaemia despite having been breastfed early. Colostrum supplementation with mothers' banked colostrum may be a useful intervention to protect exclusive or full breastfeeding for these babies.

Chapter Two – Literature Review

2.1 Search Results

This review is based on a thorough literature search of CINAHL and PubMed, using the terms antenatal, pre-natal, pre-birth, colostrum harvesting, colostrum collection, colostrum, breast milk, breastfeeding, lactation, lactogenesis, milk banking, gestational diabetes mellitus, Type 1 diabetes mellitus, or Type 2 diabetes mellitus. All identified papers were searched for relevant references or citations. The search was limited to human studies but no date or other limits were imposed.

While there are many animal studies published on colostrum very little research has been published which is directly concerned with human colostrum or antenatal colostrum harvesting. Only three articles were found which were directly concerned with antenatal colostrum harvesting and diabetes mellitus. Two of which were original research (Clay, 2005; Forster et al., 2011) and one was a review (Cox, 2006).

2.2 Introduction

The purpose of this literature review was to firstly examine historical and cultural aspects of colostrum and determine if these values are still relevant today. Strongly held beliefs about colostrum have the potential to influence any study that involves colostrum. Secondly it was to explore the current understanding of the physiology of lactogenesis and the benefits or otherwise of antenatal colostrum harvesting. Thirdly, to review what is current and accepted practice both in New Zealand and overseas, with respect to the care of neonates born to mothers with diabetes mellitus. Lastly, to identify any barriers that may exist to exclusive or full breastfeeding for mothers with any form of diabetes mellitus. These four points will lead to the rationale and aims of the study.

2.3 Colostrum and its Historical and Cultural Context

A 17th century British physician, Dr Etmueller, proposed in 1699 that newborn babies should be fed their own mother's colostrum from birth (Baumslag & Michels, 1995; Greiner, 1998). His recommendation was the polar opposite to the regular practice of purging newborn babies with substances like honey, butter, almond oil, rose water and herbs. Some of these customs continue in the present day. In the 17th century many newborns received breastmilk from surrogate mothers or wet nurses whilst their birth mother's expressed and discarded their colostrum until lactation was established (Baumslag & Michels, 1995; Odent, 2011). It appears that Etmueller's recommendation went unheeded, because in 1748 Dr William Cadogan once again recommended that

babies should receive their mother's colostrum believing that "the mother's first milk is purgative and cleanses the child of its long hoarded excrement; no child can be deprived of it without manifest injury" (Baumslag & Michels p.24, 1995; Odent, 2003). Cadogan's observation of the positive correlation between colostrum and infant health is highly commendable given that he would have been in direct opposition to his colleagues and the regular practice of the mothers of that era.

For thousands of years, humans from diverse cultures have avoided letting their babies ingest colostrum as they believed it to be toxic or even infectious and of no value to the newborn (Baumslag & Michels, 1995; Odent, 2011). Human beings are exclusive in the group of mammals in their deliberate avoidance of colostrum as first food for the baby (Baumslag & Michels, 1995; Odent, 2003). Odent considers that human colostrum can be regarded as a "symbol of the repression of instinctive forces" as it is commonplace for human babies to be deprived of it (2003, p. 77). Historically there has been a diverse and global aversion or indifference to colostrum; however the value of exclusive breastfeeding, and therefore by definition access to colostrum, is now widely recognised, at least in Western countries.

Whilst breastfeeding may be more commonly accepted as the "gold standard" for early infant nutrition there is still a degree of suspicion around colostrum. Whilst current New Zealand breastfeeding practice promotes the benefits of colostrum to the newborn baby this has not always been the case. It was commonplace for newborn babies to be given a pre-lacteal feed of lactose and water. This practice developed from the teachings of Dr Truby King, who founded the New Zealand Plunket Society. Whilst King was a staunch supporter of breastfeeding his recommendations are now regarded as having been disruptive to the natural establishment of lactation (World Alliance for Breastfeeding Action, 2006). King advocated allowing the mother to rest immediately after birth and that the baby be "put to the breast" for two or three minutes every six hours for the first 36 hours and then four hourly with a period of eight hours rest at night. If there were to be any changes to this regime then it would be decided by the doctor or maternity nurse (King, 1936).

King had created a paradox, on one hand he was exhorting women to breastfeed and on the other hand he was setting them up for failure by imposing a schedule of feeding that we now understand to be incompatible for the successful initiation of lactation. King stated that the "baby gets very little from the breasts at first" (King, 1936, p.63). King advised mothers that their milk may begin to come in on the third day but that it may be

delayed for a week or more and in this case the baby would require some supplementation until lactation was established.

It is therefore not surprising to learn that King manufactured the first commercially produced infant formula. Generations of New Zealand children have been “Plunket” babies and indeed there was some esteem attached to the title however King’s legacy of schedule feeding has clearly disturbed the establishment and continuance of lactation for generations of mothers and babies (World Alliance for Breastfeeding Action, 2006).

2.4 Physiology of Human Lactation

The foundations for human lactation are laid long before the newborn baby first suckles from his mother’s breast. Lactation is a gradual and progressive process which begins at puberty and culminates with breast involution after the cessation of breastfeeding. This next section deals with the physiology of lactation in pregnancy and in the postpartum period.

2.4.1 Lactogenesis

The preparation of the mammary glands, or breasts, for breastmilk production or lactation is called lactogenesis. There are two stages of lactogenesis: stages I and II. During lactogenesis I there is a proliferation and maturation of the breast tissue in preparation for milk synthesis. Lactogenesis II is the secretory phase of lactation which occurs at 30 – 40 hours postpartum. Lactogenesis II requires the withdrawal of progesterone, the presence of insulin, oxytocin, prolactin and hydrocortisone and is characterised by copious milk production (Chapman, 1998; Cregan, Mello, Hartmann, 2000; Hartmann & Cregan 2001, Neville & Morton 2001).

2.4.2 Benefits of Colostrum

Colostrum is the antibody rich first milk which begins being produced in the human breast in the second trimester of pregnancy. It is suggested that it perfectly satisfies the nutritional and immunological needs of the newborn in the first few days of life (Hanson, 2007; Nascimento & Issler, 2003). At birth the newborn gut does not contain any microbes but within 24 hours there is rapid colonisation of the skin and gut with micro-organisms from the mother and the environment with which the baby makes contact. Colonisation occurs through contact with vaginal and rectal secretions during vaginal birth, skin to skin contact with the mother at birth and early suckling from the breast. The mother will provide protection in her colostrum against pathogens that she has been exposed to and micro flora in her gut (Hanson, 2007; Odent, 2003). If there are potential pathogens in the mother’s gut then the mother will provide protection to her infant through the secretory

immunoglobulin A (SIgA) in her colostrum and breastmilk. This explains why breastfeeding mothers with diarrhoeal illnesses can protect their babies from disease. The transfer of the pathogen to the baby occurs as can be seen by the fact that the pathogen may be able to be cultured from the infants stool. SIgA binds to micro-organisms in the gut preventing them from attaching and entering the host through mucous membranes where they would replicate and cause manifest disease (Arifeen et al., 2001; Betran, Onis, Lauer & Villar, 2001; Hanson, 2004; Hanson, 2007; Marild, Hansson, Jodal, Oden, & Svedberg, 2004; Victora et al., 1987). Early breastfeeding promotes the colonisation of harmless micro-organisms which are vital to optimal gut health (Hanson, 2007).

Five to seven millilitres of colostrum are produced each feed for the first one to two days after birth (La L che League, 2007). The newborn stomach capacity is about seven to ten millilitres so this matches the low volume of colostrum (La L che League, 2007). Colostrum and breastmilk also contain carnitine, a protein essential for the mobilisation of lipids in the brown fat of the newborn. Brown fat mobilisation is critical for newborn temperature regulation (Riordan & Auuerbach, 1998; Takahashi & Sawaguchi, 1983 in Nascimento & Issler, 2003). It has been suggested that lactoferrin, a major milk protein in colostrum, kills or inactivates bacteria, viruses and fungi, such as candida albicans, without producing an energy consuming inflammatory response in the host (Farnaud & Evans, 2003; Hanson, 2004; Le n-Sicairos et al., 2006). The inflammatory response causes fever, lethargy and reduced appetite which are all undesirable symptoms in a newborn baby whose energy requirements are primarily required for thermo-regulation, tissue growth and repair (Hanson, 2004).

Colostrum also acts as a laxative promoting the timely passage of meconium. This reduces the incidence and severity of neonatal jaundice because the faster transit of meconium through the gut minimises the opportunity for bilirubin to be reabsorbed (Baumslag & Michels, 1995, Hartmann & Cregan, 2001; Odent, 2003). Colostrum is a “species specific” secretion which meets the physiological requirements of the human newborn as it adapts to extra-uterine life and exposure to microbes both harmful and helpful (Cox, 2004; Hanson, 2004; Riordan & Auuerbach, 1998).

2.4.3 Benefits of Breastfeeding and Having Been Breastfed

There is considerable evidence to support that there are immediate and life-long health benefits associated with breastfeeding, receiving colostrum at birth and continuing to be breastfed for between three and six months (Duijts et al., 2010; Hanson, 2004; Hanson 2007; Lawrence & Lawrence, 1999; Oddy, 2001; C sar, Victora, Barros, Santos & Flores, 1999; World Health Organisation, 2009).

There is evidence that babies who are exclusively breastfed have a lesser likelihood of suffering from acute diarrhoea, respiratory infections, otitis media, asthma, coeliac disease, Crohn's disease, ulcerative colitis, necrotising enterocolitis, botulism, urinary tract infections and some childhood cancers (Hanson, 2004; Lawrence & Lawrence, 1999; Oddy, 2001). Duijts and colleagues (2010) have demonstrated that exclusively breastfed infants have lower rates of upper and lower respiratory and gastro-intestinal infections in the first four months of life than those who had never been breastfed. Children who have not been breastfed are 17 times more likely to be admitted to hospital with pneumonia than their breastfeeding peers. The rate is even higher for infants under three month of age (César et al., 1999). The incidence of heart disease, juvenile rheumatoid arthritis, multiple sclerosis, osteoporosis, diabetes mellitus, obesity and sudden infant death syndrome are reduced in those people who have been breastfed (Hanson, 2004; Lawrence & Lawrence, 1999; Oddy, 2001).

Further evidence supports that women who have breastfed are less likely to develop epithelial ovarian cancer and breast cancer than those have not breastfed (Beral, 2002; Gwinn, Lee, Rhodes, Layde & Rubin, 1990). The development of Maternal Type 2 diabetes appears to be reduced in those women who breastfeed (Stuebe, Rich-Edwards, Willett, Manson & Michels, 2005). Exclusive breastfeeding is recommended for the first six months of life (World Health Organisation, 2009) and the American Diabetes Association recommends that women with GDM should be encouraged to breastfeed (American Diabetes Association, 2003).

2.5 Global Increase in Type 1 & Type 2 Diabetes Mellitus

Globally there is a diabetes epidemic and the situation in New Zealand seems to be similar (Joshy & Simmons, 2006; Ministry of Health 2002; Odent, 2011; Sela, Raz & Elchalal, 2009; Wild, Roglic, Anders, Sicree & King, 2004). There is also a worldwide increase in the prevalence of GDM and this includes New Zealand. The increase in GDM seems to parallel the prevalence of Type 2 DM in the general population (Sela et al., 2009). The life risk of being diagnosed in New Zealand with Type 2 DM in the decade 2001 – 2011 was calculated at being 17% for males and 14% for females. Based on multiple factors, including an increasing population size, an increasing age of that population and a projected 3% per annum rise in the obesity epidemic, the projection is for a 45% increase in new cases of Type 2 DM per year (Ministry of Health, 2007). Type 2 DM is characterised by insulin resistance and is linked to obesity (Stuebe et al., 2005; Taylor et al., 2005).

The global incidence of Type 1 DM has also increased over the past decades (Onkamo, Väänänen, Karvonen & Tuomilehto, 1999). It is considered that the rate of increase of Type 1 DM has been too rapid for the cause to be solely genetic so it is suggested that there are environmental factors which are contributing to the pathogenesis of Type 1 DM (Hyttinen, Kaprio, Kinnunen, Koskenvuo, & Tuomilehto, 2003).

2.5.1 Diabetes and Māori and Pacific Island Women

Early colonisation hazards for Māori were predominantly infectious diseases but from the mid-20th century onwards the profile of hazards changed to include, amongst other problems, obesity and diabetes (Cunningham et al., cited in Durie, 2003a). In his paper on key Māori health determinants, Durie considers that people should be enabled “to assert greater control over their own health including the management of disorders such as diabetes...and more importantly managing lifestyle so that avoidable disorders are actually avoided” (Durie, 2001b p.9). He also contends that strategies for disease avoidance should be afforded priority in disease prevention.

Māori and Pacific Island women have a higher chance of having DM diagnosed in pregnancy (Simmons et al., 2004). The prevalence of DM amongst Māori is two and a half times greater than that of the European population (Durie, 2001a). In 2008 the Nelson – Marlborough District Health Board reported Māori mortality related to DM as being six times greater than non-Māori (Nelson-Marlborough District Health Board, 2008). There is some evidence that exclusive or full breastfeeding for the first six months of life has been shown to be protective against the development of obesity which is a pre cursor to Type 2 diabetes (Arenz, Rückerl, Koletzko & Von Kries, 2004; Harder, Bergmann, Kallischnigg & Plagemann, 2005; Owen, Martin, Whincup, Davey Smith, Gillman & Cook, 2006).

2.5.2 Type 1 Diabetes Mellitus and the Suggested Cows’ Milk Link

A number of research studies have demonstrated that early exposure to bovine serum albumin, found in cows’ milk, may trigger an immune response predisposing to pancreatic damage and the development of Type 1 DM. The risk of developing Type 1 DM seems to be enhanced in those individuals with genetic predisposition or familial history of the disease (Alberti, 1993; Borch-Johnson, et al., 1984; Cavallo, Fava, Monetini, Barone & Pozilli, 1996; Karjalainen, et al., 1992; Mayer, Hamman, Gay, Lezotte, Savitz, & Klingensmith, 1988; Virtanen, et al., 1991; Vaarala, 2000).

Glatthar et al., report from a case-control study of 194 diabetic participants aged 5 – 14 years and 753 matched control participants that more diabetic participants than control participants were not breastfed. The odds ratio of not having been breastfed and being

diabetic was 1.40 (95% CI, 1.00 – 1.95; P=0.05) (Glatthaar, et al., 1988). Evidence from a case-control study, comprising 65 subjects and 390 controls, indicated infants who had been breastfed exclusively for at least four months had a lower risk of sero-conversion to islet cell antibody positivity (OR 0.24; 95% CI 0.06-0.94) than those who had been breastfed exclusively for less than two months i.e. breastfeeding for at least four months was protective against developing islet cell antibodies which is associated with the development of Type 1 DM. The authors concluded that “these observations suggest that short term breastfeeding and the early introduction of cows’ milk based infant formula predispose young children who are genetically susceptible to Type 1 diabetes to progressive signs of beta cell autoimmunity” (Kimpimiaki, et al., 2001, p.63).

Another study measured the antibody response to bovine β -casein in 28 healthy infants less than four months of age. Sixteen of these infants were exclusively breastfed and 12 were fed with cows’ milk. Elevated levels of β -casein were found in the formula fed infants compared to the breastfed infants ($p < 0.0001$). They also discovered that the β -casein antibody levels in 37 pre-pubertal children with Type 1 DM were considerably higher than the levels in 31 age-matched controls ($p = 0.03$). The researchers “confirmed specific binding to bovine β -casein in bottle fed infants, in children with Type 1 diabetes and in controls exposed to cows’ milk, but not in infants who were exclusively breastfed” (Monetini, et al., 2001, p. 51). It is acknowledged that both of these studies had very small sample sizes but the results suggest that exclusive breastfeeding rather than cows’ milk feeding within the first four months of life may prevent the generation of an antibody response to β -casein which is implicated in the development of Type 1 DM (Kimpimiaki et al., 2001; Monetini et al., 2001).

A German population-based case-control study of 760 subjects with newly diagnosed Type 1 DM and 1871 matched controls indicated that infant feeding type was associated with Type 1 DM risk and therefore considered that the disease was potentially preventable (Rosenbauer, Herzig & Giani, 2008).

2.5.3 Breastfeeding May Protect Infant from Developing Type 1 and Type 2 Diabetes

Some studies have shown breastfeeding to have an association with reduction of Type 2 DM, (Bergmann, et al., 2006; Pettit, Forman, Hanson, Knowler & Bennett, 1997), and obesity in later life (Arenz et al., 2004; Harder et al., 2005) but another study suggested that whilst initial breastfeeding protects against obesity in later life further research exploring the effects of confounders was needed (Owen, et al., 2005). It seems reasonable to suggest that if breastfeeding affords some protective effect against the

development of obesity, as was found in some studies, then by extension breastfeeding may also help prevent the incidence of Type 2 DM.

Several studies have suggested that to have been breastfed confers protection against the development of insulin dependent diabetes mellitus (Borch-Johnson et al., 1984; Cavallo et al., 1996; Glatthaar et al., 1988; Mayer et al., 1988; Virtanen et al., 1991). The clinical manifestation of Type 1 DM in an individual has multifactorial aetiology. The destruction of beta-cells leading to the development of Type 1 DM is thought to be dependent on interaction between genetic, environmental and immunological factors. It is suggested that risk factors for Type 1 DM may be to some extent modifiable hence reducing the incidence of the disease (Nerup, et al., 1974; Tuomilehto-Wolf & Tuomilehto, 1991; Rosenbauer et al., 2008). One such modifiable risk might be avoiding the ingestion of cows' milk in the first six months of life. Several studies have suggested that breastfeeding may confer protection against the development of Type 1 DM (Borch-Johnson et al., 1984; Cavallo, et al., 1996; Glatthaar et al., 1988; Mayer et al., 1988; Virtanen et al., 1991) obesity and Type 2 DM (Horta, Bahl, Martines & Victora, 2007; Owen et al., 2006).

One Finnish population based study (Virtanen et al., 1991) of 103 case-control pairs found a significant protective effect of exclusive breastfeeding for at least three months duration against the development of Type 1 DM (OR 0.33, CI 95% 0.13 - 0.84). They also reported that children, who were greater than or equal to four months old when supplementary milk feeding [cows' milk] was introduced, had a lower risk of Type 1 DM (OR 0.48, 95% CI 0.26 - 0.91). A systematic review of 23 studies demonstrated that people who were breastfed had a lower risk of developing Type 2 DM later in life than those who were formula fed (OR: 0.61; 95% CI 0.44 – 0.85) (Owen et al., 2006).

2.6 Challenges to Exclusive or Full Breastfeeding in Context of Diabetes Mellitus

A retrospective New Zealand study of 403 women with diabetes in pregnancy was undertaken (Simmons, Conroy & Thompson, 2004). Thirty women were diagnosed with Type 2 DM and 373 with GDM. The mothers with Type 2 DM were less likely to breastfeed their babies at birth compared to the mothers with GDM (41.4% vs. 68% $P=0.011$). Fifty two per cent of infants born to mothers with Type 2 DM were reported as suffering from neonatal hypoglycaemia (BGL of 1.6 - 2.6mmol/l). Of those infants born to mothers with GDM, 68% were breastfed at their first feed with 38% of those infants developing hypoglycaemia (Simmons et al., 2004). This suggests that women with Type 2 DM are less likely to breastfeed and therefore their babies are more likely to develop

hypoglycaemia compared to women with GDM who have increased success with breastfeeding and fewer babies who develop hypoglycaemia.

A study of 102 women with DM in Denmark reported that more than 50% of mothers had not breastfed their baby within the first two hours of life and all babies had been given artificial feedings (Stage, Norgard, Damm & Mathiesen, 2006). However, The World Health Organisation recommends that breastfeeding should be initiated within the first 30 minutes of life (World Health Organisation, 1998). This is often not the case for women with diabetes given the barriers to successful breastfeeding in women with diabetes.

Ball contends that, “All babies have a human right to breast milk, based on the right to life, to adequate nutrition and to the highest attainable standard of health, and based on women’s rights, which include the right to breastfeed [and] to breastfeeding education...” (Ball, 2010, p. 9).

Mothers with diabetes and their babies face many challenges in pregnancy, during birth and whilst breastfeeding. This group of mothers and babies need additional support with breastfeeding especially during the early post-partum and neonatal period. This next section identifies some of those challenges especially in the first few days after birth.

2.6.1 Labour and Mode of Birth for Women with Diabetes

Women with less than optimal diabetic control may be encouraged to have a preterm elective birth through induction of labour (American Diabetes Association, 2003; Kjos, Henry, Montoro, Buchanan & Mestman 1993; Sela et al., 2009). A prospective cohort study of 1,389 nulliparous women quantified the risk of caesarean section after an induction of labour. Women undergoing an elective induction of labour who had a pre-labour Bishop’s score of less than or equal to 5 had a 25% rate of caesarean birth compared to 13.6% rate for those women with a Bishop’s score between 6 and 8. Thus a Bishop’s score of 5 or less at elective induction of labour doubled the risk of caesarean birth outcome (Vrouenraets, et al., 2005). The Bishop’s score is a measure of fetal descent in the pelvis and cervical readiness for labour. Further to this, antenatal breast stimulation has been shown to improve cervical favourability, and by extension, Bishop’s Score (Di Lieto, Miranda, Ardito, Favale, Albanao, 1989; Finigan, 2006; Kavanagh, Kell & Thomas, 2005; Moscone & Moore, 1993; Salmon, Kee, Tan & Jen 1986). Therefore it seems likely that improved cervical favourability at the point of induction may translate to an increase in successful induction of labour which results in a vaginal birth (Baacke & Edwards, 2006). Vaginal birth in itself has been shown to improve breastfeeding outcomes (Finigan, 2006; Nissen, et al., 1996).

2.6.2 Mother – Baby Separation at birth

Babies born to women with diabetes are at a higher risk of prematurity, macrosomia, congenital malformations, hypoglycaemia, hypothermia, hyperbilirubinaemia, polycythaemia, respiratory distress and being born by caesarean section (Sela et al., 2009; Taylor et al., 2005). Each of these conditions increases the likelihood that the mother and child will be separated and that the initial breastfeed will be delayed or shortened. Not all babies born to mothers with diabetes will experience all of the abovementioned conditions. Many babies born to women with Type 1 DM, Type 2 DM or GDM have been separated from their mothers soon after birth because of the concern of neonatal hypoglycaemia. These babies have been given cows' milk formula to correct hypoglycaemia because of an insufficiency, perceived or otherwise, of available colostrum from the mother (Arthur et al., 1989; Arthur et al., 1994; Chapman, Perez-Escamilla, 1999; Hartmann & Cregan, 2001; Stage et al., 2006). Colostrum prepares and protects the newborn baby in a myriad of ways as it adapts to the challenges of extra-uterine life.

Evidence suggests that where colostrum is not the first food that a baby receives there is a potential for less than optimal health outcomes (Arifeen et al., 2001; Betran et al., 2001; Hanson, 2004; Marild et al., 2004; Victora et al., 1987). The protective and beneficial effects of colostrum will be explained in a later section. A mother who is separated from her baby will miss feeding cues and hence her breasts may have insufficient suckling stimulation for oxytocin and prolactin production which is essential for optimal lactogenesis II (Odent, 2011; Ostrom & Ferris, 1993; Vella, Shorten, & Sibbald, 2005). This is especially important for the mothers with diabetes who are already facing the possibility of delayed lactogenesis II (Neubauer, et al., 1993). If a baby does require care in the neonatal unit then the mother should be supported to attend the baby unit so that she can cuddle and feed her baby skin to skin as this will promote her lactation (Lawrence & Lawrence, 1999).

2.6.3 Delayed Lactogenesis II

Women who have diabetes and women who are obese, often experience delays of 24 hours or more in lactogenesis II (Arthur et al., 1989; Arthur et al., 1994; Bitman, et al., 1989; Chapman et al., 1999; Hartmann & Cregan, 2001; Jevitt, Hernandez & Groër, 2007). These mothers may have insufficient colostrum at birth to prevent their babies from developing hypoglycaemia. It is suggested that the delay in lactation for women with diabetes is due to lower prolactin levels as a result of maternal hyperglycaemia. Prolactin production has been found to be inhibited by the extra-placental progesterone in adipose tissue of overweight women (Hilson, Rasmussen & Kjolhede, 1997; Neubauer et al., 1993;

Rasmussen & Kjolhede, 2004). Several studies have found that delayed lactogenesis II was more likely to occur in women with poor glycaemic control (Arthur et al., 1989; Neubauer et al., 1993; Ostrum & Ferris, 1993).

2.6.4 Neonatal Hypoglycaemia

Babies born to mothers who have had poorly controlled blood glucose levels during pregnancy, i.e. had wide variations in blood glucose levels, responded in utero with islet cell proliferation and increased insulin production whereas women with diabetes in pregnancy who achieved tight antenatal glycaemic control were less likely to birth babies affected by neonatal hypoglycaemia. (Neubauer et al., 1993; Nold & Georgieff, 2004; Riordan, 2005). The baby that experiences an intra-uterine hyperglycaemic environment compensates by producing higher than normal levels of insulin (Steel, 1987). The potential for neonatal hypoglycaemia occurs when the constant supply of glucose from the mother is interrupted with the clamping and cutting of the umbilical cord at birth. This can result in rapidly decreasing blood glucose levels (BGL's) and accounts for about 50% of all babies born to mothers with diabetes developing hypoglycaemia in the early neonatal period (Maayan-Metzger, Lubin & Kuint, 2009; Nold & Georgieff, 2004; Riordan, 2005; Sela et al., 2009).

Hypoglycaemic babies are often supplemented with cows' milk thus denying them the opportunity to be exclusively or fully breastfed (Taylor et al., 2005). There is a potential for adverse health outcomes, as has been identified earlier in this chapter, in some babies who are administered cows' milk.

2.7 Skin to Skin and Early Breastfeeding

Breastfeeding provides important support to babies of diabetic mothers (Gunderson, 2007). When the newborn baby is kept warm in direct skin to skin contact with its mother and encouraged with early and frequent breastfeeding then the risk of hypoglycaemia is greatly reduced (Fig. 2.1). Research suggests that the temperature of the mother's skin in between her breasts rises to warm her baby when the baby is placed skin to skin. This response is thought to be under the control of the autonomic nervous system and elicited by direct skin to skin contact (Bergström, Okong & Ransjö-Arvidson, 2007). Hypoglycaemia is exacerbated when glucose is utilised to metabolise brown fat for thermoregulation (Clay, 2005; Finigan, 2006; Wight, 2006). Skin to skin contact between the mother and baby has been shown to facilitate the initial breastfeed and is included in Step Four of the "Ten Steps to Successful Breastfeeding" (WHO/UNICEF, 1989). In a Swedish case controlled study of 72 newborn infants (n=34 controls), it was found that

babies who had uninterrupted skin to skin contact with their mothers from birth were on average suckling from the breast at 50 minutes of age (Righard & Alade, 1990).

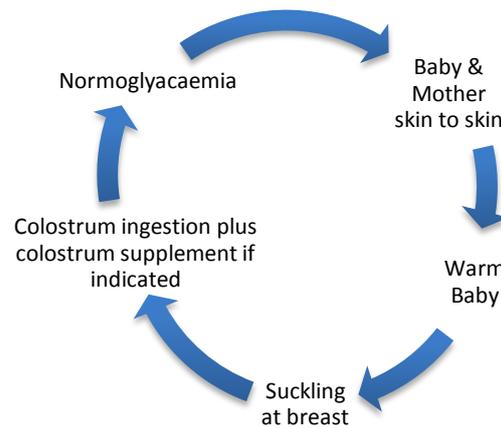


Figure 2.1 Skin to skin promoting normoglycaemia

Currently at Christchurch Women's Hospital, New Zealand, (a large tertiary level maternity facility) infants born to mothers with Type 1 DM, Type 2 DM or GDM are cared for in accordance with the Canterbury District Health Board protocols for breastfeeding and hypoglycaemia (Austin, 2008; Canterbury District Health Board, 2011). If a mother has insufficient colostrum to correct her baby's hypoglycaemia then the infant is likely to receive a cows' milk supplement (Austin, 2008). The protocol for care of the hypoglycaemic infant endorses and encourages mother-baby skin to skin contact to prevent neonatal hypothermia. It also suggests the use of expressed colostrum where available to promote neonatal normoglycaemia. This protocol appears to be supportive of exclusive or full breastfeeding for mothers with diabetes.

2.8 Colostrum Harvesting

Colostrum harvesting is the practice of collecting colostrum from the breast during the antenatal period. The art of colostrum harvesting was taught to mothers by their midwives more than fifty years ago (Myles, 1964). At that time the skill was thought to be useful for encouraging the newborn baby to feed, preventing mastitis and enabling the mother to become skilled at expressing her breasts should she ever become separated from her baby (Oscroft, 2001). In the mid-1940s Waller undertook research into lactation difficulties. He discovered that those women who expressed their colostrum antenatally were 50% more successful at breastfeeding than those who did not express (Waller, 1946).

The routine practice of breast expression was abandoned in the late 1970s when it was suggested that it had little value in preventing breastfeeding complications although

there was evidence to suggest that women who expressed were more confident with breastfeeding (Kitzinger 1987; Llewellyn-Jones, 1983). At about the same time the practice of midwifery in New Zealand was undergoing a great deal of change with doctors assuming the lead responsibility for all birthing women. In New Zealand, the Nurses Act 1971 removed the right of a midwife to attend a woman in childbirth without the participation of a doctor (Ogonowska-Coates, 2004). It may be that the medicalisation and industrialisation of human birth has influenced the decline in the practice of antenatal breast expression.

The benefits of antenatal colostrum harvesting lie in the protection and promotion of exclusive or full breastfeeding. The mother may gain confidence in handling her breasts and increase her knowledge of breast anatomy and physiology which may be of benefit to her as she establishes breastfeeding (Kitzinger, 1987). It is suggested that antenatal colostrum harvesting has the potential to promote a generous supply of colostrum at birth (Singh et al., 2009). In the event that the newborn baby develops hypoglycaemia banked colostrum can be used in the first instance instead of other nutrition substitutes such as cows' milk formula.

2.8.1 Safety Concerns Raised

Some concerns have been raised that stimulating the nipples or breastfeeding during pregnancy will lead to increased miscarriage and preterm labour. A pilot study looking at the feasibility of conducting a randomised controlled trial on diabetes and antenatal colostrum harvesting did not find any increase in pre-term labour. All of the women in their study (n=43) birthed their babies at or after 37 weeks gestation (Forster et al., 2011). Cox notes that many other activities such as eating, love-making, kissing and breastfeeding whilst pregnant also cause oxytocin release but are not discouraged for fear of causing miscarriage or pre-term labour (Cox, 2006). A survey of 57 Californian women who breastfed during pregnancy reported that all participants birthed healthy babies appropriate for gestational age (Moscone & Moore, 1993).

The human pregnancy is protected from premature parturition through a complex interaction of hormones. Prior to full term the uterus has fewer oxytocin receptor sites and their receptiveness is inhibited and restrained by the hormones relaxin, oestrogen and progesterone. Towards full term there is a proliferation of oxytocin receptor sites, progesterone levels decline and the oxytocin receptors become susceptible to the oxytocin stimulus (Condon, Pancharatnam, Fuast & Mendelson, 2004; Russell, Douglas & Ingram, 2001; Russell, Leng & Douglas, 2003, Singh et al., 2009; Steer, 1990).

Four randomized controlled studies which questioned the efficacy of nipple stimulation for the induction or augmentation of labour in term pregnancies failed to demonstrate an effective response for the induction or augmentation of labour (Curtis, Resnick, Evens, & Thompson, 1999; Di Lieto et al., 1989; Mashini, Devoe, McKenzie, Hadi, & Sherline, 1987; Stein, Bardequez, Verma, & Tegani, 1990). These studies suggest that nipple stimulation prior to term gestation will not result in pre-term labour but it was found to be effective for cervical ripening at term. One other concern could be that expressing colostrum may lead to a lowering of the maternal blood glucose level. In a pilot study with a cohort of 43 subjects by Forster et al., (2011), there was no reported evidence of maternal hypoglycaemia post expressing.

2.8.2 Colostrum Harvesting Theoretically a Solution

There is very little research on the role of colostrum as a positive alternative to cows' milk formula for women with diabetes. Colostrum harvesting may provide a mechanism for more appropriate intervention when faced with breastfeeding challenges, as is often the case with babies born to mothers with diabetes. Antenatal colostrum harvesting, personal colostrum banking and supplementing hypoglycaemic babies with freshly expressed or banked colostrum may avert the need to expose vulnerable babies to cows' milk formula and facilitate exclusive or full breastfeeding.

If the antenatal expression of colostrum proves to be an effective way of maintaining exclusive or full breastfeeding among women with diabetes mellitus then this has the potential for improving health outcomes. Such an outcome would be extremely beneficial for populations such as Māori and Pacific Island given that their rate of diabetes is disproportionately high when compared to European populations (Ministry of Health, 2002).

2.9 Proposed Study - Colostrum Harvesting for Diabetes in Pregnancy

In the search of available literature only one study was identified which had investigated the value of antenatal colostrum harvesting and banking for mothers with any form of diabetes (Forster et al., 2011). They concluded that no obvious harm occurred to mothers or babies from antenatal colostrum harvesting but were concerned that the small numbers in the study prevented them from reaching any valid conclusion around safety. The Forster study compared 43 pilot study babies with an audit group of 82 babies. Their findings show that 16% fewer babies in the pilot group received any cows' milk formula in the first 24 hours postpartum. However they stated that this difference was not statistically significant. At six weeks postpartum 90% of the babies in the pilot group were receiving

some breastmilk. Exclusive and full breastfeeding data were not identified in the Forster study and no six week postpartum data was available for the audit group. The conclusion of the Forster study was that there was evidence to suggest that it would be feasible to conduct a randomised controlled trial of antenatal colostrum harvesting for women with diabetes requiring insulin during pregnancy. They also recommended that the practice of antenatal colostrum harvesting should cease until statistical evidence was available with respect to its safety and efficacy (Forster et al., 2011).

2.9.1 Rationale for the Study

This literature review has identified that there is a gap in literature with respect to measures which support women with diabetes to exclusively or fully breastfeed their babies. Colostrum harvesting and banking may provide a successful solution for women with diabetes in pregnancy.

2.9.2 Aim of the Study

The aim of this study is firstly; to find out if a woman with Type 1, Type 2 or gestational diabetes mellitus can effectively achieve antenatal colostrum harvesting and banking. Secondly, to examine the feasibility of mothers and core midwifery staff using banked colostrum in the hospital setting as part of the care for babies with hypoglycaemia.

2.10 Conclusion

Concerns have been raised by recent research with respect to the need for the development of practical strategies to facilitate breastfeeding, amongst vulnerable populations (Jackson, 2004; Paul et al., 2006). It seems feasible that a study into antenatal colostrum harvesting, colostrum banking and colostrum supplementation for the vulnerable group of neonates influenced by diabetes, may be a useful intervention strategy. Antenatal colostrum harvesting may promote a good flow of colostrum prior to birth. It could be argued that a woman with diabetes who has a generous supply of colostrum at birth is likely to remain skin to skin with her baby longer because its nutritional needs are being met thus reducing the likelihood for the need to supplement with cows' milk formula. Evidence suggests that harvested colostrum is a more appropriate supplement for babies who are clinically hypoglycaemic than cows' milk formula for many reasons including that avoiding the ingestion of cows' milk in the first six months of life is thought to help prevent the incidence of Type 1 DM.

Chapter Three – Methodology

3.1 Introduction

Anecdotal evidence suggests that antenatal colostrum harvesting and banking might decrease the need for babies born to mothers with diabetes mellitus to receive supplementary feeding with cows' milk formula or other breastmilk substitutes. The question as to whether or not colostrum harvesting might be useful in the care of babies born to mothers with diabetes mellitus needs some answers. There are important questions with respect to the safety and efficacy of antenatal colostrum harvesting that will need addressing. The methodology used needs to be able to produce a level of evidence robust enough to inform practice. The cohort needs to be large enough to yield statistically significant results that will convince practitioners and policy makers of their importance (Flick, 2006; Sheldon, Guyatt & Haines, 1998).

Prior to undertaking a large study that might be able to address these questions, a pilot study is required to trial essential parts of the methodology. Findings from the pilot study may lead to changes in the design for a larger study. It may also provide some credibility to a funding application for the main study with respect to that methodology. No decision has been made as to the methodology that would be used for a larger study but what is clear is that it will involve women collecting their colostrum antenatally for postpartum use in the hospital setting. Pilot studies are an efficient and cost effective way of testing the feasibility of the study design tools and processes that may be used in a large or main study. External pilot studies, such as this one, are independent of the main study as data from an external pilot would not be included in the main study (Arain, Campbell, Cooper & Lancaster, 2010; Lancaster, Dodd & Williamson, 2004). A quantitative method was used for this pilot study because the outcomes are measurable (O'Leary, 2004). A robust level of evidence about antenatal colostrum harvesting may inform midwifery and medical practice guidelines around preparation for breastfeeding for women with diabetes in pregnancy.

It is acknowledged that for the main study a randomised control study would provide the most rigorous level of evidence when looking for an effect of the intervention but more than likely a case-control study or an intervention study would be used due to ethical concerns over randomisation (Cox, 2010). Such a large scale study would be beyond the scope of a Master of Midwifery project.

This chapter describes the pilot study design, the rationale for using this method including details of the pilot study protocol.

3.2 Study Design

This pilot study used quantitative methodology with an opportunity for participants to give written feedback in the participant satisfaction survey as it was important to capture some of the experiences of colostrum harvesting for the women in the study. Before a large study is undertaken it needs to be established that antenatal colostrum harvesting is an acceptable and sustainable activity for women. It is also important to determine whether or not the banked colostrum can be utilised as part of the care of hypoglycaemic babies in the hospital setting.

Given there is very little research on the subject of antenatal colostrum harvesting on which to base a quantitative study, a pilot study was devised to test participant and hospital feasibility of such a study, e.g. the compliance rate of mothers expressing and banking colostrum and the feasibility of hospital processes to ensure that banked colostrum could be used. There was no statistical significance in the results so the utilisation of a control group was not necessary. The aims of the pilot study were;

1. To determine if pregnant woman with Type 1, Type 2 or gestational diabetes mellitus could effectively achieve antenatal colostrum harvesting and banking.
2. To assess the feasibility of mothers and core midwifery staff using banked colostrum as part of the care of hypoglycaemic babies in the hospital setting.

3.3 Consultation

Prior to applying for ethical approval to conduct this pilot study the researcher consulted widely with allied health and welfare professionals. Consultation with Māori was held at a local level and through the Otago Polytechnic. Letters of consultation (Appendix 2) were sent to Christchurch Women's Hospital (CWH), Maternity Outpatients Department Diabetes Team, Kaitohutohu at Otago Polytechnic, Dr Khyla Russell, Te Komiti Whakarite who represent Ngai Tahu tangata whenua, the Canterbury District Health Board Director of Women's Health, the Neonatologist at CWH, Clinical Midwifery Coordinators in Birthing Suite and Maternity ward, Lactation Consultants at CWH, the Clinical Director of Endocrinology/Diabetes at CWH, Privacy Officer Clinical Records at CWH and the CWH Clinical Director of Obstetrics. The consultation letter outlined the proposed pilot study and invited any of the parties to raise questions or suggestions about the study either by phone contact or face to face discussion. One recommendation from Dr Peter Moore, the Clinical Director of Endocrinology/Diabetes was that the researcher developed a simplified version of the pamphlet, "Diabetes Mellitus in Pregnancy and Colostrum Harvesting in Preparation for Breastfeeding" (Appendix 1). This pamphlet was duly modified and made available as an alternative resource should any study participants

require a simpler version (Appendix 3). A second recommendation came from Te Komite Whakarite to include Māori health support details with the Participant Information Sheet. The sheet was amended to include these details (Appendix 4).

3.4 Cultural Considerations

Globally the health of indigenous peoples is adversely affected by colonisation and the situation for New Zealand Māori is no different (Durie, 2003a). This pilot study was conducted in Aotearoa New Zealand and reflects the principles of Te Tiriti o Waitangi of partnership, participation and protection (Te Tiriti o Waitangi, 1840). The focus of this study was to pilot a study protocol which could ultimately enable pregnant women with diabetes to have the option to exclusively or fully breastfeed their babies. The increasing impact of diabetes on Māori and the general population is well documented (Durie 2001a, Durie 2003a, Durie 2003b). Research into a diabetes avoidance strategy such as colostrum harvesting has the potential to impact significantly on the future health of Maori.

An integral part of consultation with Māori was the reflection on the researchers understanding of the Te Kura Matatini ki Otago Māori Strategic Framework 2007-11 (Otago Polytechnic, 2006) and associated Memorandum of Understanding. The Guidelines for Researchers on Health Research involving Māori were read and reflected on (Health Research Council, 2010) and I accept that as a non- Māori researcher I have specific responsibilities to the principles of partnership and collaboration as embodied in the Treaty of Waitangi. Prior to undertaking the study, there was consultation with Dr Khyla Russell, Kaitohutohu at Otago Polytechnic and Te Komiti Whakarite at the Canterbury District Health Board. Both parties offered support for the research application and had no further requirements.

3.5 Ethical Considerations

The project required ethical approval because it involved human participants and colostrum which is human tissue. The principle of respect for study participants and their family/whanau was an ethical consideration of paramount importance. The study was designed to minimise any adverse impact on study participants. Prospective participants were given the opportunity to have questions or concerns responded to at any stage during the study. The study participants were encouraged to have a support person present at any of the face to face contacts with the researcher. The education sessions were scheduled at a time and a place to suit the study participant. Colostrum harvesting education sessions were conducted using a breast mannequin to minimise embarrassment for the participant. Informed written consent was obtained from all participants and participation in the study

confirmed this consent. Study participants were informed from the outset that their participation was entirely voluntary and that they were free to withdraw from the study at any time without giving any reasons. They were also informed that their midwifery care, medical care and their legal rights would not be affected by their withdrawal from the study. Colostrum is considered to be human tissue and as such required a written undertaking that it would not be retained for any other use. All colostrum remained the property of the study participant. The disposal of any unused colostrum was at the study participant's discretion.

Steps were taken to minimise any financial burden on study participants. Each participant was supplied with all the equipment required for antenatal colostrum harvesting (Appendix 5). Extra syringes and pottles were supplied on the request of the study participant.

Ethical approval was granted by the Multi-Centre Ethics Committee (Reference number MEC/10/10/107). This process involved submitting an application to the Multi-Centre Ethics Committee. I had fully intended to be present at the ethics committee hearing but the September 4th 2010 Canterbury earthquake meant that the submission was ultimately heard at a much later than anticipated date by the Multi-Centre Ethics Committee in Wellington. Attendance by teleconference was invited but technical failures on the day prevented this from happening. Ethical approval was granted on the 1st December 2010 for a period of twelve months.

3.6 Protecting Confidentiality and Anonymity

Each participant signed the consent form which gave permission for me to access her Christchurch Women's Hospital clinical health record subject to the legal provisions of the Privacy Act 1993 and the Health Information Privacy Code 1994. For the purpose of this study it was necessary to collect personal data regarding each study participant. The participant's confidentiality and anonymity was respected and any identifiable data remained confidential to the research team. Each participant was assigned a study number and no personal identifying details were included in the discussion which could have breached study participant anonymity. Each study participant knew her study participant number so she would be able to identify herself in the results.

Study participant information was stored in paper copy in a locked filing cabinet in my office. At the point of writing up the study all information was anonymised. The report did not include any names or identifiable characteristics of any of the participants. All participants involved in the study were given a copy of the final report. All study participant data records used in the process of this pilot study have been sent electronically

to Otago Polytechnic School of Midwifery for confidential storage for a period of ten years. All paper records have been shredded.

3.7 Recruitment

This study involved recruiting eleven women with any form of diabetes mellitus attending the maternity out-patients department diabetic clinic at Christchurch Women's Hospital (CWH). Using the inclusion criteria (see below), the midwife diabetes educator made the initial approach to prospective participants explaining the study and inviting participation. The prospective participants were also given written information about the study to review at home (Appendix 4). Prospective participants contacted me by phone or email indicating that they would like to learn more about the study and possibly be included in the study. A time was arranged for the initial contact. After discussing the study and having an opportunity to ask any questions the study participants were asked to consent in writing to participate in the study.

3.8 Inclusion and Exclusion Criteria

Inclusion Criteria

- Nulliparous or multiparous women with Type 1, Type 2 or Gestational Diabetes Mellitus.
- Women with an expected date of birthing no later than 31/7/11.

Exclusion Criteria

- Women who required the services of an interpreter.
- Women whose babies were stillborn, born with significant congenital defects or born prior to 37/40 gestation.
- Women whose babies were born at a centre other than Christchurch Women's Hospital.
- Women whose babies were admitted to NICU for reasons other than hypoglycaemia.
- Women for whom I was also the Lead Maternity Carer.

3.9 Procedure Pathways

The steps involved in the development of the protocol for this study have been identified from the perspective of the participant and also from the perspective of the researcher.

3.9.1 The Participant's Pathway

A meeting was arranged at the earliest opportunity to gain written consent to participate in the study (Appendix 5). Each prospective participant was given the opportunity in a face to face interview to have questions or concerns regarding the study addressed. The signed consent form was photocopied in triplicate with a copy for the participant, a copy for the study records and the original was retained in the study participants CWH clinical health record. Once the consent had been signed basic demographic and personal information was gathered and recorded on the Antenatal Colostrum Harvesting Birth and Breastfeeding Data Sheet (Appendix 6). The signed consent form also provided me with permission to access her CWH clinical records for the purpose of gathering data for the study. An Antenatal Colostrum Harvesting Study Participant sticker was placed on the outside of the study participant's CWH clinical file. An information sheet for CWH staff indicating that this woman was a participant in the study was placed in the participant's CWH clinical record (Appendix 7). Each study participant was given a clear file which contained the following documents:

- Antenatal Colostrum Harvesting Pamphlet, Information Flyer and researcher business card
- Antenatal Colostrum Harvesting Consent form
- Antenatal Colostrum Harvesting Log Sheet
- Antenatal Colostrum Harvesting Participant Pathway
- Information sheet on storage of colostrum and breastmilk
- Information for Christchurch Women's Hospital Staff
- Information sheet on thawing and warming of colostrum and breastmilk
- Colostrum Harvesting syringe labels

The study participants consented to courtesy letters being sent to their Lead Maternity Carer informing of the woman's participation in the study (Appendix 8). At around 32 weeks gestation each study participant received their colostrum harvesting kit (Appendix 9) and education on manual breast expression using the Marmet Breast Expression technique. A breast mannequin (Appendix 10) and a breast self-expression online video clip (<http://video.about.com/breastfeeding/Hand-Expression-Technique.htm>) were utilised as education tools. Education and advice was also provided about the safe storage of expressed colostrum (Appendix 11). At 34 weeks gestation the participants were asked to commence colostrum harvesting from each breast for five minutes twice daily until the birth of their baby. Anecdotal evidence from women who had experience of

antenatal colostrum harvesting showed that twice daily expressions from 34 weeks gestation yielded sufficient quantities of colostrum. The information sheet given to the women in preparation for colostrum harvesting (Appendices 1 & 3) suggested expressing up to three times a day however twice daily expressions were more realistic so this was the recommendation in the education session. Each participant was shown how to record their expressions on the Antenatal Colostrum Harvest Log Sheet (Appendix 12). During the course of the study I remained available to the participant for additional advice, education or replacement kit supplies pertaining to the study. The study participant's regular midwifery care was provided by her Lead Maternity Carer/midwife and the Diabetes Specialist Team. It was the responsibility of the study participant to inform me when her baby was born. The participant's clinical record was accessed between day two and seven to extract information about the baby's blood glucose levels and any supplementation that may have been given. Core midwives were responsible for assisting the participant to access her banked colostrum when it was required for supplementation of the participant's hypoglycaemic baby. An information sheet detailing the protocol for any supplementation was in the participant's CWH clinical file (Appendix 7).

The first postnatal point of contact with the participant was through a phone call to the participant between day eight and eleven to gather information about the participant's breastfeeding experience in the first week. The second point of contact was at two weeks postnatally when a letter of thanks and a satisfaction survey were posted to the study participant to complete and return in the supplied stamped addressed envelope (appendices 13 & 14). At this point the study participant's role in the study was complete. The data collected postnatally was recorded on the Antenatal Colostrum Harvesting Birth and Breastfeeding Data Sheet (Appendix 6). A schematic diagram of the participant's pathway is shown in Figure 3.1.

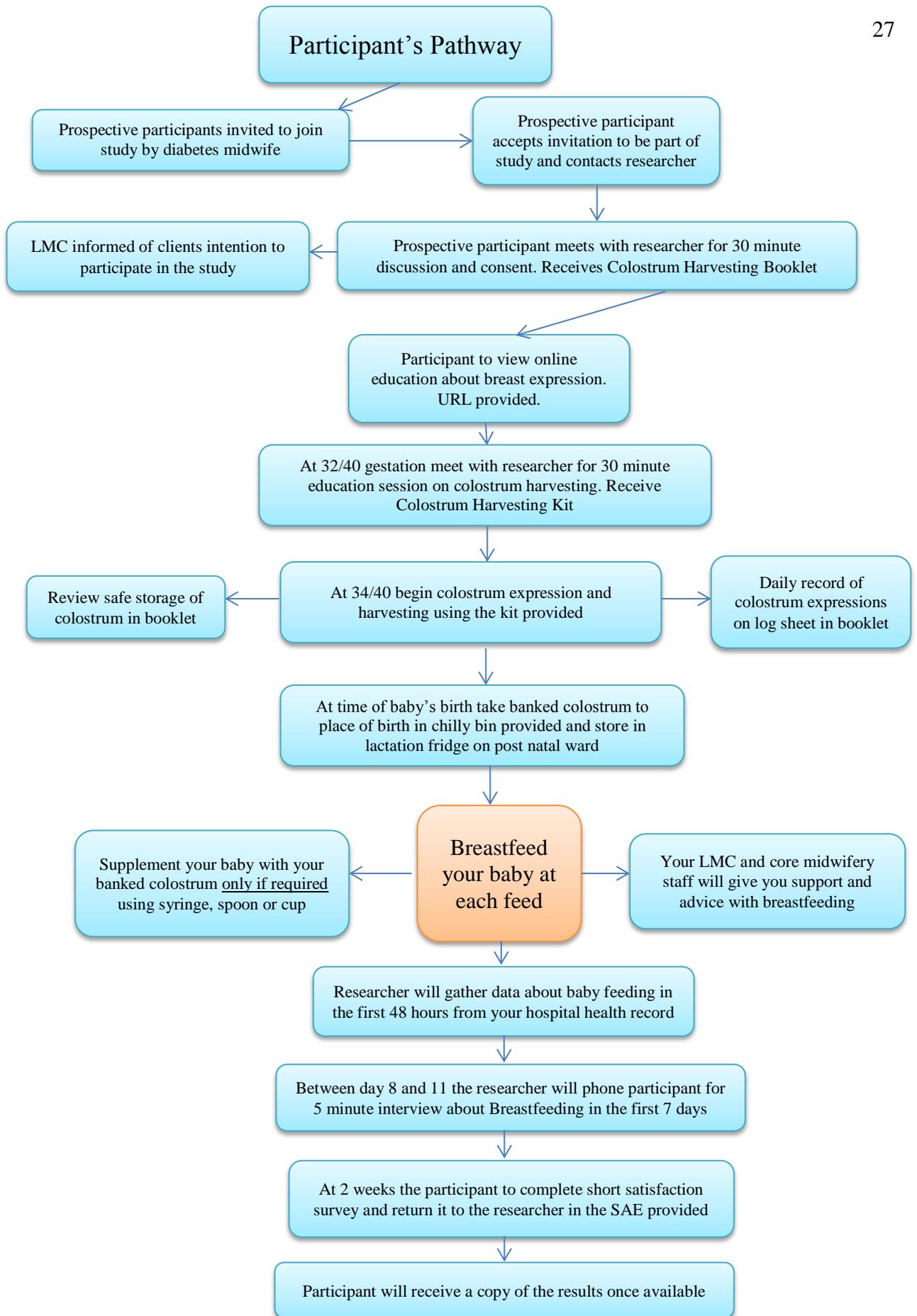


Figure 3.1 Participant Pathway

3.9.2 Researchers' Pathway

Prior to initiating the study there were important steps which I was required to complete. Consultation was undertaken with all the interested parties as listed previously. Ethical approval to undertake the study was granted by the Multi-Centre Ethics Committee. Research funding was secured from Health Workforce New Zealand for a Post Graduate Midwifery Grant and an Otago Polytechnic Study Grant. Sponsorship for pottles and plastic bags for the colostrum harvesting kits was obtained from Southern Community Laboratory.

The recruitment period was from December 2010 to April 30th 2011. The midwifery diabetes educator was provided with the Information for Prospective Participants sheets (Appendix 4) and a laminated copy of the participant inclusion criteria. The midwifery diabetes educator was asked to continue offering letters of invitation until the recruitment level was achieved. A small degree of over recruitment occurred to act as a buffer for natural attrition in order that I would have complete results for at least six participants. As soon as all the data had been collected the phase of collation, analysis and writing commenced. A schematic diagram of the Researcher's Pathway is shown in Figure 3.2.

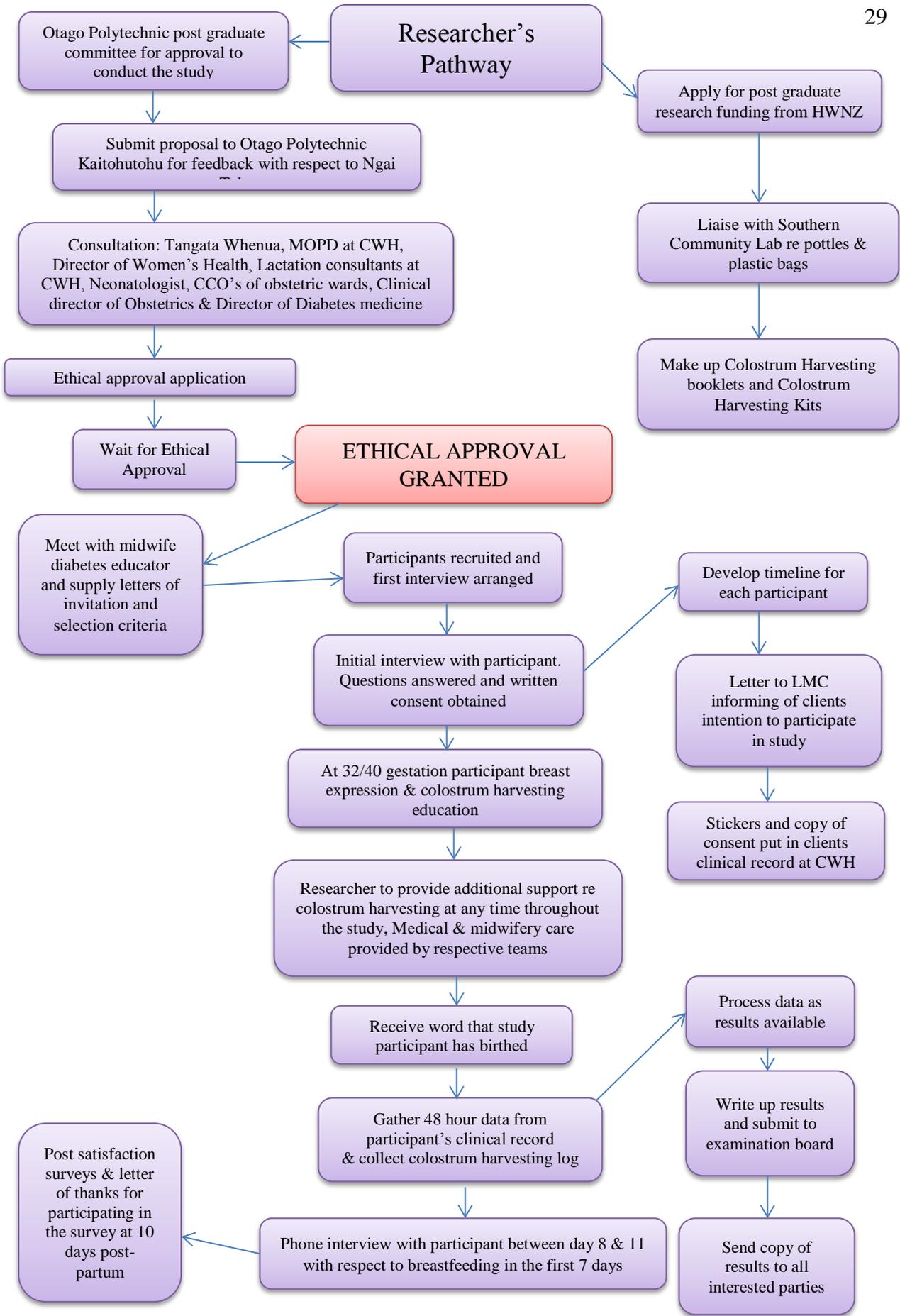


Figure 3.2 Researchers' Pathway

3.10 Safety Considerations

Each study participant was responsible for the safe storage and transportation of their frozen colostrum (Appendix 11). They transported their colostrum in a polystyrene chilly bin on an ice pad which was supplied as part of the Colostrum Harvesting Kit (Appendix 9). The participant stored her colostrum in the named chilly bin in the lactation fridge or freezer in the post natal ward at CWH where it was accessed as required.

With respect to the care of hypoglycaemic babies in this pilot study, core midwifery staff followed the CWH Hypoglycaemia protocol (Austin, 2008). This protocol emphasises the importance of skin to skin contact for maintaining warmth and breastfeeding within the first hour of birth. Although not formalised in a protocol, supplementation of colostrum that occurs at CWH is by providing colostrum in one millilitre increments to a maximum of seven millilitres at any one feed in consideration of the small capacity of the newborn stomach (personal communication, Ruth O'Donovan, lactation consultant, September, 2011).

3.11 Data Collection and Analysis

Data analysis and reporting was primarily quantitative but participants were asked to record comments on the satisfaction survey (Appendix 13).

Data was collected using three types of data collection as described below: Participant's Antenatal Colostrum Harvesting Log Sheet to document colostrum harvesting during the antenatal period (Appendix 12).

The participant's and baby's health records were accessed to collect data on labour, birth, breastfeeding, baby supplementation and baby blood glucose levels in the first two to seven days (Appendix 6).

The participants completed a satisfaction survey on various aspects of the study at two weeks postnatally (Appendix 13).

The collected data was entered into a Microsoft Excel spread sheet and descriptive analysis completed to produce means and ranges. There was no control group for this pilot study and thus results do not provide statistically significant conclusions. Common themes were identified from the comments provided in the satisfaction survey.

3.11.1 Antenatal Point Data Analysis

The data were analysed to identify:

- the compliance rate in antenatal breast expression.
- whether the participants achieved the recommended frequency of twice daily breast expression.

- the volumes of colostrum expressed.

Each participant's log sheet was analysed quantitatively on an individual basis and then collectively. The data was presented in bar graph format which is typical for nominal data.

3.11.2 Labour and Birth Point Data Analysis

The information in this data set was analysed quantitatively to identify:

- the date of birth and the gestation of the baby
- the type and length of labour and birth
- whether or not the mother and baby had skin to skin at birth
- the volume of colostrum that the participant had available at birth
- the time until the first breastfeed
- whether the baby received any supplementation in the first 48 hours and again at seven days.

3.11.3 Post Natal Point Data Analysis

The satisfaction survey (Appendix 13) was designed using a Likert type scale for responses with spaces for comments underneath (O'Leary, 2004). The information in this data set was analysed quantitatively with respect to the responses and comments were grouped according to common themes. Each question in the survey was tabulated for satisfaction level and frequency. Trends in satisfaction and common themes in the participants' comments were identified.

3.12 Dissemination of Results

A copy of the thesis will be held on record at the Bill Robertson Library in Dunedin. It is intended that a condensed version of this study will be submitted for journal publication. A copy of the final report will be made available to the Director of Midwifery, the Director of Obstetrics and the Director of Neonatology at Christchurch Women's Hospital. The report may then be made available to any other interested party.

3.13 Summary

The methodology for the pilot study into antenatal colostrum harvesting for diabetes in pregnancy has been outlined in this chapter. This included recruitment of participants, the pathway for both participant and researcher clearly showing the steps in the study, ethical and safety considerations and the rationale for using this study method. Data collection, storage and analysis have also been described.

In the next chapter the results of the pilot study will be presented.

Chapter Four - Results

Overview 4.1

The pilot study had two aims. The first aim related to whether or not antenatal participants would be able to express and store their colostrum. The second aim was concerned with whether or not the banked colostrum could be utilised by mothers and core midwifery staff in the hospital setting. This chapter discusses the results of this pilot study.

4.2 Data Collection Process

The participants were asked to inform me once they had birthed their babies. This occurred via text message or phone call for nine out of ten of the participants. One participant forgot to contact me so when she had exceeded her “due date” I contacted her and discovered that her baby had been born one week previously. This did not affect the data collection as I was able to access the information through clinical records. The antenatal colostrum harvesting log sheets were either collected from the participants at the hospital or participants were asked to return them in the pre-paid envelope with the client satisfaction survey. One participant did not return her colostrum harvesting log sheet despite being followed up on two occasions. The partial results of this participant were included in the data analysis. Participant six withdrew from the study after having signed the consent - hence the reason for her missing data.

4.3 Data Presentation

There were eleven study participants originally enrolled in the pilot study. One participant withdrew from the study because she was concerned that expressing colostrum might trigger the onset of pre-term labour and was not reassured by the current evidence presented to her. Ten participants continued to meet the criteria. Due to the disruptions from the Canterbury earthquake and despite follow up, one participant did not return her colostrum harvesting log or satisfaction survey, thus nine participants fully completed the study.

4.3.1 Participant Characteristics (Table 4.1)

The participants ranged in age from 23 to 38 years with an average age of 33 years. Seven participants were diagnosed with gestational diabetes mellitus and three were diagnosed with Type 1 diabetes mellitus. Of the ten participants five were nulliparous women and five were multiparous women. All of the multiparous women had breastfed

previously. Eight women identified as New Zealand European, one woman as Māori woman and one as “other” European. Participant details are identified in table 4.1.

Table 4.1 Participant Details

Participant Details	n
Enrolled in study	11
Withdrew from study	1
Partially completed study	1
Fully completed study	9
Ethnicity	
Māori	1
NZ European	8
Other European	1
Pregnancy History	
Nulliparous	5
Multiparous	5
Breastfeeding History	
Breastfed previously	5
Never breastfed	5
Type of diabetes mellitus	
Type 1 DM	3
Gestational DM	7

4.3.2 Antenatal Data Regarding Colostrum Harvesting

All of the participants managed to undertake breast expression on most days from 34 week’s gestation until the birth of their baby. Participant three’s data sheets were unavailable but she reported verbally that she had achieved most of her daily expressions

and had a supply of colostrum available at birth. The range of expression frequency was 19 to 80 episodes with an average of 53 expressions. (Figure 4.1)

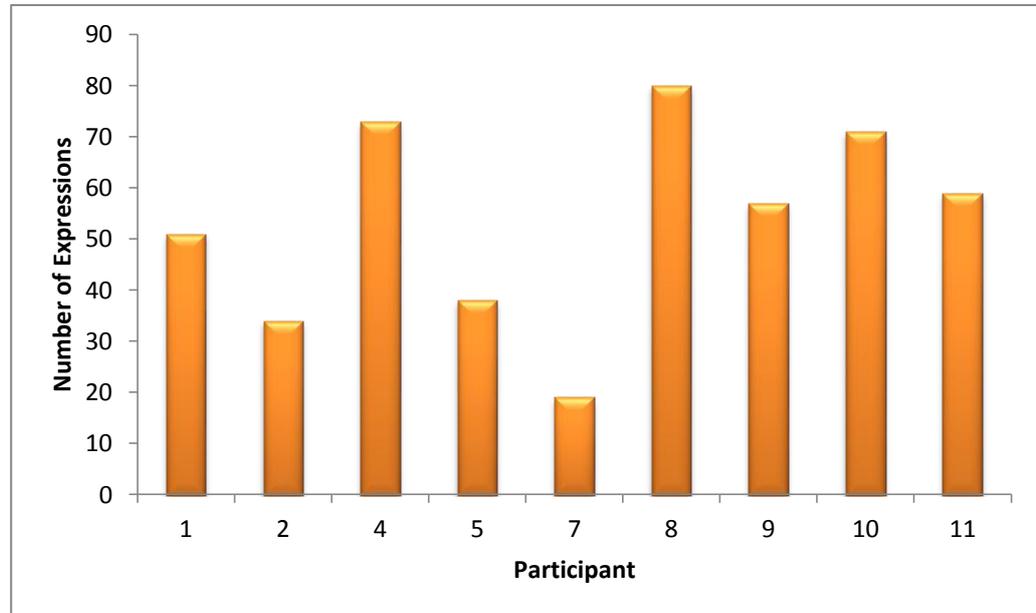


Figure 4.1 Number of Breast Expressions

In the study group there was an average of 32 days on which a participant could express with a range of 15 to 42 days. This translates to an average of 64 expressing opportunities with a range of 30 to 84 expressing opportunities if the recommended twice daily expressions were achieved. Most of the study participants were able to achieve twice daily expressions but some missed a few days expressing due to the Canterbury earthquakes.

All of the study participants achieved colostrum collection with a range of total volumes from 2.8mls to 322mls and an average of 88.5mls (Figure 4.2).

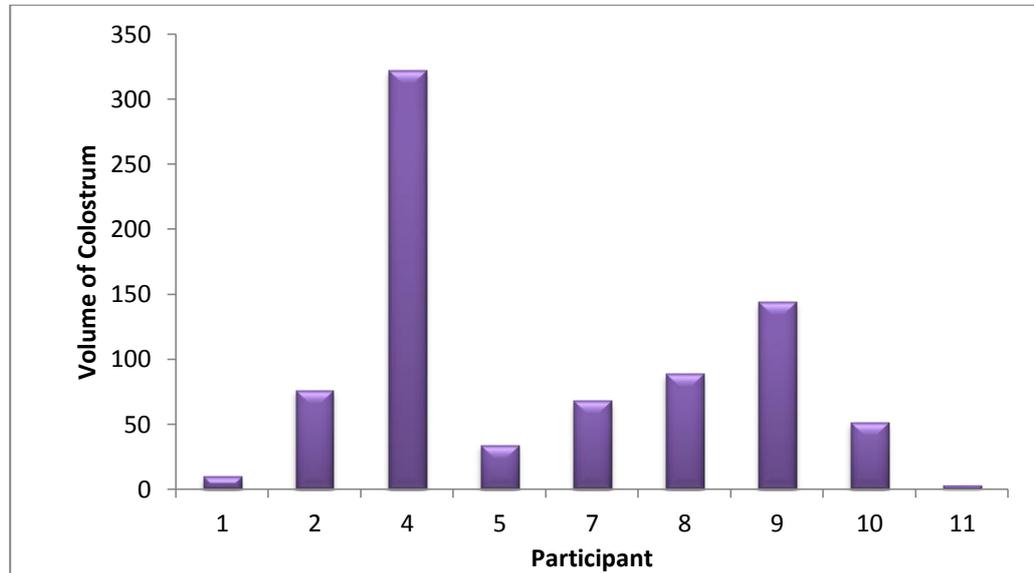


Figure 4.2 Total Volumes of Colostrum Expressed (mls)

All study participants achieved an increase in their weekly volumes of expressed colostrum from 35 to 38 weeks gestation. The volumes that the participants collected in weeks one to four are shown in Figure 4.3. These volumes do not represent the total volume expressed for each participant. The combined average weekly volumes show a steep upward trend of volume expressed with a plateau reached about 38 weeks gestation (Figure 4.4). None of the study participants required any additional education regarding breast expression. One participant called to ask about the volume of colostrum she was collecting. I advised her that the most important aspect was to keep up with the twice daily expressions until the birth of her baby. The volume increased for this participant and whilst low, matched the trend of other study participants.

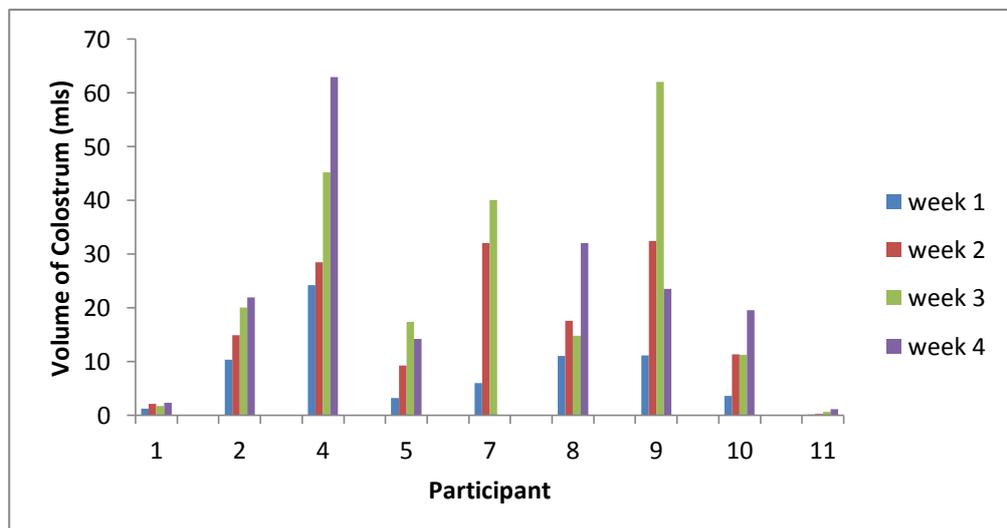


Figure 4.3 Volume of Colostrum (mls) - Weeks 1 to 4 only

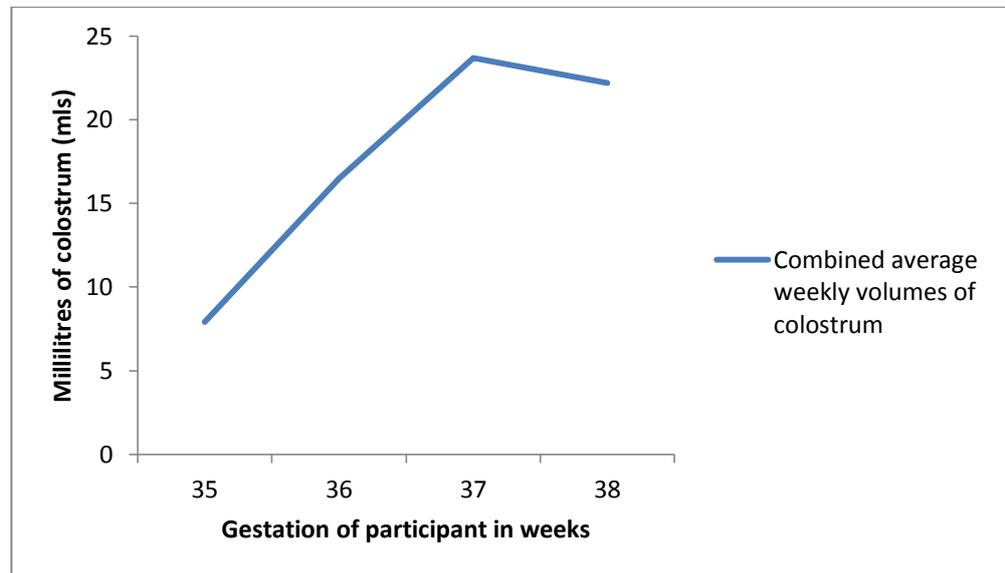


Figure 4.4 Combined Average Volumes of Colostrum Weeks 1 – 4 (mls)

4.3.3 Birth Data

All participants birthed after 37 completed weeks of pregnancy. The average gestation at birth was 38 weeks and five days (Table 4.2). Of the ten participants, two went into labour spontaneously, six were induced and two did not labour as they underwent elective caesarean sections (Table 4.2). There were five normal vaginal births, three emergency caesarean sections births and two elective caesarean section births. The two participants who laboured spontaneously both had emergency caesarean section births. Of the six participants who were induced five had vaginal births and one had an emergency caesarean section birth. (Table 4.2)

Table 4.2 Participant Birth Details

Variable	Number of Infants	Nulliparous	Multiparas
Type of labour			
Spontaneous onset	2	2	
Induction of Labour	6	3	3
No Labour	2		2
Type of Birth			
Normal vaginal	5	3	2
Assisted Vaginal (Forceps or ventouse)	0		
Acute caesarean section	3	1	2
Elective caesarean section	2	2	
Skin to Skin at Birth	10	5	5

All participants cuddled their babies skin to skin at birth or very soon after. The range of elapsed time from birth to first breastfeed was 30 to 82 minutes with an average time of 49 minutes. (Figure 4.3)

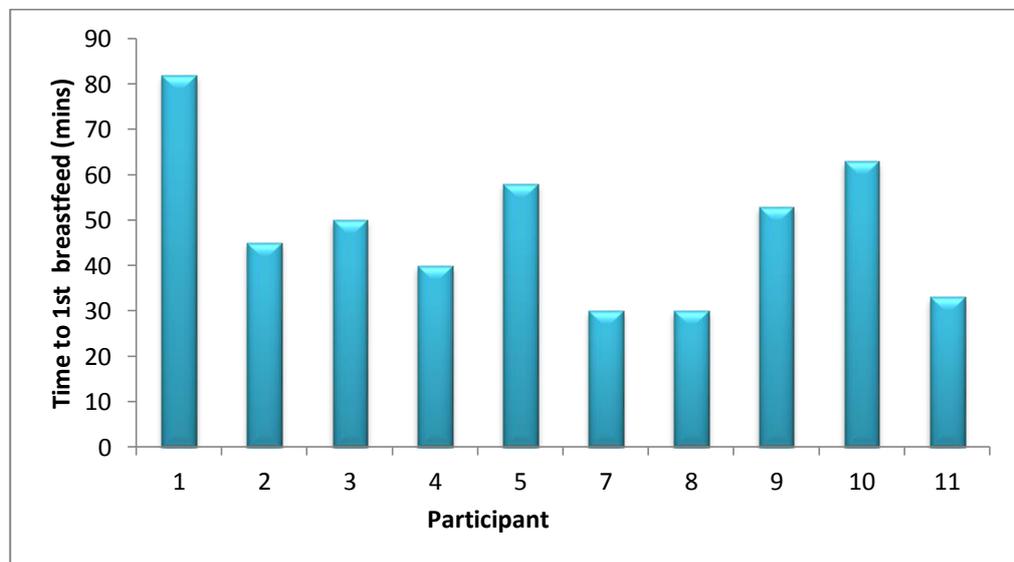


Figure 4.5 Time to First Breastfeed (mins)

4.3.4 Postnatal Data – Baby Blood Glucose Levels (BGL's)

Baby BGL's were obtained prior to the second breastfeed at around two to three hours of age and then prior to each feed until three BGL's >2.5mmol/l had been achieved. Table 4.3 shows the first three BGL's for each baby participant (Table 4.3 & Figure 4.6).

Table 4.3 Baby Blood Glucose Levels

Baby of Participant	BGL 1 (mmol/l)	BGL 2 (mmol/l)	BGL 3 (mmol/l)
1	3.9	2.8	3.5
2	2.7	3.0	3.0
3	3.4	3.7	3.1
4	2.9	3.4	3.7
5	3.2	3.1	3.7
7	3.2	3.1	2.6
8	3.7	3.6	2.7
9	3.1	3.2	3.1
10	1.7*	2.4*	3.2
11	3.6	3.3	2.8

* BGL in the treatment range according to the CDHB Hypoglycaemia Protocol for Infants

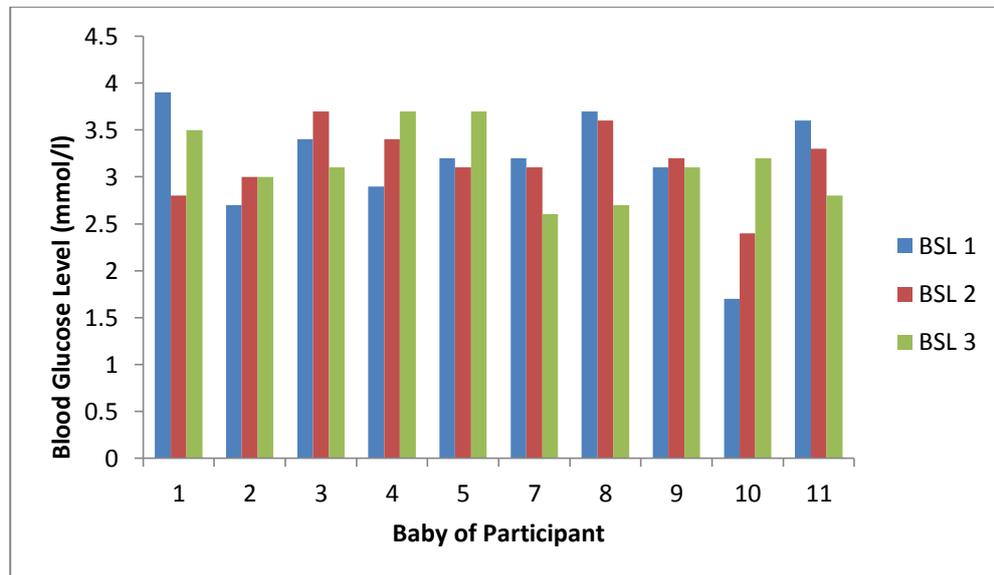


Figure 4.6 Baby Blood Glucose Levels (mmol/l)

Baby of participant 10 returned an initial low BGL of 1.7mmol. At this level the CDHB Hypoglycaemia Protocol for Infants (Austin, 2008) recommends offering the baby another breastfeed or supplementing with expressed colostrum if available or with cows' milk formula. Baby of participant 10 received 30mls of milk mixture after returning a low BGL however this study participant had 51.45 millilitres of banked colostrum available. No reasons were given as to why baby participant 10 was not offered banked colostrum in the first instance. Baby of participant 10's BGL was 2.4mmol/l prior to the third feed. At this stage she was offered expressed colostrum after a breastfeed. Baby of participant 10's BGL prior to the fourth feed was 3.2mmol/l. No further episodes of hypoglycaemia were recorded for this baby. All other babies had initial BGL's greater than 2.6mmol/l with a range over all participants of 1.7mmol/l to 3.7mmol/l. According to the CDHB Hypoglycaemia for Infants Protocol there were two instances where baby supplementation for hypoglycaemia was indicated. Baby of participant 10 required a supplementation on two occasions (Figure 4.7). Babies of participants 1, 2 and 7 received colostrum supplementation at their mother's discretion. This type of usage was not included in the study protocol.

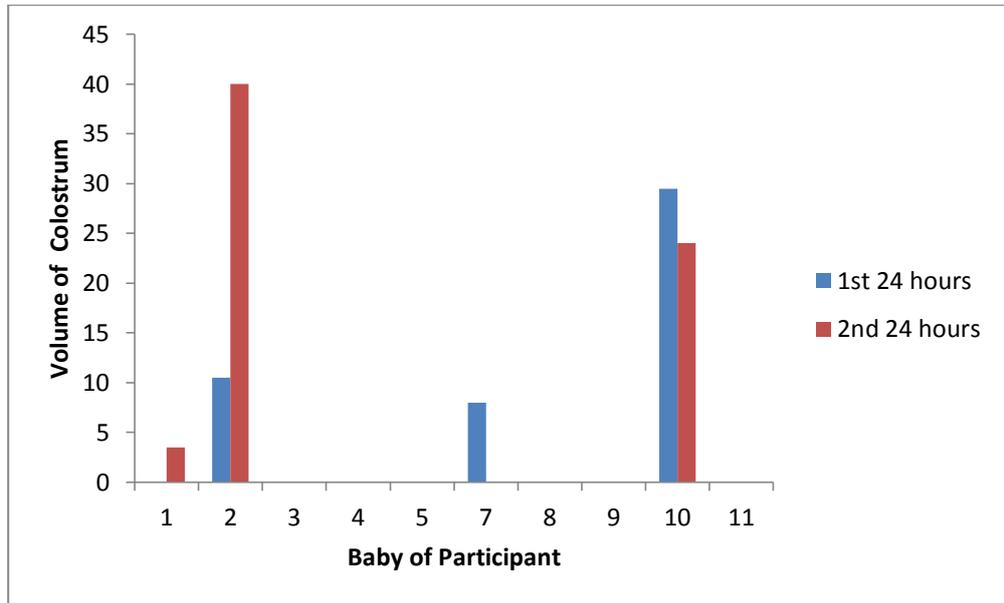


Figure 4.7 Volume of Colostrum Supplementation (mls)

4.3.5 Postnatal Data – Baby Supplementation

Prior to the second feed 90% of babies had a BGL of 2.6mmol/l or greater. Only one baby (10%) required supplementation according to the hypoglycaemia protocol. One baby (10%) received a supplement of cows’ milk formula and then subsequently banked colostrum (Figure 4.8). In the first 48 hours 60% of babies (n=6) did not require any additional supplementation with colostrum or cows’ milk formula.

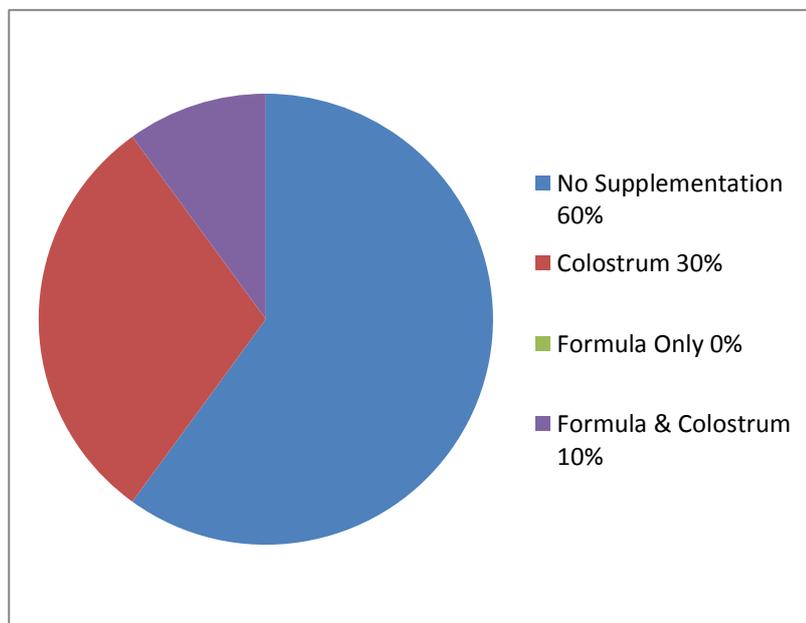


Figure 4.8 Supplementation Type

4.3.6 Breastfeeding Rates at 48 Hours and Seven Days Post-partum

In the first 48 hours 90% of babies (n=9) were exclusively breastfed and 10% of babies (n=1) were partially breastfed (Figure 4.9).

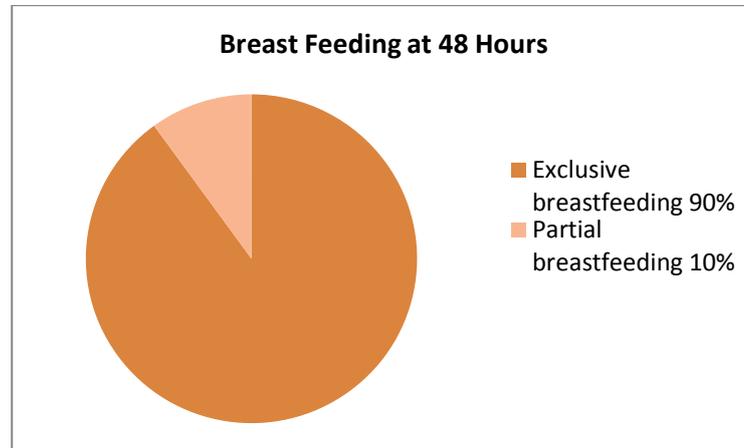


Figure 4.9 Breastfeeding at 48 Hours

At seven days 90% of all babies (n=9) in the study were exclusively or fully breastfed with 10% of all babies (n=1) partially breastfed (Figure 4.10). The partially breastfeeding participant reported having difficulty latching her baby at the breast and was supplementing with some cows' milk formula.

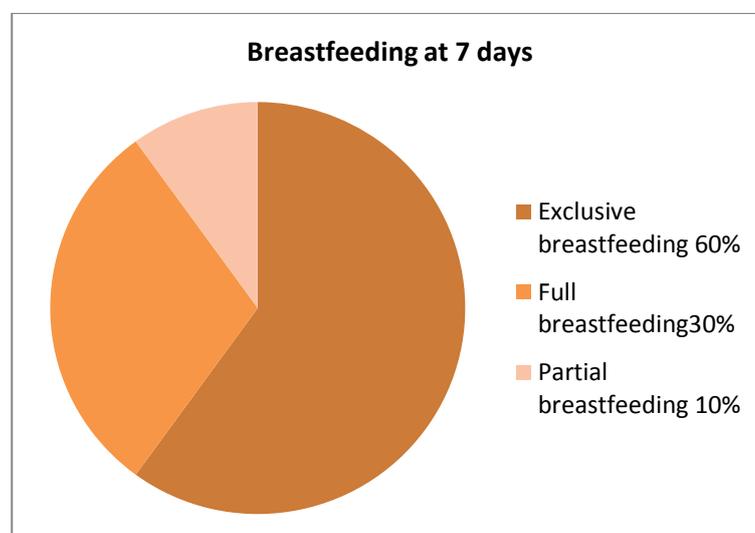


Figure 4.10 Breastfeeding at 7 Days

4.3.7 Client Satisfaction Survey Analysis

The study participant's comments for each question in the survey have been analysed quantitatively according to the Likert scale rating where a rating of one indicated a low level of satisfaction and a rating of five indicating the highest level of satisfaction. (Figure 4.11) There were nine out of a possible ten surveys returned. There was a section under the Likert scale for study participants to make further comments on the question and responses have been grouped into common themes. The verbatim comments are presented in Appendix 15.

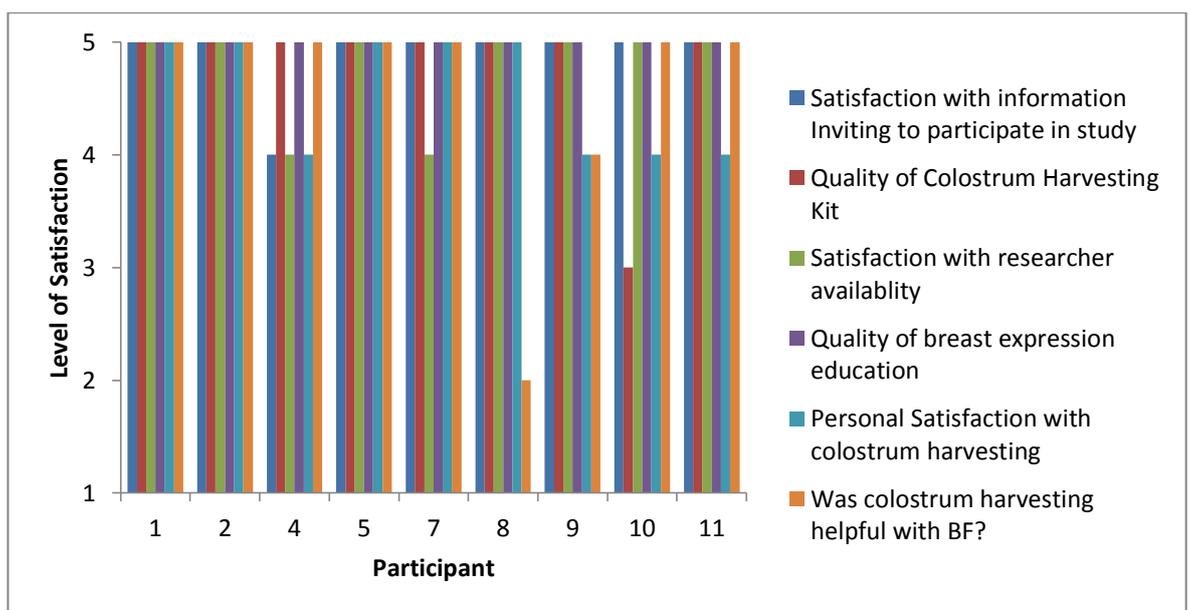


Figure 4.11 Client Satisfaction Survey

Figure 4.12 shows that there was a high degree of satisfaction amongst the study participants towards the tools and processes utilised in the study. The participant who was dissatisfied was actually commenting on an aspect of care that was not part of the study¹. When responses for each group were collated it can clearly be seen that the participants were most commonly very satisfied. (Figure 4.13)

¹ One participant was disappointed that the LMC had not informed her about the study and indicated that she was most grateful that the opportunity had been presented to her by the midwife diabetes educator. This participant recorded her dissatisfaction with services outside the researchers control on the satisfaction survey.

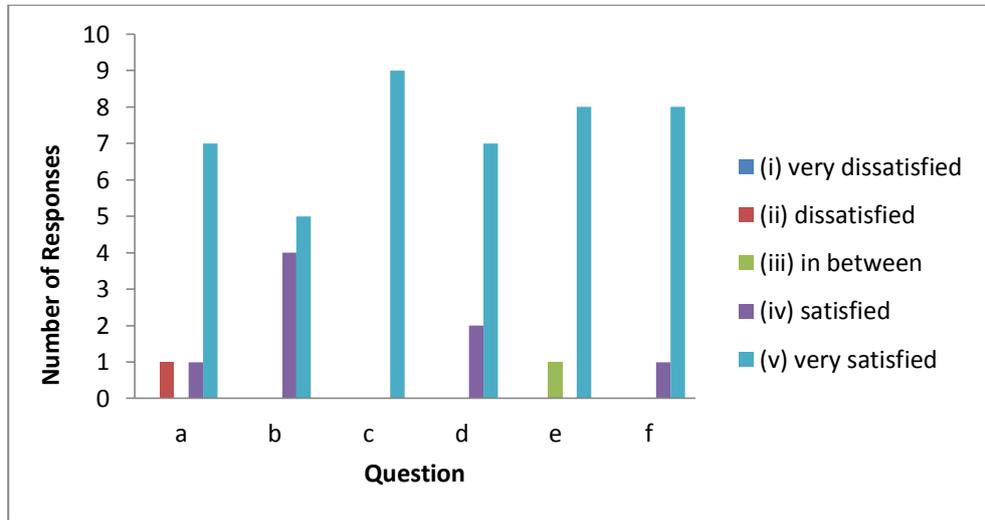


Figure 4.12 Combined scores for Participant satisfaction survey

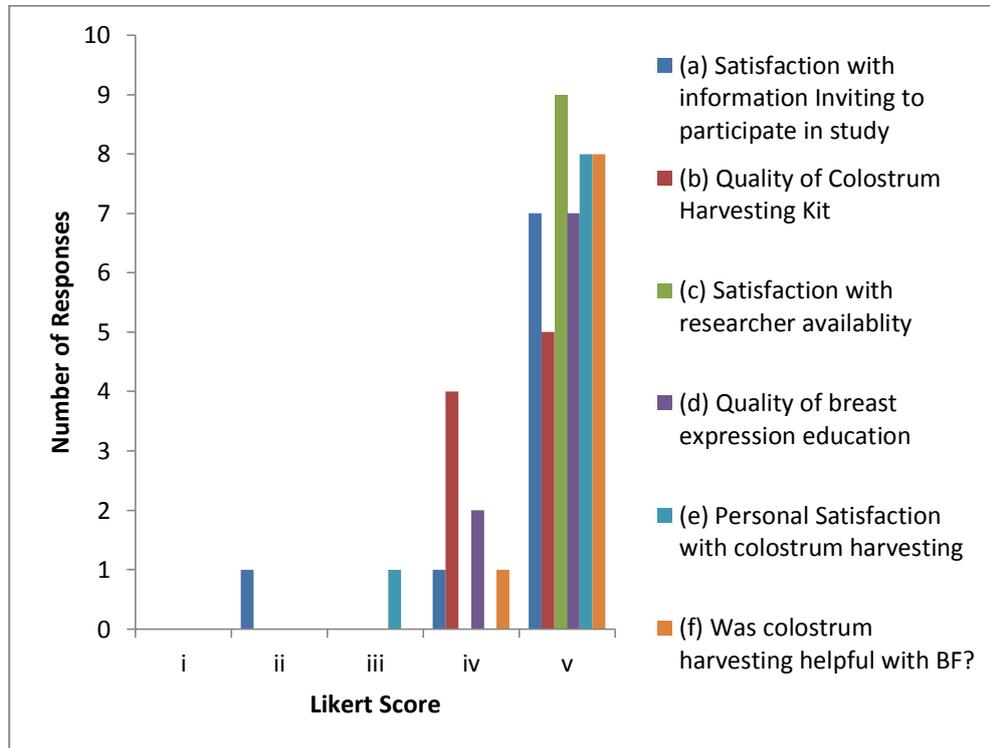


Figure 4.13 Likert Satisfaction Scale

Common responses have been grouped from the comments that participants made in the satisfaction survey. Appendix 15 details the verbatim comments from study participants.

All participants who responded in the survey were satisfied (22%, n=2) or very satisfied (78%, n=7) with the information they received inviting them to be part of the study stating that it was clear and informative.

The information supplied in the colostrum harvesting kit was reported as being easy to understand with 88% (n=8) of participants very satisfied with the quality of the kit. One participant was not fully satisfied with the kit stating that it did not contain enough syringes and pottles.

The participants reported that they were satisfied or very satisfied with the researcher, finding her to be pleasant, prompt, approachable and easily accessible. The education that the participants received about manual breast expression was well received with 100% (n=9) of participants reporting that they were very satisfied. Participants reported that the education was both appropriate and useful.

The lowest degree of satisfaction was reported as being with the participants own experiences with manual breast expression. However 44% (n=4) were satisfied and 54% (n=5) very satisfied with their breast expression. The comments seem to indicate that there were more issues with breast expression at the beginning but that most of these problems resolved with practice. Women reported that expressing could be tricky and time consuming but engendered feelings of confidence, excitement, satisfaction and happiness. Two participants would have liked to have had more colostrum available but they were reassured by the knowledge that any colostrum collected was beneficial. Eight participants (78%) reported that were satisfied or very satisfied with how antenatal colostrum harvesting had helped them with their breastfeeding. One participant reported that she was dissatisfied with the volume of colostrum she had collected but reported that antenatal colostrum harvesting had been some help with her breastfeeding.

Participants reported that expressing seemed to encourage an earlier onset of lactation with a better milk supply than they were expecting. They also felt that antenatal colostrum harvesting was a reassuring, productive and positive step towards successful breastfeeding. Feelings of confidence, comfort and security were generated for the study participants as a result of antenatal colostrum harvesting. All of the study participants would consider antenatal colostrum harvesting in a future pregnancy.

Chapter 5 – Discussion & Conclusion

5.1 Colostrum Harvesting Pilot Study Outcomes

This study clearly showed that it was feasible for mothers to express and bank their colostrum for use in the early neonatal period. All participants had success with the expressing and storing of their colostrum at home despite the difficulties that arose from the 6.3 magnitude earthquakes that Christchurch sustained on 22nd February and 13th June 2011. Some of the study participants were residing in the worst affected eastern suburbs where loss to supply of water, power and sewage services were commonplace. Roads became impassable in many areas due to flooding, liquefaction and land slippage. However there were no reports of any issues with transporting the colostrum to Christchurch Women's Hospital and storing it in the lactation fridge. Evidence from this pilot study was less compelling regarding the feasibility of the hospital processes to ensure that banked colostrum could be used as a supplement for babies with hypoglycaemia.

5.2 Colostrum Volumes

All participants were able to express their colostrum and achieve a volume that they could use in the post natal period if required. It was found that expressed colostrum volume increased by about three-fold over a three week period and then plateaued. It was not possible to tell whether this was due to the stage of gestation or if it was influenced by the process of expression. No explanation can be offered for this finding but perhaps there is a maximum increase that can occur prior to birth and the onset of lactogenesis II. A control group would be required to explore the role of breast expression as a factor in increasing the volumes of colostrum available and as far as I am aware there is no published data with which to compare these results.

A newborn baby's stomach capacity is in the range of five to seven millilitres (La Léche League, 2007) which suggests that a baby who is feeding three hourly ingests approximately 40 to 60 mls of colostrum in 24 hours. Therefore it would seem that 80 to 100 millilitres of banked colostrum would be adequate for supplementary feeding in the event of neonatal hypoglycaemia. The average amount of colostrum expressed by the participants in this study was 88.5 millilitres indicating that antenatal expression of a potentially useful volume of colostrum was achievable by the women in this pilot study. The volumes of expressed colostrum achieved by the participants in an earlier study were between 5 – 310 millilitres with a median volume of 39.6 millilitres (Forster et al., 2011) which equates to about half the volume achieved by the participants in this pilot study.

It was recommended that participants expressed their colostrum twice daily. This was based on anecdotal observations of women who had voluntarily engaged in antenatal colostrum harvesting. Participants in this pilot study expressed, on average, 1.6 times per day. Whilst this did not quite reach the twice daily recommendation all participants achieved some banked colostrum. Despite various challenges associated with the 2011 Canterbury earthquakes all participants continued with their colostrum harvesting when it was safe to do so. They are to be commended for their efforts. The participants in the Forster study commenced their expressions at 36 weeks gestation and managed an average of 24 expressing episodes with a range of 7 – 56 episodes (Forster et al., 2011).

Feedback from the study participants suggested that all were satisfied with the quality of the colostrum harvesting kit, the availability of the researcher and the quality of the education they received about breast expression and colostrum banking. The participants found the Antenatal Colostrum Harvesting Pamphlet (Appendix 1) useful and easy to understand. A simplified version was available but was not required by any of the participants in this study. The documentation used in this study such as the Consent Form (Appendix 5), the Birth and Breastfeeding Data Sheet (Appendix 6) and the Participant Satisfaction Survey were effective. Minor changes to the format and fields of the Colostrum Harvesting Log Sheet (Appendix 12) such as column totals could facilitate analysis.

5.3 Birth

All study participants birthed after 37 completed weeks of pregnancy and there were no reports of any episodes of spontaneous pre-term labour or preterm births. This finding is consistent with that of Forster et al., (2011) despite suggestions that antenatal breast expression may lead to premature labour. However, Forster et al., expressed concern that there is insufficient evidence available that this practice does not induce preterm labour. Research has identified that nipple stimulation, breastfeeding [colostrum harvesting], eating and love-making will cause a release of oxytocin but uterine quiescence is maintained by elevated levels of progesterone which persist in humans until labour has commenced (Condon et al., 2004; Russell et al., 2001; Russell et al., 2003; Singh et al., 2009). Research suggests that the fetus has a crucial role in stimulating the onset of labour in a healthy pregnancy at term (Condon et al., 2004). It appears that there is a mechanism whereby the fetal lungs excrete a hormone critical to the hormonal cocktail that initiates the onset of labour (Condon et al., 2004). Several randomised controlled trials concluded that nipple stimulation was not helpful for inducing labour (Curtis et al., 1999; Di Lieto et al., 1989; Mashini et al., 1987; Stein, et al., 1990).

Babies born spontaneously at term are more likely to breathe spontaneously and are more likely to have a mature suckling reflex both of which are vital components in the initiation of lactation (Kitzinger, 1987). Preterm infants with an immature suckling reflex may not provide adequate nipple stimulation and therefore the mother may experience a delay in the onset of lactation.

Six participants in this pilot study underwent an induction of labour at around 39 week's gestation. Five participants (83%) birthed vaginally, four of whom were multiparous women, and one was a nulliparous woman. The sixth participant who had her labour induced underwent an emergency caesarean section after eight hours of labour. The reason for the surgery was not part of the data collection. The average duration of labour resulting in a vaginal birth was 3 hours 42 minutes with a range of 2 to 7 hours. Evidence suggests that successful induction of labour resulting in a vaginal birth occurs more frequently when the Bishop's score is greater than five (Vrouenraets, et al., 2005). Cervical favourability has been shown to be improved by nipple stimulation [antenatal colostrum harvesting] (Vrouenraets, et al., 2005). In a future study it might be useful to record the participant's Bishop's score at the time of induction of labour to determine whether nipple stimulation improves cervical favourability in the group of women who have diabetes. Labour and vaginal birth has been shown to facilitate successful breastfeeding (Finigan, 2006; Nissen et al., 1996).

The protocol for notification of birth worked efficiently and all but one participant followed this. Data collection for this woman was still possible as the backup strategy of the researcher contacting the woman one week after her due date identified that she had already birthed. This did not raise any issues as the participant's clinical record was able to be accessed and the required data collected in the medical records department at CWH.

5.4 Skin to Skin

It is recommended is that newborn babies and their mothers have uninterrupted skin to skin contact from birth for as long as possible but for at least the first hour (Righard & Alade, 1990; WHO/UNICEF, 1989). Mother-baby skin to skin contact regulates the baby's temperature and puts the baby in close proximity to the mother's nipple so that breastfeeding can be initiated when the baby is ready. These actions facilitate the secretion of oxytocin and prolactin which are critical determinants in establishing lactation in mothers with and without diabetes (Clay, 2005; Finigan, 2006; Grattan, 2001; Wight, 2006). Therefore mother-baby skin to skin contact and frequent breastfeeding are likely to enhance prolactin secretion and are amongst the steps that can be taken to promote successful breastfeeding for women with diabetes. All babies in this pilot study were skin

to skin with their mothers at birth but there was no data collected on the duration or if there were any interruptions to the skin to skin contact. It is suggested that babies who have the opportunity for uninterrupted skin to skin contact will be suckling by 50 minutes of age (Righard & Alade, 1990). The average time to the first breastfeed for infants in this study was 49 minutes. Despite the range of birth situations the mothers in this study all engaged in skin to skin with their babies at birth.

5.5 Baby Blood Glucose Levels

Literature suggests that 50% of babies born to mothers with diabetes will develop hypoglycaemia in the hours following birth (Simmons et al., 2004; Stage et al., 2006). In this study only 10% (n=1) met the local definition of hypoglycaemia. The reasons for the low rate of hypoglycaemic babies in this pilot study are not clear. There are several confounding influences present such as the women self-selected to participate in the study and therefore may have been highly motivated to comply with the protocol and complete the study. The same set of women may also have been motivated to maintain tight glycaemic control which is a known factor in reducing the incidence of neonatal hypoglycaemia (Neubauer, et al., 1993; Nold & Georgieff, 2004; Riordan, 2005). A larger study which is representative of the population of mothers with diabetes in pregnancy may yield different results.

Another reason for the low rate of neonatal hypoglycaemia may have been that the women in the study had a supply of colostrum that met the needs of their babies. This is an assumption which is not able to be validated in this study as the methodology was not designed to test this outcome but it is recommend that it be the focus of a larger study.

Further to this, since work began on this topic of antenatal colostrum harvesting, there have been advances in the care of babies born to women with diabetes. One of the advances is in the timing of the first neonatal blood glucose recording. Past practices included measuring the first neonatal blood glucose level soon after birth. It is now understood that there is a physiological nadir in the BGL of any newborn baby at around one to two hours after birth (Singh et al., 2009). Any studies which have recorded neonatal BGL within the first one to two hours after birth have the potential to return larger numbers of hypoglycaemic results than those studies which measured the BGL prior to the second breastfeed. The timing of the BGL testing is not explicit in any of the studies used in the literature review. It is possible that the literature reviewed reflects a different protocol to the one used in this pilot study. The baby participants in the pilot study had their initial blood glucose levels taken just prior to the second feed or at around three hours of age. At

this stage all babies in the study had been breastfed and one baby was hypoglycaemic with a BGL of 1.7mmol/l.

5.6 Supplementation

It was not anticipated that the study participants would supplement their babies with their colostrum in the absence of hypoglycaemia. However given the fact that the participants had invested a great deal of time and effort into achieving a bank of colostrum one can understand why they wouldn't want to waste it. The purpose of the banked colostrum was for the treatment of neonatal hypoglycaemia according to the CDHB protocol. However the colostrum remained the property of the mother for her to use as she saw fit. It is of concern however that there may be a potential for lactogenesis II to be influenced by reduced suckling time if babies are given a feed of banked colostrum in place of a direct breastfeed. It is not clear from this small study whether or not the extra supplementation given at the mother's discretion caused any problems with the initiation of their lactation but 90% of babies in the study were exclusively breastfed at seven days.

The baby who required supplementation for hypoglycaemia was given cows' milk formula even though the participant had over 50 millilitres of banked colostrum available in the post natal ward lactation fridge. It appears that in this instance that the pilot study protocol may not have been adhered to. There is insufficient data to comment on the hospital processes for the administration of banked colostrum to hypoglycaemic babies.

In some instances participants had left unused colostrum in the lactation fridge/freezer after they had been discharged from the hospital. It has become apparent from this study that a process for the proper disposal of unused colostrum needs to be instituted.

5.7 Breastfeeding

Odent (2011) contends that there is an adrenaline-oxytocin antagonism that inhibits physiological responses such as the spontaneous onset of labour and lactation. A mother with diabetes who is aware that her lactation may be delayed is likely to be feeling anxious. If Odent's theories are correct then efforts to mitigate a mother's stress levels, such as antenatal colostrum harvesting, may indeed encourage and support her lactation.

The type of birth is likely to have an impact on breastfeeding as the hormones of labour are important for the onset of lactogenesis II. Delayed lactation is noted in women who have an elective caesarean section birth (Nissen et al., 1996) and also with those who have diabetes (Arthur et al., 1989; Arthur et al., 1994; Chapman & Perez-Escamilla, 1999;

Hartmann & Cregan, 2001; Hutt, 1989; Jackson, 2004; Paul et al., 2006). A combination of both of these variables may impact on breastfeeding outcomes.

Despite being, as Paul et al., (2006) describe as “vulnerable babies” the babies in this study were having their first breastfeed on average at 49 minutes after birth. They were all initiating breastfeeding during skin to skin contact with their mothers at birth. This time frame was in line with the World Health Organisation recommendation that breastfeeding initiation should be facilitated through mother/baby skin to skin contact within half an hour of birth (WHO/UNICEF, 1989). All the multiparous women had previous breastfeeding experience and some verbally reported poor breastfeeding outcomes with a previous baby. In a future study it would be advantageous to collect data about previous breastfeeding issues to determine if antenatal colostrum harvesting helped to mitigate any of these problems. Babies who were born vaginally were breastfeeding at a slightly earlier average time of 46 minutes than those who were born by caesarean section who were first breastfed at an average of 51 minutes. There is insufficient data to identify if this time difference is statistically significant but the trend is one supported by the literature (Finigan, 2006; Nissen et al., 1996). It should also be noted that the reported time for the first breastfeed may be subject to recall bias. A more accurate method for capturing this data, such as asking the LMC as it is part of her birth data collection, should be considered in a future study. At 48 hours 90% (n=9) of babies were exclusively breastfeeding and 10% (n=1) were partially breastfeeding. At seven days 60% (n=6) of babies were exclusively breastfeeding, 30% (n=3) were fully breastfeeding and 10% (n=1) were partially breastfeeding.

All of the women reported that they believed that antenatal colostrum harvesting had been helpful with the establishment of breastfeeding and they all indicated that they would do it again in another pregnancy.

Although no conclusions can be formed with respect to the impact of colostrum harvesting and banking on the long term breastfeeding rates from this small cohort study the available literature suggests that there are health benefits from being exclusively or fully breastfed up to six months (Duijts et al., 2010; Hanson, 2004; Hanson 2007; Lawrence & Lawrence, 1999; Oddy, 2001; César et al., 1999; World Health Organisation, 2009).

Literature also suggests that wherever possible the avoidance of ingesting cows' milk in the first few months of life is likely to yield additional health benefits such as reducing the risk of developing Type 1 and Type 2 DM (Borch-Johnson et al., 1984;

Cavallo, et al., 1996; Glatthaar et al., 1988; Mayer et al., 1988; Virtanen et al., 1991; Horta, et al., 2007; Owen et al., 2006).

This pilot study suggests that a large study with a control group could collect statistically significant data which may be useful for informing the practice of health professionals as they support women with diabetes to breastfeed.

5.8 Limitations of the Study Design

The small numbers of participants in this pilot study and the lack of a control group meant that it was not possible to determine whether or not antenatal colostrum harvesting made a difference to the breastfeeding experience of mothers and babies. The recruitment of participants for this study was by self-selection which suggests a possible bias towards women motivated to express colostrum and to breastfeed. Antenatal colostrum harvesting may be a more challenging process for the general population of women with diabetes. There were no funds available in the budget for this pilot study to include participants who would require the services of an interpreter. This limitation is likely to have excluded some prospective participants as Asian, Indian and Pacific people have an increased risk of developing diabetes mellitus during pregnancy (Ministry of Health, 2007). Therefore it would be prudent to include funds for interpreter services in the budget of a larger study.

In February and June 2011 Canterbury experienced two significant earthquakes which disrupted the normal day to day life of many people including those enrolled in the antenatal colostrum harvesting study. There were extensive interruptions to the electricity supply which meant that two study participants suspended collection until they had power returned to their refrigerators and freezers.

A further limitation of this study design was that the pilot study protocol was not followed with respect to the baby who developed hypoglycaemia. The reasons for non-adherence to the study protocol are not clear but it highlights the need for improving the process around LMC and core staff awareness of the importance of following the protocol for any future study. I acknowledge that a situation may arise where a departure from the protocol is necessary and in this instance it would be useful to have documented reasons for this.

5.9 Strengths and Weaknesses of the Study Design

In the satisfaction survey (Appendix 13) the women consistently reported that they were satisfied with most aspects of the study. They reported that the information was informative, clear and easy to understand. Study participants reported that the researcher was approachable and accessible. Some participants reported that expressing could be

tricky and time consuming but engendered feelings of confidence, excitement, satisfaction and happiness. Two participants would have liked to have had more colostrum available. They were reassured that any colostrum collected was beneficial. Participants stated that expressing colostrum seemed to encourage an earlier onset of lactation with a better milk supply than they were expecting. The study cannot provide an objective measure of this, but it suggests that antenatal colostrum harvesting was a reassuring, productive and positive step towards successful breastfeeding for these women. A feeling of confidence, comfort and security was generated for the study participants as a result of antenatal colostrum harvesting. Therefore a significant strength of this study design was that antenatal colostrum harvesting was achievable. The guidelines and policies around the promotion of exclusive and full breastfeeding for women with diabetes via the intervention of antenatal colostrum harvesting are already changing in the absence of evidence (personal communication with CWH lactation consultant, 2011). This pilot study is the initial step in providing evidence around this practice.

One of the weaknesses of this pilot study was that the sample size was small. This meant that statistically significant results could not be obtained. This was a pilot study designed to test the feasibility of the protocol therefore a control group was not necessary. Another weakness of the study could be self-selection bias. The sample of women in this is not representative of the total population of women with diabetes in pregnancy.

5.10 Links of this Study to Current Research

Little has been written about the effectiveness of colostrum harvesting and its role in the management of breastfeeding support for women with diabetes in pregnancy. Since beginning this study two similar studies have been published. Singh and colleagues (2009) carried out a prospective study of 180 pregnant women at term. A random selection of 90 cases was selected to breast express at least once a day from 37 weeks gestation. They concluded that antenatal breast expression significantly reduced the time for establishing lactation and reduced breastfeeding failures (Singh et al., 2009). Forster and her research team (Forster et al., 2011) were aware that some hospitals were encouraging women to express and bank their colostrum antenatally for use in the newborn period, so they carried out a pilot study where they recruited 43 pregnant women with diabetes in pregnancy requiring insulin. Their aim was to establish the feasibility of conducting a randomised control trial to evaluate this practice. They published their findings with respect to diabetes and antenatal milk expression and concluded from their pilot study that it would be feasible and desirable to conduct a randomised controlled trial of antenatal milk expressing for women with diabetes. They acknowledged that the numbers in their pilot study were too

small to make statistical conclusions however they did report that their pilot study showed no obvious harm to mothers or babies. However they recommended that the practice cease until safety around the process had been established. They were concerned that more babies in their pilot group who were admitted to the special care nursery than a similar group of infants from an audit study. They also expressed concern that the women who expressed antenatally laboured on average one week earlier than those in a retrospective cohort study who did not express. It was suggested that other ways of moving forward should be explored with the option of using donor human milk when the mother's milk was insufficient or unavailable.

5.11 Links to Future Research

Antenatal colostrum harvesting has been promoted in Canterbury New Zealand at least since 2007 as being a positive step towards exclusive or full breastfeeding for women with diabetes in pregnancy however this is not an evidence based practice. Antenatal colostrum harvesting for use in the newborn period is becoming more common for women with diabetes. The outcomes from this New Zealand pilot study clearly show the women in this study were happy to be involved in the process of antenatal colostrum harvesting. They were able to express their colostrum, store it safely and transport it to the hospital and use it in the post natal period.

The tools and processes used in this study have been reviewed for their effectiveness and on the whole they performed well enabling the collection of quantifiable data about antenatal colostrum harvesting. Modifications to the methodology and some of the tools and processes may be indicated, as specified below, to improve their usability.

Recommendations for future research include:

- The use of a comparison or non-intervention group
- Minor changes to the lay out and data fields of the Colostrum Harvesting Log Sheet to facilitate analysis
- Contact the participant on her “due date” if birth notification has not been received
- At the time of induction of labour record the participant's Bishop's score
- Make education available for study participants with respect to the importance of direct breastfeeding the baby at each feed
- Provide further education for LMC and core staff with respect to the importance of complying with the study protocol
- Identify a process for recording information when a departure from the study protocol has occurred

- Formulate a plan regarding the proper return or disposal of any unused colostrum

5.12 Conclusion

The results from this pilot study clearly show that the women in this study were able to learn how to express their breasts effectively so that they could harvest their colostrum. They stored the harvested colostrum safely and transported it to hospital for use in the postnatal period. The results from this pilot study are less compelling with respect to effectively using the banked colostrum in the hospital setting because only one baby was clinically hypoglycaemic soon after birth and the study protocol was not followed for this baby. However other mothers did use colostrum even though it was not clinically indicated suggesting that it was feasible to access and administer the banked colostrum. It is not clear if there would be barriers to this procedure for babies who were clinically hypoglycaemic.

The results from this study suggest that it would be feasible to conduct a larger study to determine whether or not antenatal colostrum harvesting and banking facilitates exclusive or full breastfeeding for women with diabetes. Further study is needed in this area to provide evidence for an existing practice which may have positive outcomes for mothers with diabetes and their babies.

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Appendices

- Appendix 1 Diabetes Mellitus in Pregnancy: Colostrum Harvesting in Preparation for Breastfeeding p.1 & 2.
- Appendix 2 Letter of Consultation
- Appendix 3 Diabetes Mellitus in Pregnancy: Colostrum Harvesting in Preparation for Breastfeeding. – Simplified version p.1 & 2.
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- Appendix 14 Letter of Thanks
- Appendix 15 Verbatim Participant Satisfaction Survey comments

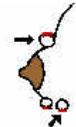
Appendix 1 DM in Pregnancy: Colostrum Harvesting in Preparation for Breastfeeding p.1

Marmet Technique for Breast Expression (18)

1. POSITION the thumb and first two fingers about 2—3 cm behind the nipple.



2. PUSH straight into the chest wall. Avoid spreading the fingers apart. For large breasts, first lift and then push into the chest wall.



3. ROLL thumb and fingers forward as if making thumb and fingerprints at the same time.



4. FINISH ROLL The rolling motion of the thumb and fingers compresses and empties the milk reservoirs without hurting sensitive breast tissue.

* The use of a breast pump is not recommended ante-natally

Ask your LMC/midwife or diabetes midwife educator to help you learn to express your colostrum.

Consider attending breastfeeding education sessions. Ask your LMC/ midwife about providers in your area, La Leche League, Lactation Consultants, District Health Boards

Researched & authored by Catherine Rietveld, NZRM, 2007

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Diabetes Mellitus in Pregnancy (Gestational Diabetes, Type 1 & Type 2) & Colostrum Harvesting in Preparation for Breastfeeding



Picasso

Appendix 1 DM in Pregnancy: Colostrum Harvesting in Preparation for Breastfeeding p.2



I have Diabetes Mellitus in Pregnancy

Can I exclusively or fully breastfeed my baby?

Yes you can! With a little extra knowledge, support and planning, it is possible for you to exclusively or fully breastfeed your baby. (1) (21) Globally there is a diabetes epidemic and the situation in New Zealand appears to be similar. (2) (3) There is increasing evidence that breastfeeding has a protective effect against obesity and diabetes later in life. (4) (5)

What is Colostrum?

Colostrum is the nutrient and antibody rich first milk produced by your breasts from about the 16th week of pregnancy. It is an unbeatable first food for your baby. (1)(6)

What is Colostrum Harvesting?

Harvesting colostrum ante-natally is not a new concept. Between the 1960's and 1980's midwives encouraged women to express colostrum in preparation for breast feeding. (1) The practice discontinued when extensive research into breastfeeding found little benefit from the practice other than helping the woman gain confidence in handling her breasts! (1) (13) A knowledge of hand breast expression is now regarded as an advantage as women have the skills to maintain lactation even when separated from their baby. (19)

Colostrum harvesting is the collection of colostrum from your breasts before your baby is born. This is done to promote exclusive or full breast feeding and protect the baby from supplement feeding with artificial infant milk. Infants born to mothers with GDM may require additional feeding to correct low blood sugar also known as hypoglycaemia. (1) Expressing colostrum antenatally can promote a generous supply of colostrum which will be readily available for your baby at birth. (13)

Why could my baby need extra colostrum at birth?

Babies born to mothers with diabetes often experience hypoglycaemia in the first 24–48 hours of life. This occurs because high blood sugar levels in the mother during the pregnancy have triggered increased insulin production in the baby which has the potential to cause hypoglycaemia soon after birth. (6) (11) (13) (14) If your baby's blood sugar is low then it may interfere with his or her ability to suckle effectively from your breast. (6) It would be a good idea to discuss the need for skin-to-skin, (7) early breastfeeding and the supplementary feeding of colostrum to your baby with your midwife. These details should be included in your birth plan.

Why should I consider harvesting my colostrum?

It is widely accepted that colostrum is the best first food for your baby. (1) (6) It is likely that your baby will need additional nutrition soon after birth to prevent hypoglycaemia. It is better for your baby to receive your colostrum rather than a breast milk substitute. (10) Breast milk promotes the mobilisation of alternative sources of fuel whereas infant formula, which is usually made from cow's milk, stimulates the increased production of insulin which may in turn lead to more hypoglycaemia. (13) If your baby's blood sugars remain above 2.6 mmol/l then the likelihood of your baby needing care in the neonatal unit are greatly reduced. Breast milk production is enhanced when you and your baby are together. When you "room-in" with your baby you are able to respond immediately to feeding cues. (11) (19)

What is lactogenesis?

Lactogenesis means making milk. This process starts during your pregnancy and continues as a response to the physiological changes that occur during labour and birth. Cuddling your baby skin to skin and early suckling at your breast will release the milk production hormones prolactin and oxytocin. (1) (7) (8) Sometimes mothers with diabetes may experience delays in lactogenesis (milk production). This is probably a combined effect of reduced suckling by the baby and subsequently a slower release of prolactin which is one of the hormones vital in the initiation and maintenance of breast milk production. (5) (15)

What will happen during my labour?

Your physician and obstetrician will decide if you need to be on an insulin/dextrose intravenous infusion during your labour or if you can be managed more conservatively. In either case you will need to monitor your blood sugar levels (BSL) every hour once you are in established labour. Your midwife will plot these on a special chart. Ideally your BSL should remain between 4–8 mmol/l as this will help protect your baby from hypoglycaemia. (11) You may like to express some fresh colostrum during your labour.

How will I know if my baby's blood sugar is low?

Ideally your baby should be skin to skin with you from birth which will help baby keep warm and give your baby the opportunity to breastfeed early. **Skin to skin contact and early breast feeding should be the first actions taken to prevent neonatal hypoglycaemia.** (7) (16) (20) After breast feeding, your baby may be cup fed expressed colostrum either fresh or from your frozen supply. Your midwife will then check the baby's blood sugar just prior to the **second feed** and then prior to each feed until 3 consecutive readings above 2.6 mmol/l have been achieved. (11) (17) Your midwife will also be observing your baby for other signs of hypoglycaemia such as jitteriness, sleepiness or lack of interest with feeding. (20)

Is it safe to express colostrum during pregnancy?

Yes, the pregnant body has mechanisms to protect it from the effects of oxytocin, a hormone released during breastfeeding which also stimulates uterine muscle to contract. Many women continue to breastfeed another child while they are pregnant and the pregnancy is unaffected. The oxytocin receptor sites in the uterus are sparse until the pregnancy is at term when proliferation occurs. Oxytocin blockers are also in effect for most of the pregnancy the major one being progesterone which binds to the oxytocin receptor sites preventing oxytocin from initiating significant uterine activity until the body is ready to labour and birth. (12)

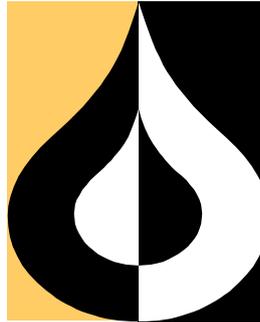
Will I still have enough colostrum for my baby at birth?

Yes, your body will continue to make colostrum until after your baby and placenta have been born. Milk production (lactogenesis) is stimulated by the changing hormonal levels at birth, skin-to-skin contact of mother and baby and early and frequent suckling at the breast. (7) (8)

Harvesting and storage of your colostrum.

- ◆ Contact your LMC or diabetes midwife educator for extra support or education on learning how to hand express safely.
- ◆ You may start **hand expressing*** from 34 weeks gestation.
- ◆ Select a warm comfortable space.
- ◆ Wash your hands prior to expressing.
- ◆ It may help to have a bath or a shower prior to expressing as the warmth may help the colostrum to flow more easily.
- ◆ Sit upright with easy access to your breasts.
- ◆ From 34 weeks you may **hand express** up to three times a day for a few minutes each side at the start increasing the time as your flow increases. Use the Marmet Breast Expression Technique (18) as explained on the next page.
- ◆ Initially the amount of colostrum may be small. When you notice beads of colostrum you can draw them up into a syringe. Once your colostrum is flowing more freely then you can collect it directly in sterile containers.
- ◆ Colostrum can be stored in the refrigerator between sessions on the same day and then frozen until required. It is a good idea to put the date of expressing on the container.
- ◆ Remember to take your frozen colostrum with you to the hospital when you are in labour. Ideally in a chilly bin so that it doesn't thaw before required.
- ◆ You can also collect some fresh colostrum during labour, ask your partner, birth assistant or midwife to help you. (13)

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18 August 2010

Name
 Address
 Address

Dear

I am proposing to undertake a small pilot study into Antenatal Colostrum Harvesting for pregnant women with Type 1, 2 or Gestational Diabetes Mellitus. This study will complete my requirements for my Master in Midwifery degree. I am writing to invite your comments on my proposed study. I have been granted approval from the Otago Polytechnic to proceed with this study. I am now in the process of applying for ethics approval from the Upper South B Ethics Committee. I have enclosed the condensed proposal that is drawn from the work completed in my literature review. If you require more information I would be very happy to provide you with an electronic copy my literature review and full research proposal.

I would be happy to meet with you in person if you would like to discuss this study face to face.

I am hoping to begin the recruitment phase in October of this year. I look forward to your favourable response.

Yours sincerely,

Catherine Rietveld

Appendix 3 DM in Pregnancy: Colostrum Harvesting in Preparation for Breastfeeding. – Simplified version p.1

Marmet Technique for Breast Expression

1. POSITION the thumb and first two fingers about 2—3 cm behind the nipple.



2. PUSH straight into the chest wall. Avoid spreading the fingers apart. For large breasts, first lift and then push into the chest wall.



3. ROLL thumb and fingers forward as if making thumb and fingerprints at the same time.



4. FINISH ROLL The rolling motion of the thumb and fingers compresses and empties the milk reservoirs without hurting sensitive breast tissue.

<http://video.about.com/breastfeeding/Hand-Expression-Technique.htm>

*** The use of a breast pump is not recommended ante-natally**

Ask your LMC/midwife or diabetes midwife educator to help you learn to express your colostrum.

Consider attending breastfeeding education sessions. Ask your LMC/ midwife about providers in your area, La Leche League, Lactation Consultants, District Health Boards

Researched & authored by Catherine Rietveld, NZRM, 2007, updated September 2010.



Diabetes Mellitus in Pregnancy (Gestational Diabetes, Type 1 & Type 2) & Colostrum Harvesting in Preparation for Breastfeeding (abridged version)



Picasso

Appendix 3 DM in Pregnancy: Colostrum Harvesting in Preparation for Breastfeeding. – Simplified version p.2



I have Diabetes Mellitus in Pregnancy

Can I exclusively or fully breastfeed my baby?

Yes you can! With a little extra knowledge, support and planning it is possible for you to exclusively or fully breast feed your baby. World-wide there is a diabetes epidemic and the situation in New Zealand appears to be similar. There is increasing evidence that breastfeeding has a protective effect against obesity and diabetes later in life.

What is Colostrum?

Colostrum is the nutrient and antibody rich first milk produced by your breasts from about the 16th week of pregnancy. It is the best first food for your baby.

What is Colostrum Harvesting?

Colostrum harvesting is the collection of colostrum from your breasts before your baby is born. This is done to promote exclusive or full breast feeding and protect the baby from supplement feeding with artificial infant milk. Infants born to mothers with GDM may require additional feeding to correct low blood sugar also known as hypoglycaemia. Expressing colostrum antenatally can promote a generous supply of colostrum which will be readily available for your baby at birth.

Why could my baby need extra colostrum at birth?

Babies born to mothers with diabetes often experience hypoglycaemia in the first 24–48 hours of life. This occurs because high blood sugar levels in the mother during the pregnancy have triggered increased insulin production in the baby which has the potential to cause low blood sugar or hypoglycaemia soon after birth. If your baby's blood sugar is low then it may interfere with his or her ability to suckle effectively from your breast. It would be a good idea to discuss the need for skin-to-skin, early breastfeeding and the supplementary feeding of colostrum to your baby with your midwife. These details should be included in your birth plan.

Why should I consider harvesting my colostrum?

It is widely accepted that colostrum is the best first food for your baby. It is likely that your baby will need additional nutrition soon after birth to prevent or correct hypoglycaemia. It is better for your baby to receive your colostrum rather than a breast milk substitute. If your baby's blood sugars remain above 2.6 mmol/l then the likelihood of your baby needing care in the neonatal unit are greatly reduced. Breast milk production is enhanced when you and your baby are together. When you "room-in" with your baby you are able to respond immediately to feeding cues.

What is lactogenesis?

Lactogenesis means making milk. This process starts during your pregnancy and continues after baby is born. Cuddling your baby skin to skin and early suckling at your breast will release the milk production hormones prolactin and oxytocin. Sometimes mothers with diabetes may experience delays in their milk production. This will be minimised if you and your baby stay together so that you can cuddle your baby skin to skin and feed when baby is showing signs of hunger.

What will happen during my labour?

Your physician and obstetrician will decide if you need to be on an insulin/dextrose intravenous infusion during your labour or if you can be managed more conservatively. Once you are in established labour your medical team will determine how often your blood sugar levels will be monitored and what sort of treatment you need for your diabetes during labour. Ideally your BSL should remain between 4–8 mmol/l as this will help protect your baby from hypoglycaemia. You may like to express some fresh colostrum during your labour.

How will I know if my baby's blood sugar is low?

Ideally your baby should be skin to skin with you from birth which will help baby keep warm and give your baby the opportunity to breastfeed early.

Skin to skin contact and early breast feeding should be the first actions taken to prevent neonatal hypoglycaemia.

After breast feeding, your baby may be cup fed expressed colostrum either fresh or from your frozen supply. Your midwife will then check the baby's blood sugar just prior to the **second feed** (or at 3 hours of age) and then prior to each feed until 3 consecutive readings above 2.6 mmol/l have been achieved. Your midwife will also be observing your baby for other signs of hypoglycaemia such as jitteriness, sleepiness or lack of interest with feeding.

Is it safe to express colostrum during pregnancy?

Yes, the pregnant body has mechanisms to protect it from the effects of oxytocin, a hormone released during breastfeeding which also stimulates uterine muscle to contract. Many women continue to breastfeed another child while they are pregnant and their labour does not start prematurely.

Will I still have enough colostrum for my baby at birth?

Yes, your body will continue to make colostrum until after your baby and placenta have been born. Milk production (lactogenesis) is stimulated by the changing hormonal levels at birth, skin-to-skin contact of mother and baby and early and frequent suckling at the breast.

Harvesting and storage of your colostrum.

- ◆ Contact your LMC or diabetes midwife educator for extra support or education on learning how to hand express safely.
- ◆ You may start **hand expressing*** from 34 weeks gestation.
- ◆ Select a warm comfortable space.
- ◆ Wash your hands prior to expressing.
- ◆ It may help to have a bath or a shower prior to expressing as the warmth may help the colostrum to flow more easily.
- ◆ Sit upright with easy access to your breasts.
- ◆ From 34 weeks you may **hand express** up to three times a day for a few minutes each side at the start increasing the time as your flow increases. Use the Marmet Breast Expression Technique as explained on the next page.
- ◆ Initially the amount of colostrum may be small. When you notice beads of colostrum you can draw them up into a syringe. Once your colostrum is flowing more freely then you can collect it directly in sterile containers.
- ◆ Colostrum can be stored in the refrigerator between sessions on the same day and then frozen until required. It is a good idea to put the date of expressing on the container.
- ◆ Remember to take your frozen colostrum with you to the hospital when you are in labour. Ideally in a chilly bin so that it doesn't thaw before required.
- ◆ You can also collect some fresh colostrum during labour, ask your partner, birth assistant or midwife to help you.

Appendix 4 Prospective Participant Information Brochure

If I take part in this study, what will be expected of me?

Once you indicate to the researcher that you would like to participate in this study you will be asked for your written consent.

After the consent form has been signed the researcher will explain the next steps in the process.

- Your researcher will ask you for your contact details. Your privacy will be respected and your data remain confidential to the research team.
- Your researcher will make contact with your LMC informing that you have decided to take part in this study.
- You will be supplied with an antenatal colostrum harvesting kit.
- You will meet with the researcher at about 32 weeks gestation to learn more about the process of antenatal colostrum harvesting and colostrum banking or storage.
- You will be asked to keep an accurate record of your colostrum harvesting on the log sheet provided. You may start expressing from 34 weeks gestation.
- You will be required to inform the researcher of your baby's birth. You may delegate this task to another person.
- Your researcher will review your hospital health record after your baby is 48 hours old. She will contact you by phone between 8 and 11 days to record your breast feeding experience in the first week. At 2 weeks post natally you will be asked to complete a short satisfaction survey which will ask you questions about your experience of antenatal colostrum harvesting and breastfeeding. You may contact your researcher at any time during this period if you have any questions or concerns.
- Your LMC and specialist team at Christchurch Women's Hospital will continue to provide you with all of your midwifery and diabetes care.

What happens if I decide not to participate in the study any more?

You have the right to withdraw from the study at anytime without having to give a reason. Your withdrawal will not affect your ongoing midwifery or medical care.

Thank you for taking the time to read this information.

If you would like to offer yourself as a participant in this study please contact the researcher

Catherine Rietveld
rietveld@ihug.co.nz

03 3237490

027 2286 747.

Thank you



Masters of Midwifery
Research Project

Information Sheet for Prospective Participants

Antenatal Colostrum Harvesting for Diabetes in Pregnancy Study



Catherine Rietveld
Principal Researcher Masters of Midwifery
Student

Dr Sally Baddock
Research Supervisor—Otago Polytechnic

Lindsay Irons
Midwifery Diabetes Educator &
Research Assistant

Appendix 4

Prospective Participant Information Brochure

Invitation to Participate

This study has been approved by the Multi-region Ethics Committee – Ref No: MEC/10/10/107

You are invited to take part in a small study of 6-12 women with diabetes (Type 1, 2 or Gestational Diabetes) in pregnancy. The first aim of this study is to determine if women can effectively achieve antenatal colostrum harvesting and banking. Secondly to discover if colostrum harvesting and banking will decrease the need for supplementary feeding with cow's milk formula or other breast milk substitutes.

Please read the following information, discuss with your family and ask questions before making a decision to participate or not over the next 3–4 days.

You will continue to receive your full entitlement to midwifery and medical care whether you take part in the study or not.

Diabetes, breastfeeding and the newborn

Health professionals agree that exclusive or full breastfeeding for the first 6 months of a baby's life will afford lifelong benefits against many diseases.

Babies born to mothers with diabetes often experience low blood sugar in the first 24–48 hours of life. This occurs because the mothers blood sugar levels during the pregnancy may have triggered high insulin production in the baby. This can cause low blood sugar in the baby soon after birth. The baby may need supplementary feeding to bring his/her blood sugar level back to normal. If a mother has been expressing her colostrum antenatally she may have a greater supply of colostrum available for her baby at birth and if this is still not enough then her baby may be fed some of her banked colostrum.

What is the problem with artificial infant milk?

Artificial infant milk is most likely to be made from cow's milk. A large number of research studies have demonstrated that early exposure to bovine serum albumin, found in cow's milk, increases the risk of a person developing Type 1 and Type 2 diabetes especially in those individuals with genetic predisposition.

Why should I consider harvesting my colostrum?

It is widely accepted that colostrum is the best first food for your baby. Fifty percent of babies born to mothers with diabetes develop low blood sugar levels. It is better for your baby to receive your colostrum rather than an artificial infant formula which is likely to be made from cow's milk. If your baby's blood sugars remain within the acceptable limits then the likelihood of your baby needing care in the neonatal unit are greatly reduced. Breast milk production is enhanced when you and your baby are together. When you "room-in" with your baby you are able to respond immediately to feeding cues.

Is it safe to express colostrum during pregnancy?

The pregnant body has mechanisms to protect it from the effects of oxytocin, a hormone released during breastfeeding which also stimulates uterine muscle to contract. Many women continue to breastfeed another child while they are pregnant and the pregnancy is unaffected.

What are the benefits to being in this study?

The benefits of antenatal colostrum harvesting lie in the protection and promotion of you and your baby's right to breastfeed.

Will I still have enough colostrum for my baby at birth?

Your body will continue to make colostrum until after your baby and placenta have been born. Milk production is stimulated by the changing hormonal levels at birth, skin-to-skin contact of mother and baby and early and frequent suckling at the breast.

Will the study add any costs to my care?

The study will not involve any financial costs to you. You will be supplied with all the equipment (apart from the freezer!) needed to express and store your colostrum. There will be a time related costs related to the education, log record keeping, telephone interview, survey completion and the 10 minutes per day with respect to expressing. There is no payment for being involved in this study.

Will I be given the results of the study?

You will be sent a full copy of the report. The results of this small study may suggest a larger study is required. The results of that larger study may inform the development of strategies to more effectively support breastfeeding amongst mothers with diabetes.

Are my rights protected if I participate in this study?

This study has been approved by the Multi-Centre Ethics Committee – approval number MEC/10/10/107. Your confidentiality is protected and none of your personal details will be included in the report. In the unlikely event that you sustained a physical injury as result of your participation in this study you will be covered by accident compensation (ACC) legislation. If you have any queries about ACC please feel free to ask the researcher before agreeing to participate in this study. If you have any questions or concerns that have not been answered to your satisfaction by the researcher then you may wish to contact the Health and Disabilities Advocates Trust. Ph 03 377 7501.

Additional Support for Participants

If you need the support of a Maori Health Worker at any stage during this study you may contact

Debbie Rawiri

(Maori Diabetes Nurse Specialist)

Maureen Reason

(Diabetes Maori Health Worker).

Ph 364 0860

Both Debbie and Maureen are based at the Canterbury District Health Board Diabetes Centre

Appendix 5

Consent Form

Catherine Rietveld

NZRCpN, NZRM, Post Grad Diploma of
Midwifery

560 Marshland Road

Ouruhia

Christchurch 8083

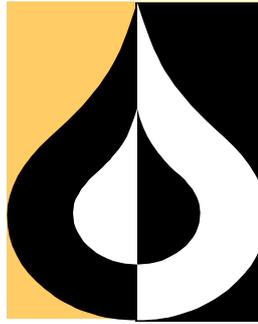
New Zealand

Telephone: **03 323 7490**

Mobile: **027 2286 747**

Fax: **03 323 7418**

email:rietveld@ihug.co.nz



**Masters of Midwifery
Research Project**

Consent Form

This study has been approved by the Multi-region Ethics Committee – Ref No: MEC/10/10/107

Title of Project: Antenatal Colostrum Harvesting and Diabetes in Pregnancy

Participant's Name:..... **Study Participant Number**

Name of Researcher: Catherine Rietveld

Research Supervisor: Dr Sally Baddock

English	I wish to have an interpreter	Yes	No
Deaf	I wish to have a NZ sign language interpreter	Yes	No
Māori	E hiahia ana ahau ki tetahi kaiwhaka Māori/kaiwhaka pakeha korero	Ae	Kao
Cook Island Māori	Ka inangaro au i tetahi tangata uri reo	Ae	Kare
Fijian	Au gadreva me dua e vakadewa vosa vei au	Io	Sega
Niuean	Fia manako au ke fakaaoga e taha tagata fakahokohoko kupu	E	Nakai
Sāmoan	Ou te mana'o ia i ai se fa'amatala upu	loe	Leai
Tokelaun	Ko au e fofou ki he tino ke fakaliliu te gagana Peletania ki na gagana o na motu o te Pahefika	loe	Leai
Tongann	Oku ou fiema'u ha fakatonulea	Io	Ikai

I confirm that I have read and understand the Information for Prospective Participants which explains the purpose of this study. Yes/No

I have had the opportunity to consider the information, ask questions and I have had these answered to my satisfaction. Yes/No

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. Yes/No

I understand that relevant sections of any of my medical notes and data collected during the study may be viewed by responsible persons from Otago Polytechnic and from CDHB where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. Yes/No

I agree to my LMC being informed of my participation in the study. Yes/No

I agree to take part in the above research study. Yes/No

Name of Participant

Date

Signature

Name of Person taking consent
(if different from researcher)

Date

Signature

Researcher

Date

Signature

1 copy for participant, 1 copy for researcher's file: 1 (original) to be kept in clinical notes

Appendix 6 Birth and Breastfeeding Data Sheet

Antenatal Colostrum Harvesting Birth & Breastfeeding Data Sheet

Participant..... Study Participant Number

.....

Address.....

Phone..... Mob.....

LMC.....

Breastfeeding Experience Y/N Comment.....

EDD/...../..... G.....P.....

Birthed/...../.....

Gestation at Birth/40

Type of Labour

Length of Labourhrs.....mins

Type of Birth

Skin to Skin Y/N

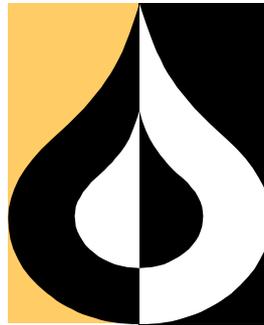
Time of 1st B/Fhrs

Supplementation in 1st 48 hours

Reason	Time	Type	Amount	Baby BGL

B/F @ 48hours	Exclusive	Fully	Partial	A/F
B/F @ 7 days	Exclusive	Fully	Partial	A/F

Antenatal Colostrum Harvesting for Diabetes in Pregnancy



Information for CWH Staff

.....is a study participant in the Antenatal Colostrum Harvesting for Diabetes in Pregnancy Study.

If her baby is clinically hypoglycaemic and a supplementary feed is indicated could you please first check with to see if she has any available banked colostrum.

Ifhas banked colostrum available please support her to feed her baby in 1 ml increments to a maximum of 7 mls per feed in the first 24 – 48 hours.

In every instance baby should be offered a direct breastfeed first and banked colostrum only be given if the baby is clinically hypoglycaemic.

Please refer to the WHD OPS W&WC0743 Hypoglycaemia : Management of (infant)

This study has Ethics Committee approval number MEC/10/10/107

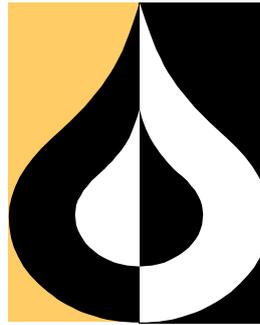
Thank you.

Catherine Rietveld
Research Midwife

027 2286747
rietveld@ihug.co.nz

Catherine Rietveld

NZRCpN, NZRM, Post Grad
 Diploma of Midwifery
 560 Marshland Road
 Ouruhia
 Christchurch 8083
 New Zealand



Telephone: **03 323 7490**
 Mobile: **027 2286 747**
 Fax: **03 323 7418**

email:rietveld@ihug.co.nz

Date

Name
 Address
 Address

Dear

I am writing to inform you that your client.....has consented to participate in a the **Antenatal Colostrum Harvesting for Diabetes in Pregnancy study in 2010.**

The first part of this study utilises a convenience sample of 6 women with diabetes in pregnancy. The main aim of the study is to review the tools and processes which will inform a larger study looking at the same subject.

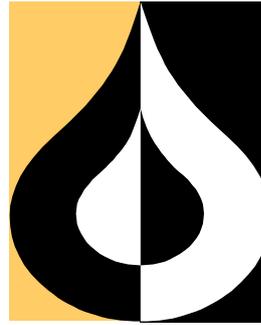
You will not be required to undertake any additional responsibilities as a result of your client enrolling in this study.

I have enclosed the information sheet that I have given to all prospective participants.

If you have any questions about this study or any concerns about your client in relation to this study please call me. Thank you

Yours sincerely

Catherine Rietveld
 Research Midwife
 Encl. (1)



Colostrum Harvesting Kit List

- 1) Antenatal Colostrum Harvesting Pamphlet
- 2) Information for Prospective Study Participants
- 3) Antenatal Colostrum Harvesting Consent Form
- 4) Antenatal Colostrum Harvesting Log Sheet
- 5) Information sheet on storage of colostrum and breastmilk
- 6) Information sheet on thawing and warming of colostrum and breastmilk
- 7) 1 sheet of Colostrum Harvesting labels
- 8) Researcher Contact Business Card
- 9) 6 x 1ml syringes
- 10) 6 x 2ml syringes
- 11) 4 Sterile Pottles
- 12) 6 ziplock Bags
- 13) Chilly Bin for transport and storage of colostrum away from home
- 14) Ice Bricks to be used in the Chilly Bin for transportation of frozen colostrum



Appendix 10

Breast Mannequin



Appendix 11

Colostrum Storage Information

HUMAN MILK STORAGE - QUICK REFERENCE CARD		
	Temperature	Storage Time
Freshly expressed milk		
Warm room	79°F / 25°C	4-6 hours
Room temperature	66-72°F / 19-22°C	10 hours
Insulated cooler / Icepacks	60°F / 15°C	24 hours
Refrigerated Milk (Store at back, away from door)		
Refrigerator (fresh milk)	32-39°F / 0-4°C	8 days
Refrigerator (thawed milk)	32-39°F / 0-4°C	24 hours
Frozen Milk (Do not refreeze! Store at back, away from door/sides)		
Freezer compartment inside refrigerator (older-style)	Varies	2 weeks
Self-contained freezer unit of a refrigerator/freezer	Varies	3-6 months
Separate deep freeze	0°F / 19°C	6-12 months
<i>These guidelines are for milk expressed for a full-term healthy baby. If baby is seriously ill and/or hospitalized, discuss storage guidelines with baby's doctor.</i>		

www.kellymom.com

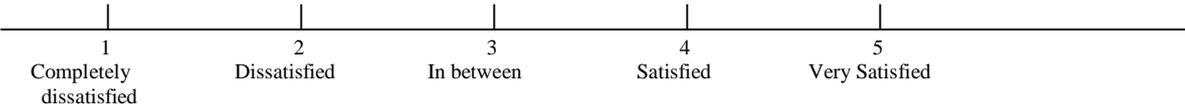
Antenatal Colostrum Harvesting For Diabetes in Pregnancy Client Satisfaction Survey

Study Participant Number.....



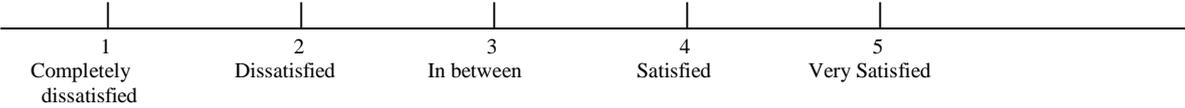
Thank you for taking part in this study. Your contribution is most valuable. You are now invited to rate your satisfaction with the processes. Using the scale please circle the number that most closely represents your level of satisfaction in each area.

1. How satisfied were you with the information you received inviting you to be part of the study?



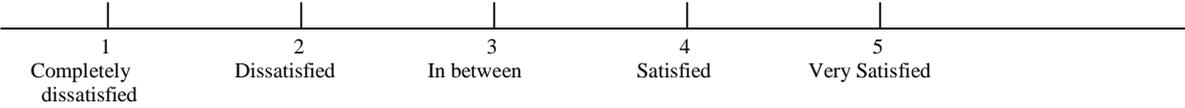
Comments.....
.....
.....

2. How satisfied were you with the quality of information and products in the Colostrum Harvesting Kit?



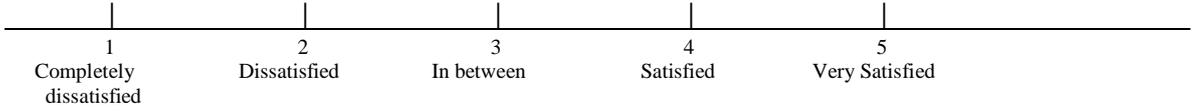
Comments.....
.....
.....

3. How satisfied were you with the availability of the researcher?



Comments.....
.....
.....

4. How satisfied were you with the education you received about manual breast expression?



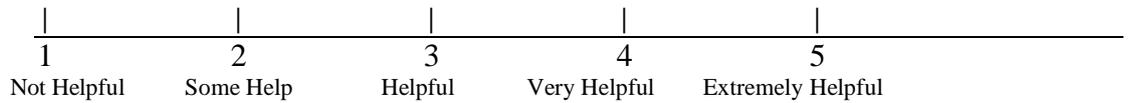
Comments.....
.....
.....

5. How satisfied were you with your manual breast expression?



Comments.....
.....
.....

6. Do you feel that antenatal colostrum harvesting helped you with your breastfeeding?



Comments.....
.....
.....

7. Would you consider antenatal colostrum harvesting in a future pregnancy? Please circle.

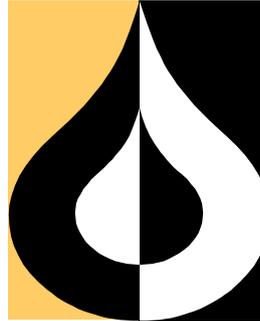
Yes

No

Comments.....
.....
.....

**Thank you for completing this survey.
Please post it back to the researcher in the envelope provided.**

Catherine Rietveld
NZRCpN, NZRM, Post Grad
Diploma of Midwifery
560 Marshland Road
Ouruhia
Christchurch 8083
New Zealand



Telephone: **03 323 7490**
Mobile: **027 2286 747**
Fax: **03 323 7418**

[email:rietveld@ihug.co.nz](mailto:rietveld@ihug.co.nz)

Date

Name
Address

Dear

Congratulations on the safe arrival of your baby

Thank you for participating in the Antenatal Colostrum Harvesting for Diabetes in Pregnancy Study. Your contribution has been most valuable. I enclose with this letter your Client Satisfaction Survey which should only take you a few minutes to complete. The Client Satisfaction Survey and your Colostrum Harvesting Log Sheet can be returned in the stamped and addressed envelope provided.

Thank you once again and all the best for the future for you and your family.

Kind regards,

Catherine Rietveld
Research Midwife

Appendix 15 Verbatim Participant Satisfaction Survey comments

How satisfied were you with the information you received inviting you to be part of the study?

- “very clearly explained both written and verbally”
- “my LMC asked first but didn’t follow up on it even though I agreed first time around. Thanks to Lindsay it got organised later”
- “Very informative and thorough leaflet. Well referenced and of much interest to family and colleagues I showed it to”
- “Very informative and easy to comprehend”

How satisfied were you with the quality of information and products in the Colostrum Harvesting Kit?

- “Again clear purpose, clear understanding and direction. Good research references”
- “Lots of information in an easy to digest way”
- “Required more syringes and containers”

How satisfied were you with the availability of the researcher

- “Very approachable and accessible”
- “Always pleasant, informative and prompt”
- “Got questions answered and follow up material in easy and efficient way”
- “Accessible and regular visit made my researcher just as she described”
- “Always available via phone or txt”

How satisfied were you with the education you received about manual breast expression?

- “It was great to have the leaflet and the demonstration by Catherine”
- “The link to online video was very useful and I watched this a few times to get the hang of things”
- “Already knew from my previous child how to do this”

How satisfied were you with your manual breast expression?

- “It was tricky expressing twice daily with a toddler so I did it once a day at night time for convenience but I was very happy with the volume of colostrum I harvested”
- “Having a lot of colostrum made it hard to use the syringes for collection, I found it easier to use sterile container and measure the amount later”
- “Initially very slow and quite time consuming but extremely satisfying to be doing such a valuable thing”
- “Was very excited to be able to feed as I couldn’t with my first child”
- “I did give myself a few bruises to start with but it got better when I was a bit gentler”
- “Would have liked to have more colostrum available”

Do you feel that antenatal colostrum harvesting has helped you with your breastfeeding?

- “I have had exceptionally good milk volumes and would thoroughly recommend it to pregnant diabetic women as a positive step towards breastfeeding their newborn. Gave a feeling of security knowing I had a supply to supplement my feeds if necessary”
- “It gave me time and confidence for the technique”
- “I feel my milk came in very promptly. I felt confident handling my breasts and expressing and I feel this has helped a lot with learning to breastfeed”
- “My milk took 4 days to come in properly and bub was extremely hungry so the colostrum was very helpful”

Would you consider antenatal colostrum harvesting in a future pregnancy?

- All study participants responded affirmatively to this question.