A Study to Evaluate the Association between Prophylactic Ecbolics for the

Third Stage of Labour and Exclusive Breastfeeding at Two Weeks

Postpartum

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A thesis submitted to

Auckland University of Technology

In partial fulfillment of the requirements for the degree of

Master of Health Science (MHSc)

2010

School of Health and Environmental Sciences

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Attestation of Authorship

I hereby declare that this submission is my own work and that, to the best of my knowledge and belief, it contains no material previously published or written by another person (except where explicitly defined in the acknowledgements), nor material which to a substantial extent has been submitted for the award of any other degree or diploma of a university or other institution of higher learning.

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Acknowledgements

Abstract

Breastfeeding has considerable benefits for both mothers and infants. Current research evidence is demonstrating that events during labour and birth may have an effect on establishing exclusive breastfeeding (Forster & McLachlan, 2007). This study used a retrospective cohort methodology to assess for an association between prophylactic ecbolic medication used for the third stage of labour and exclusive breastfeeding at two weeks postpartum. *Method:* The study took advantage of data that had been collected and stored as part of routine maternity care. Two data sets were merged: one from a New Zealand District Health Board maternity database (Ecbolic data); and one from the New Zealand Ministry of Health maternity database (Breastfeeding data). After exclusions the final cohort consisted of 5988 well women giving birth to a normal healthy infant with no medical interventions. Binary regression analysis was used to evaluate an association between the confounding variables and exclusive breastfeeding at two weeks, and then multivariate analysis was performed with prophylactic ecbolics and the significant confounding variables to examine the relationship between exclusive breastfeeding and prophylactic ecbolics. *Results:* Univariate analysis revealed that ethnicity was significantly associated with exclusive breastfeeding at two weeks, with Chinese women OR *0.49 95% CI (0.37 – 0.64)* and Samoan women OR *0.81 95% CI (0.66 – 0.99)* being less likely than New Zealand/European women to be exclusively breastfeeding at two weeks. Multivariate analysis established that use of prophylactic ecbolics was not an independent factor predicting exclusive breastfeeding at two weeks in this cohort. *Conclusions:* Further research is needed to understand why women elect to stop exclusive breastfeeding prior to the recommended 6 months and what factors may be successful in influencing changes in behaviour in this regard. Given that Chinese and Samoan women are most likely to stop exclusive breastfeeding this would be a priority area for both health intervention and research.

Glossary

To aid the reader the following meanings have been attributed to the terms used in this study.

Apgar score   A scale from 1-10 developed by Dr Virginia Apgar to assess a newborn for the need for medical assistance (Apgar, 1975).

Antenatal   Occurring before birth, during pregnancy (Winson & McDonald, 2005).

Breastfeeding   New Zealand Ministry of Health definitions (Ministry of Health, 2002):

> **Exclusive Breastfeeding**   The infant has <u>never</u> had any water, infant formula, or other liquid or solid food: only breastmilk and prescribed medicines have been given from birth.

> **Fully Breastfeeding**   Within the past <u>48 hours</u>, the infant has taken breast milk only and no other liquids or solids, except minimal amounts of water or prescribed medicines

> **Partial Breastfeeding**   The infant has taken some breastmilk and some infant formula or other solid food in the past 48 hours

> **Artificial Feeding**   The infant has had no breast milk but has had alternative liquid such as infant formula, with or without solid food, in the past 48 hours

Ecbolic   A medication given to the woman during or immediately after the birth of a baby which causes the uterine muscles to contract rapidly to effect the separation of the placenta and reduce bleeding from the placental site. In international literature it is referred to as an oxytocic (Baddock & Dixon, 2006).

> **Prophylactic ecbolic**   The ecbolic medication is given preventatively to reduce the risk of postpartum bleeding

> **Treatment ecbolic**   The ecbolic medications is given as a treatment for postpartum haemorrhage (Baddock & Dixon, 2006).

Intrapartum   Occurring during labour and childbirth (Winson & McDonald, 2005).

Lead Maternity Carer (LMC) A Midwife, General Medical Practitioner (GP) or Obstetrician who provides continuity of primary maternity care to a woman and her infant (Ministry of Health, 2007). For the purposes of the study different midwife roles have been included:

> **Self-employed Midwife** An LMC Midwife who provides maternity care and is remunerated by the Ministry of Health
>
> **Employed Caseload Midwife** An LMC Midwife who provides maternity care and is employed by a District Health Board.
>
> **Employed Core Midwife** A midwife who provides maternity care as a District Health Board employee but does not provide continuity of care.

Multigravida A woman having her second or subsequent pregnancy

Multiparous A woman who has had two or more babies over 24 weeks gestation

NHI   National Health Index, a unique number given to every person at birth or at first contact with a health service if not born in New Zealand. All health events and health data are stored using this unique number.

Oxytocic   see ecbolic

Plunket   Royal New Zealand Plunket Society, a New Zealand organization that provides child health and developmental screening, and advice and support to parents of children under the age of 5 years to approximately 92% of the New Zealand population funded via a Ministry of Health contract and public donations

Postnatal   Occurring after birth, usually up to a period of six weeks (Winson & McDonald, 2005).

Postpartum Haemorrhage   Excessive bleeding from the genital tract, usually in excess of 500mls, following the birth up to a period of six weeks (Tiran, 1997)

Primigravida   A woman having her first pregnancy

Primiparous   A woman who has only one pregnancy progressing beyond 24 weeks gestation, whether it is live or stillborn, singleton or multiple infants.

Third stage of labour The period of time from the birth of the baby to the expulsion of the placenta and control of bleeding (Baddock & Dixon, 2006).

Uterotonic   see ecbolic

Chapter One: Introduction

Breastfeeding is now widely acknowledged as the ideal method of feeding and nurturing an infant (World Health Organisation, 2008). It is concerning therefore that as little as 14% of New Zealand babies are exclusively breastfed for the first six months of life (National Breastfeeding Advisory Committee, 2008a). As barriers to the initiation of breastfeeding are being identified, it is becoming clearer that events during a woman's labour and birth have an impact on her ability to initiate breastfeeding successfully (Forster & McLachlan, 2007). Ecbolic drugs are commonly used during the third stage of labour to prevent postpartum haemorrhage; however despite their efficacy and widespread use in clinical practice there has been little research to evaluate whether there are any unintended adverse effects on lactation and breastfeeding. This study examined the association between the use of prophylactic ecbolics for the third stage of labour and the establishment of exclusive breastfeeding in a retrospective cohort of well mother and baby dyads from a New Zealand District Health Board.

This chapter will describe the background to the study including the model of maternity care in New Zealand; the context of the study in terms of the midwife's role and responsibilities in relation to the third stage of labour and the support of breastfeeding; and the purpose of the study including the research statements and hypotheses.

Background

In New Zealand all pregnant women are entitled to free maternity care providing they are a New Zealand citizen or resident or are eligible in some other way. All women are encouraged to select a lead maternity carer (LMC); this could be a Midwife, General Practitioner or Obstetrician. The LMC provides primary maternity care for the woman during her pregnancy, birth and for six weeks after the birth. The roles and responsibilities of the lead maternity carer are prescribed by the Ministry of Health via the Primary Maternity Notice, Section 88 of the Health and Disability Services Act (Ministry of Health, 2007). The Primary Maternity Notice directs the Lead

Maternity Carer to discuss and document a plan for the birth with the woman during late pregnancy (Ministry of Health, 2007). Information regarding the physiology of the third stage and management options are discussed and documented at this time.

The third stage of labour is defined as the period of time from the birth of the baby to the expulsion of the placenta and control of bleeding (Baddock & Dixon, 2006). Maternity clinicians will identify this period as an anxious time as postpartum haemorrhage is a significant cause of maternal morbidity. There is an average of one maternal death per year in New Zealand attributable to postpartum haemorrhage (PMMRC, 2009; World Health Organisation, 2006). Management of the third stage of labour has been a contentious issue in the maternity sector and numerous research studies have examined the advantages and disadvantages of alternative management options (McDonald, Abbott, & Higgins, Updated April 29, 2007). Two alternative options for management of the third stage have emerged: "Physiological" also called expectant management; and "Active" management. Physiological management aims to ensure that the physiology of birth is protected and supports the underlying belief that the natural process was designed in the interest of mother and baby, and therefore intervention in this process is likely to be detrimental to their wellbeing (Buckley, 2002). Active management recognizes the risks inherent in childbirth and the fact that physiological birth is uncommon in the current technology abundant maternity environment. Active management involves a combination of three interventions: i) early administration of an ecbolic drug to stimulate contraction of the uterus; ii) immediate clamping of the umbilical cord; iii) controlled cord traction to deliver the placenta (Royal Australian and New Zealand College of Obstetricians and Gynaecologists, 2007).

The ecbolics currently available and in common usage in New Zealand are Syntocinon™ (synthetic oxytocin) and Syntometrine™ (a combination of oxytocin and Ergometrine). Choice of ecbolic rests with the clinician and the woman. Comparison between the two drugs shows that Syntometrine has a longer half life and may be slightly more effective than Syntocinon alone in preventing moderate postpartum haemorrhage less than 1000mls (McDonald, Prendiville, & Blair, 1993). However Syntometrine has some common and unpleasant side effects including nausea, vomiting, headache and hypertension (Orji, Agwu, Loto, & Olaleye, 2008). A small

number of women decline the use of pharmaceuticals and choose a physiological third stage of labour with no ecbolic medication or active management techniques. These women are encouraged to use physiological approaches following birth to encourage expulsion of the placenta and control of bleeding including early skin to skin contact between mother and baby and early breastfeeding, and following the natural urge to expel the placenta when it has detached from the uterine wall and descended into the vagina. Women understand that this physiological approach may take slightly longer than a managed approach, up to 1 hour, and that a slightly higher blood loss may occur, but in a well mother the possible sequelae of this blood loss is likely to be minimal (Begley, 1990a).

Most of the research regarding management options for the third stage of labour has focused on the implications for the mother in terms of preventing postpartum haemorrhage, shortening the duration of the third stage, reducing pain requiring analgesia and preventing surgical intervention to remove the placenta (Liabsuetrakul, Choobun, Peeyananjarassri, & Islam, 2007). When the baby has been included in the research outcomes, only short term sequelae have been considered such as neonatal jaundice and polycythemia (Prendiville, Elbourne, & McDonald, 2000). To date, little research has been undertaken to examine the effects of ecbolic use on breastfeeding. Two studies have identified a possible association between the use of Ergometrine and breastfeeding difficulties (Begley, 1990b; Pei & Zhao, 1996). However, both these studies have design limitations which make application of the results to clinical practice difficult (see Chapter 2).

Midwifery Context

Supporting breastfeeding is an essential component of the work of a midwife in promoting and protecting the health of the mother and baby dyad (Yorke, 2004). It is therefore disappointing when a mother decides to stop breastfeeding before the maximum benefit can be achieved. As a midwife I am keen to ensure that treatments we recommend to optimize the health of a woman in relation to postpartum blood loss do not compromise the wellbeing of the mother and the baby in relation to breastfeeding. As a clinician I am in a position to give advice to women and their

families about their choices for the management of the third stage of labour. In order for a woman to make an informed choice about a treatment option she needs to be aware of the risks and benefits of the treatments proposed and any alternative treatments (Health and Disability Commissioner, 2006). Clearer information about the effects of ecbolics in relation to breastfeeding will help maternity clinicians and mothers make better informed choices.

Study Purpose

The aim of the study was to describe the breastfeeding rates at two weeks postpartum for a cohort of well mother and baby dyads, to identify factors associated with lower rates of exclusive breastfeeding in the cohort, and to identify whether ecbolic use was an independent factor predicting exclusive breastfeeding at two weeks (after controlling for confounding factors) . The question guiding this research was: "Is there an association between prophylactic ecbolic use and exclusive breastfeeding rates at two weeks postpartum?" The specific objectives were to provide the answers to the following research statements:

1. Describe the prophylactic ecbolic use for the third stage of labour for a cohort of well mothers

2. Describe the exclusive breastfeeding rate at two weeks postpartum for a cohort of well mother baby dyads

And the following hypotheses

3. Maternal age, parity, ethnicity, and deprivation, type of LMC, and infant birth weight and Apgar score are not associated with exclusive breastfeeding rates at two weeks.

4. Ecbolic use will have no effect on exclusive breastfeeding rates at two weeks:

    a) Women receiving syntometrine (compared to no ecbolics) will not be less likely to be exclusively breastfeeding at two weeks

    b) Women receiving syntocinon (compared to no ecbolics) will not be less likely to be exclusively breastfeeding at two weeks

c) Ecbolic use is not an independent factor predicting exclusively breastfeeding at two weeks (after controlling for confounding factors)

Summary

This chapter provided a background to the study by introducing the importance of breastfeeding for the wellbeing of the mother and the baby and identifying that factors during labour and birth may have an influence on the successful establishment of breastfeeding. From a clinical perspective it is important to understand the potential side effects of labour medications so that practitioners and women make informed choices about treatment options. This study identified factors associated with exclusive breastfeeding in a cohort of well mothers and babies and aimed to establish whether there was an association between prophylactic ecbolic use and exclusive breastfeeding at two weeks.

The following chapter presents a review of the current literature in relation to the benefits of breastfeeding, factors associated with successful breastfeeding, labour and birth interventions and breastfeeding and the association between prophylactic ecbolic use and breastfeeding.

Chapter Two: Literature review

Introduction

This review will briefly summarize some of the key findings from the extensive evidence in relation to the benefits of breastfeeding. The physiology of breastfeeding initiation will be described and factors known to influence this initiation will be presented. Literature surrounding the origin of ecbolic medications and their therapeutic and incidental effects will be described, and the clinical management options for the third stage of labour will be reviewed. Finally, literature studying the association between prophylactic ecbolic use and breastfeeding will be presented and critiqued.

Search Strategies

A number of search strategies were employed including an electronic search of the following databases: MIDIRS; MEDLINE; EBSCO, ScienceDirect; and the Cochrane Library for the period January 1989 to January 2009. A review of references in relevant studies was also conducted. A combination of the following key words and phrases was used: ecbolics; oxytocics; uterotonics; Syntocinon; Syntometrine; Ergometrine; Methylergometrine; Ergometrine-maleate; Ergonovine; Ergonovine-maleate; third stage of labour; physiological third stage; active third stage; breastfeeding; breast feeding; prolactin; labour; labor; and intrapartum, not induction, not augmentation. Earlier sources particularly in reference to the original synthesis of Oxytocin and Ergometrine were located via the "Google Scholar" internet search engine.

Benefits of breastfeeding

There is now a large body of research evidence demonstrating the significant health benefits of breastfeeding for mothers and babies. A summary of the literature was prepared in 2008 for the New Zealand National Breastfeeding Advisory Committee, and concluded that the benefits are not limited to nutritional advantages

but extend to include greater resistance to illnesses such as bacterial meningitis, otitis media, necrotising enterocolitis, diarrhoea, and urinary tract infections (National Breastfeeding Advisory Committee, 2008b). Breastfed infants are also less likely to develop asthma, obesity, cardiovascular disease and type 1 and 2 diabetes. Cognitive benefits can also be expected including better visual acuity, improved cognitive development and improved academic outcomes in adolescence. There are also advantages for breastfeeding women, including a reduction in the incidence of both ovarian and breast cancer, and a trend towards a reduction in post-menopausal hip fractures. Socially, breastfeeding has been associated with improved mother infant attachment (Britton, Britton, & Gronwaldt, 2006); and economically, with a reduction in health care costs (Cattaneo et al., 2006).

Despite clear evidence of benefits, and central government support for breastfeeding, rates have been slow to increase. In 2002 the Ministry of Health set the following targets:

- *To increase the breastfeeding (exclusive and fully) rate at six weeks to 74% by 2005 and 90% by 2010*

- *To increase the breastfeeding (exclusive and fully) rate at 3 months to 57% by 2005, and 70% by 2010*

- *To increase the breastfeeding (exclusive and fully) rate at 6 months to 21% by 2005 to 27% by 2010*

(Ministry of Health, 2002 p10)

Monitoring the data has been difficult because disappointingly there has not been a system for ongoing collection of national breastfeeding data. Plunket (New Zealand's primary "Well Child" service provider) provides the most complete data, and this at best offers only 90% coverage. From this data it would appear that only 14% of New Zealand babies are exclusively breastfed at 6 months of age (see Table 1).

Table 1: New Zealand Breastfeeding rates trends 2002 – 2007

Six weeks	Exclusive (%)	Full (%)	Partial (%)	Artificial (%)
2002	46	19	15	19
2003	49	18	15	19
2004	50	18	14	19
2005	51	16	15	19
2006	51	15	16	18
2007	51.5	12.5	17	19
Three months	Exclusive (%)	Full (%)	Partial (%)	Artificial (%)
2002	33	19	18	30
2003	36	19	15	30
2004	37	18	15	30
2005	38	17	15	29
2006	39	16	16	29
2007	39	15	17	29
Six months	Exclusive (%)	Full (%)	Partial (%)	Artificial (%)
2002	9	12	38	41
2003	10	14	35	41
2004	10	14	35	41
2005	11	14	35	40
2006	13	12	35	40
2007	14	11	34	41

Data for table from National Breastfeeding Advisory Committee Report (2008)

Ethnicity and breastfeeding

Current data confirms that breastfeeding rates are not equally spread amongst ethnicities. Women who identify as New Zealander or of European descent have consistently higher breastfeeding rates across all time frames - see Table 2 (Ministry of Health, 2008).

Table 2: Breastfeeding by ethnicity at *six weeks* and *six months* 2002 - 2007

Six weeks	Maori (%)	Pacific (%)	Asian (%)	European *NZ + Other* (%)	All (%)
2002	59	61	-	68	66
2003	62	62	49	71	67
2004	60	59	55	71	67
2005	58	58	58	71	66
2006	59	57	55	70	66
2007	58	53	56	70	65
Six months	Maori (%)	Pacific (%)	Asian (%)	European *NZ + Other* (%)	All (%)
2002	16	20	-	25	23
2003	16	19	20	26	23
2004	17	20	22	27	24
2005	17	19	23	28	25
2006	18	19	25	29	25
2007	16	18	26	29	26

Data for tables from National Breastfeeding Advisory Committee Report (2008)

In a cross-cultural qualitative study of infant care practices in New Zealand, women and their families were interviewed from six different ethnic groups: Maori; Samoan; Tongan; Niuean; Cook Island Maori; and Pakeha (Glover, Manaena-Biddle, & Waldon, 2007). Amongst all these groups women demonstrated a strong desire to breastfeed and an appreciation that not only did breastfeeding have nutritional benefits but that it was also important for bonding with the baby. However, women who stopped breastfeeding did so because they received inadequate or conflicting advice from health professionals and in some cases family members. The women who stopped breastfeeding commonly held the belief that they had insufficient milk; this belief was vindicated in their minds when their infants settled more easily and slept for longer when complementary formula feeding was introduced.

In a study to identify risk factors for not breastfeeding in Pacific Island mothers the following issues were identified: smoking; being in paid employment; not receiving

a visit from a well child provider; the infant being cared for by others; the infant not discharged with the mother and infant not sharing the same room as the mother (Butler, Williams, Tukuitonga, & Paterson, 2004). Even though there is a very strong traditional association with breastfeeding, social factors appear to have a significant impact on breastfeeding rates amongst these groups.

In Maori culture, breastfeeding is viewed as a traditional practice and is seen as essential in maintaining and sustaining child development and wellbeing (Rimene, Hassan, & Broughton, 1998). Despite these strong cultural beliefs breastfeeding rates for Maori infants continue to remain low (See Table 2).

Socioeconomic status and breastfeeding

Research looking into the antecedents of initiation and continuance of breastfeeding has consistently found that women from lower socioeconomic groups are less likely to initiate breastfeeding, and more likely to have a shorter duration of breastfeeding (Khoury, Moazzem, Jarjoura, Carothers, & Hinton, 2005). This is attributed to a number of factors including poor social and family support, early return to work, and working in roles where there is low tolerance for breastfeeding.

In New Zealand, socioeconomic deprivation is measured on a neighbourhood basis. This system assumes an association between socioeconomic deprivation and health outcomes at the neighbourhood level, for example deprived neighbourhoods may adversely affect health outcomes for individuals living in those neighbourhoods (Anderson, Sorlie, & Backlund, 1997). Although there has been much debate about the choice of variables and their weighting there is general agreement that area measures of deprivation provide a useful means of measuring variations in health status (Curtis, 1990).

The New Zealand Index of deprivation (NZDep06) is a census based index, with a relative deprivation score assigned to each neighbourhood or "mesh block" in New Zealand. It combines nine variables from the 2006 census reflecting eight dimensions of deprivation. The variables that make up NZDep06 are listed in order of importance in Table 3 (White, Gunston, Salmond, Atkinson, & Crampton, 2008). Neighbourhoods are rated using the variables listed in Table 3 and given a score between 1 and 10, with

10 being the most deprived. The NZdep06 score is allocated automatically by the District Health Board patient management IT system via the residential address given by the woman on registration.

Table 3: Nine variables that construct the New Zealand Index of Deprivation (NZDep06)

Deprivation dimension	Census variables
Income	aged 18–64 years receiving a means-tested benefit
Income	living in households with equivalised* income below an income threshold
Owned home	not living in own home
Support	aged under 65 years living in a single-parent family
Employment	aged 18–64 years and unemployed
Qualifications	aged 18–64 years and without any qualifications
Living space	living in households below an equivalised* bedroom occupancy threshold
Communication	with no access to a telephone
Transport	with no access to a car

*Equivalisation: methods used to control for household composition

Physiology of lactation initiation

To understand how breastfeeding can be compromised by intrapartum events and medications it is important to understand the physiology of the initiation of lactation. The human breast develops the biochemical capacity to produce milk during pregnancy, this occurs in two phases: mammogenesis and lactogenesis (Jones & Spencer, 2007). Mammogenesis is the development of functioning breast tissue that starts to occur during early pregnancy and involves the expansion of the ductal tree and an increase in the number of alveoli (see Figure 1). Lactogenesis I occurs during mid pregnancy and is the time when milk components such as lactose, casein and α-lactalbumin are produced and fat droplets increase in size. The breast becomes fully competent to produce milk at this time but high levels of the pregnancy hormones oestrogen, progesterone and human placental lactogen prevent lactation at this time (Jones & Spencer, 2007).

Immediately following the birth, the abrupt withdrawal of progesterone in the presence of high prolactin levels causes the initiation of lactogenesis II, where the ability to re-absorb colostrum is significantly reduced, leading to rapid increase of milk volume. Concentrations of lactose, lactoferrin, oligosaccharides and immunoglobulin all rise dramatically during this time (Jones & Spencer, 2007). The woman generally experiences this as an increase in breast fullness which occurs at around 60 hours postpartum, but can occur between 24 and 102 hours (Kent, 2007).

After lactogenesis II, there is a switch from primarily endocrine to primarily autocrine control, and nutritive suckling resulting in milk removal is the primary driver for milk synthesis. This phase of lactation is called galactopoiesis or lactogenesis III. Under normal circumstances as long as milk removal occurs milk production will continue (Jones & Spencer, 2007).

Prolactin has an essential role in the establishment and maintenance of breastfeeding. Prolactin is a peptide hormone; that was first identified in the 1970s and named after its lactogenic qualities, although it actually has over 300 other functions in the body (Prabhakar & Davis, 2008). Thyrotrophin-releasing hormone (TRH), oxytocin, and vasopressin all promote prolactin secretion. Whereas Dopamine is the main inhibitor of prolactin secretion, Bromocriptine and other ergot alkaloids such as Cabergoline and Quinagolide are known dopamine agonists (Prabhakar & Davis, 2008).

Figure 1: Anatomy of a lactating breast, reproduced with permission from Medela AG, Switzerland (Medela, 2006)

1. Cooper's Ligaments
2. Retromammary Fat
3. Glandular Tissue
4. Intraglandular Fat
5. Subcutaneous Fat
6. Main Milk Duct
7. Milk Duct
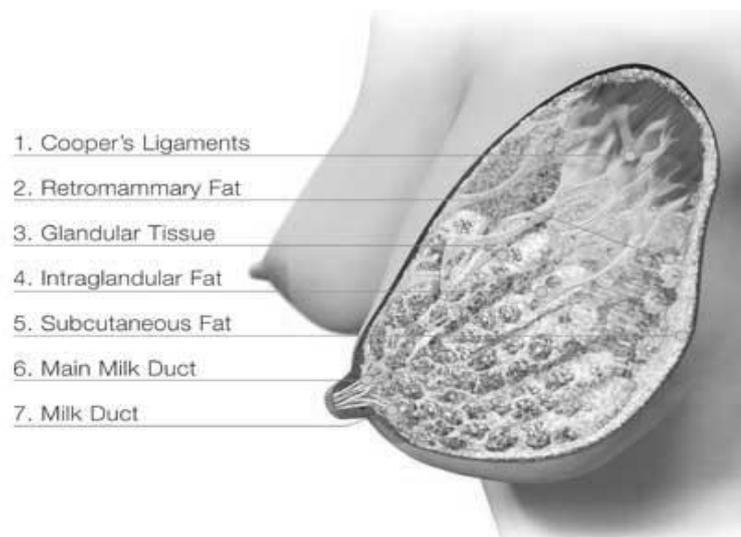
Intrapartum events and breastfeeding

There is evidence that some events during labour and birth have an effect on successful initiation of lactation. Location of birthing is known to have an association with breastfeeding. In the New Zealand College of Midwives report on care outcomes for 9953 mothers, 87.5% of women who gave birth at home were exclusively breastfeeding at two weeks, compared to only 75.3% who gave birth in a primary unit and only 68% who gave birth in a secondary unit (New Zealand College of Midwives, 2008). There are probably a number of factors that influence this, firstly women who are confident to give birth away from medical support are likely to be more confident in their bodies and in their ability to breastfeed and secondly they are less likely to have experienced complex pregnancies, low birth weight babies or exposure to medical interventions in birth.

Another important factor related to place of birth is whether the maternity facility is accredited as a "Baby Friendly Hospital". The Baby Friendly Hospital initiative (BFHI) is a World Health Organisation and UNICEF sponsored programme that ensures that the maternity facility has undertaken the 10 steps to promote, protect and support breastfeeding (see Table 4). Evidence shows that babies born in "Baby Friendly" facilities are more likely to breastfeed exclusively (Forster & McLachlan, 2007).

Table 4: World Health Organisation Baby Friendly Hospital Initiative 10 Steps

1	A written breastfeeding policy that is regularly communicated to all health workers
2	An education programme for staff caring for new mothers and babies to ensure that they are able to implement the policy
3	Inform all women about the benefits and management of breastfeeding.
4	An opportunity for skin to skin contact for the first hour after birth and a breastfeed as soon as the infant shows feeding cues
5	Show mothers how to breastfeed and how to maintain lactation even if they should be separated from their infants
6	Rooming in with the mother at all times
7	Baby led cue based feeding, not feeding based on schedules.

8   No supplementary or complimentary feeds unless medically indicated

9   Breastfed babies should not be offered artificial teats or pacifiers (also called dummies or soothers).

10   Foster the establishment of breastfeeding support groups and refer mothers to them on discharge from the hospital.

(World Health Organisation, 1998)

In addition to place of birth there are factors associated with the labour and birth that are known to have an effect on breastfeeding success. These include for example analgesia in labour, length of second stage of labour and caesarean birth (Dewey, Nommsen-Rivers, Heinig, & Cohen, 2003). There has been ongoing debate about whether epidural analgesia has an effect on breastfeeding; however research has established a dose related effect between Fentanyl, a drug now commonly used in epidural anaesthesia for labour, and breastfeeding. In one study women who received greater than 150µg of Fentanyl were significantly less likely to be breastfeeding at six week postpartum than women who had received a lower dose of Fentanyl (p=0.005) (Beilin et al., 2005). Another study in the same year found no significant difference in women who had received either Entonox or Pethidine in bottle feeding rates but again noted a dose related effect for Fentanyl (Jordan, Emery, Bradshaw, Watkins, & Friswell, 2005). Both authors speculate that even at levels below those likely to cause respiratory depression, opioids may have subtle neurobehavioral effects on the neonate. These effects would influence muscle tone and reflexes making the neonate less likely to rouse appropriately to hunger and more likely to exert nipple trauma and pain, which would act as a deterrent to the mother.

The length of second stage of labour has also been shown to be a factor in delayed lactation and reduced breastfeeding at six weeks postpartum with 44% of women who had a second stage lasting longer than one hour suffering from delayed lactation, compared to only 22% of women who had a second stage less than one hour (Chapman & Perez-Escamilla, 1999; Rajan, 1994), this may be due to the effect of exhaustion and stress and may also be attributed to the effect of assisted birth trauma on neonatal behaviors (Smith, 2007).

Caesarean birth is associated with a diminished rate of breastfeeding success, and this is especially but not exclusively linked to emergency caesarean birth (Chapman & Perez-Escamilla, 1999). Emergency caesarean is probably the most stressful of all births and stress is frequently associated with poor breastfeeding performance (Chen, Nommsen-Rivers, Dewey, & Lonnerdal, 1998). An underlying cause may be an effect on the natural pattern of hormone release, as it has been shown that women who give birth vaginally have higher prolactin levels during breastfeeding, and a higher frequency of pulsatile oxytocin release during breastfeeding than women who have given birth by caesarean section (Nissen et al., 1996). One study showed that babies born by caesarean were only half as likely to regain their birth weight by day six as babies born normally, 20% and 40% respectively. This was thought to be caused by reduced breastmilk transfer between days 2 and 5 postpartum (Evans, Evans, Royal, Esterman, & James, 2003).

Infant condition and breastfeeding

The successful breastfeeding partnership is dependent on both maternal and infant participation. In addition to maternal factors and events during the birth, the maturity and condition of the infant at birth and in the first few days are known to have an impact on breastfeeding success. A UK study by Rajan (1994) looking at a variety of factors influencing successful breastfeeding found that babies who were born earlier were significantly less likely to breastfeed with only 26% of babies born between 30 - 35 weeks gestation breastfeeding at six weeks compared to 44% of babies born at 39 weeks gestation (P 0.02). Similarly babies who were low birth weight were also less likely to breastfeed at six weeks with only 27% of babies weighing <2700g compared to 52% of babies weighing >4000g (P 0.07) (see Table 5). The rationale proposed for this difference was that babies who are immature are likely to have underdeveloped reflexes and uncoordinated suck swallow responses; they are less likely to wake spontaneously for feeding and more likely to develop conditions that inhibit breastfeeding such as hypoglycemia, hypothermia and neonatal jaundice. They are also more likely to be separated from their mother at birth or early in the postnatal period (Rajan, 1994).

Table 5: Breastfeeding rates at six weeks by gestation and birth weight (Rajan, 1994)

Gestation	Breast (%)	Bottle (%)	Mixed/Other (%)
30 - 35 weeks	26	48	26
36 - 37 weeks	34	63	3
38 weeks	44	50	6
39 weeks	44	48	8
40+ weeks	42	48	9

Birth weight	Breast (%)	Bottle (%)	Mixed/Other (%)
< 2500g	27	61	12
2500g - 2999g	47	47	6
3000g - 3499g	40	50	10
3500g - 3999g	43	49	8
≥ 4000g	52	41	7

Postpartum haemorrhage and breastfeeding

It is likely that women who experience significant postpartum haemorrhage are less likely to breastfeed exclusively (Willis & Livingstone, 1995), although the evidence is weak. There are a number of probable explanations for this including antecedents to the haemorrhage such as prolonged labour and cesarean birth, use of a variety of treatment ecbolics to arrest bleeding, separation from the infant for surgical procedures, and subsequent maternal anaemia (Rioux, Savoie, & Allard, 2006).

Third stage of labour and prevention of postpartum haemorrhage

The third stage of labour is defined as the period from the birth of the baby until the complete birth of the placenta/whenua and membranes (New Zealand College of Midwives, 2006). The placenta that formed in early pregnancy and created a unique interface between maternal and fetal circulation is no longer required after the birth of the infant. Separation occurs shortly after the birth as the uterine muscles continue to contract and the uterus retracts reducing the size of the placental site and causing the arteries and veins of the intervillous spaces to tear. The bleeding from

these torn vessels creates a retroplacental clot which dislodges the placenta and causes it to shear away from the decidua basalis. As the placenta lifts away from the placental bed the spiral arterioles are exposed but these are rapidly ligated by the contracting uterine muscles, thus preventing further bleeding (Baddock & Dixon, 2006).

There has been much debate amongst maternity clinicians regarding the most effective way to manage the third stage of labour to ensure effective placental separation thereby minimizing the risk of postpartum haemorrhage. Two alternative options have emerged: "Physiological" also called expectant management, and "Active" management.

Physiological management aims to ensure that the physiology of birth is protected and supports the underlying belief that the natural process was designed in the interest of mother and baby and intervention in this process is likely to be detrimental to their wellbeing (Buckley, 2002). Physiological management involves leaving the umbilical cord intact, placing the baby skin-to-skin with the mother, encouraging early breastfeeding and allowing the placenta to separate naturally and be expelled by maternal effort alone (New Zealand College of Midwives, 2006).

Active management recognises that there are risks inherent in childbirth and that true physiological birth is uncommon in the modern maternity environment. Active management involves a combination of interventions including early administration of an ecbolic drug to stimulate contraction of the uterus, immediate clamping of the umbilical cord, and controlled cord traction to deliver the placenta (Thorpe & Anderson, 2006)

There has been considerable debate over the advantages and disadvantages of these management options. A large randomised controlled trial to compare the two methods was undertaken in Bristol, England (Prendiville , Harding, Elbourne, & Stirrat, 1988). This trial showed that the incidence of postpartum haemorrhage was 5.9% in the active management group and 17.9% in the physiological group (OR 3.13, 95% CI). However there were important limitations in the study design and conduct. The midwives were unskilled in physiological management of the third stage as this was not a customary approach to care in the UK at that time. The analysis was performed on an intention to treat basis, but only half the women allocated to physiological third

stage received it. Also the study participants included women who were being exposed to other interventions that would have affected the physiological process.

A similar trial undertaken in Dublin (Begley, 1990a) on low risk women revealed results consistent with the Bristol trial in that there was a significant difference in postpartum haemorrhage rates between the two groups: 2% in the active management group; and 8% in the physiological management group. However Begley concluded that the additional blood loss did not have a significant impact for the women as blood transfusion rates were similar for both groups, and the actual mean difference in blood loss was only 85mls, however this was sufficient to move a proportion of women over the 500ml blood loss threshold and into the postpartum haemorrhage group. It was interesting to note that the postpartum haemorrhage rate was initially high in the physiological group but as the trial progressed the rates became lower. The researcher suggests that this was due to increasing confidence of the midwives with the trial protocol. However the trial protocol was unusual as it involved the use of intravenous Ergometrine as the ecbolic for active management; this formulation is rarely seen in other centres and limits the relevance to other populations (such as New Zealand) where different active management protocols are used.

A third large randomized controlled trial was conducted at Hinchingbrook Hospital in the UK (Rogers et al., 1998). This study addressed some of the failings of the previous research, however the postpartum haemorrhage pattern remained similar (6.8% of 748 active management versus 16.5% of 764 physiological management; RR 2.42, CI 1.78-3.30). The participant group was better selected and met the profile for women more likely to experience physiological birth. The issue of midwife confidence again was problematic with only 54% of midwives feeling very confident in physiological management as opposed to 82% feeling very confident in active management. Lack of blinding was also an issue as the midwife who managed the third stage also estimated blood loss; this may have led to observer bias.

A meta-analysis of these trials and two other similar trials involving a total of 3000 women (Prendiville et al., 2000) concluded that compared to physiological management, active management was associated with the following reduced risks: increased maternal blood loss (mean difference 79.33mls, 95% CI 64mls – 94mls);

postpartum haemorrhage of >500mls (RR 0.38, 95% CI 0.32 to 0.46); and prolonged third stage of labour (mean difference 9.77 minutes, 95% CI 10.00 to 9.53). As a result, obstetric practice guidelines changed to recommending active management of the third stage for all women (Royal Australian and New Zealand College of Obstetricians and Gyneacologists, 2007).

More recently the value of active management of the third stage of labour as a universal treatment protocol has again been challenged with the publication of data from a cohort of 9953 births by the New Zealand College of Midwives. This retrospective data suggests that women who elected to have physiological management of the third stage, even if later a treatment ecbolic was required, had a lower postpartum haemorrhage rate of 8.1% compared to 21% of women who elected to have active management with or without a treatment ecbolic (New Zealand College of Midwives, 2008). This suggests that outside the controlled research environment, women and midwives make choices based on the individual situation and this approach is likely to have a clinical benefit as opposed to the one size fits all approach of universally recommending active management. The New Zealand College of Midwives practice guidelines (2006) state that:

> *"Midwives must be competent in both supporting physiological third stage, and implementing its active management. Midwives must also recognise the need to change from physiological to active management when appropriate." (New Zealand College of Midwives, 2006 p1)*

Use of ecbolic drugs in labour and birth

There are two ecbolic drugs that are commonly used in labour in New Zealand: Syntocinon® (synthetic oxytocin) which is used to induce labour, to augment labour, to prevent and to treat postpartum haemorrhage; and Syntometrine® (a synthesis of oxytocin and Ergometrine) which is used to prevent and to treat postpartum haemorrhage.

Syntocinon®

The hormone oxytocin is a nonapeptide released by the posterior pituitary gland; it was first identified by Henry Dale in 1909, and given its Greek name meaning "quick birth" (den Hertog, de Groot, & van Dongen, 2001). Oxytocin was first synthesised by Vincent du Vigneaud in 1953, work for which he received the Nobel Prize for Chemistry (du Vigneaud, Ressler, & Trippett, 1953). Synthetic oxytocin called Syntocinon® in New Zealand has been used in clinical practice for induction and augmentation of labour and active management of the third stage of labour since the late 1950s (Dillon, Bonsnes, & Douglas, 1958).

Syntocinon® is available in 1ml ampoules of 10IU and 5IU (International Units). Current research favours 10 IU as more effective in the prevention of postpartum haemorrhage (McDonald et al., Updated April 29, 2007). Syntocinon® acts on the myometrium and "when given by a single injection, the drug is capable of causing sustained tetanic uterine contractions" (MEDSAFE, 2006b). Syntocinon® acts rapidly with a latency period of less than one minute by intravenous injection and of two to four minutes by intramuscular injection. The oxytocic response lasts for thirty to sixty minutes after intramuscular administration, possibly less after intravenous injection (MEDSAFE, 2006b). Side effects include headache, nausea and tachycardia, and rarely arrhythmia and anaphylaxis. Due to its antidiuretic properties, prolonged administration with intravenous fluids can lead to water intoxication with hyponatraemia or pulmonary oedema (MEDSAFE, 2006b).

Syntometrine®

Syntometrine is a synthesis of Syntocinon and Ergometrine maleate. Ergometrine is an ergot alkaloid, derived from a fungus that occurs in rye grain called *claviceps purpurea* (De Costa, 2002). It has been used in maternity care for centuries dating back to 1582 when it was first described as a treatment for prolonged labour. Its use became widespread in obstetric practice in both Europe and North America in the 18th and early 19th century to expedite birth (De Costa, 2002). However its popularity declined after 1822 when reports from the USA were published regarding the increased incidence of uterine rupture and stillbirth (de Groot, van Dongen, Vree,

Hekster, & van Roosmalen, 1998). In 1935 Moir and Dudley were able to isolate the active substance and called it Ergometrine (or ergonovine in the USA). Ergometrine has very specific uterotonic effects and has been a popular choice for the prevention and treatment of postpartum haemorrhage since this time (de Groot et al., 1998).

Syntometrine$^{®}$ contains 0.5mg of Ergometrine maleate combined with 5 IU of synthetic oxytocin. This combination has the advantage of both rapid action and sustained effect. Following intramuscular administration the uterine response occurs within two and a half minutes, with Ergometrine alone the response would be around seven minutes. The uterotonic effect lasts several hours compared to only thirty to sixty minutes with oxytocin alone (MEDSAFE, 2006c). Despite its efficient uterotonic effects Syntometrine compared to Syntocinon has some unpleasant and sometimes severe side effects. The most common side effects noted are nausea (OR 4.07, 95% CI 3.43 - 4.84); vomiting (OR 4.92, 95% CI 4.03 - 6.00) and raised blood pressure (OR 2.40, 95% CI 1.58 - 3.64) (McDonald et al., Updated April 29, 2007); headache (OR 3.93 95% CI 0.51 - 30.50); and after-pains requiring analgesia (OR 2.53 95% CI 1.34 - 4.78) (Liabsuetrakul et al., 2007). Concern has also been raised about some rare but severe adverse effects such as myocardial infarction (Liao, Cockrill, & Yurchak, 1991); cardiomyopathy (Citro, Pascotto, Provenza, Gregorio, & Bossone, 2008); acute bronchospasm (Hill, Geraghty, Hughes, Sever, & Schachter, 1987; Louie, Krzanowski, Bukantz, & Locky, 1985); and eclampsia (Dua, 1994).

A meta-analysis comparing the outcomes between Syntometrine and Syntocinon found that Syntometrine is associated with a small reduction in the risk of blood loss greater than 500 mls (OR 0.82, 95% CI 0.71 - 0.95) but no statistically significant difference in blood loss greater than 1000mls (McDonald et al., Updated April 29, 2007). The authors conclude that the advantages of reducing the risk of a small postpartum haemorrhage need to be weighed against the disadvantages of these adverse effects. A World Health Organisation systematic review comparing Syntometrine with Syntocinon showed that for every 100 women who are treated with Syntometrine rather than Syntocinon, there will be 3 fewer episodes of blood loss greater than 500 ml, but at the same time there will be 1 additional case of high blood pressure and 10 additional cases of vomiting (Abalos, 2007).

Ecbolic drugs and breastfeeding

There is little research evidence available on the effects of ecbolics on breastfeeding. Some small research studies were identified that examined the effect of ecbolics on prolactin levels. An American study in 1975 compared 14 women who had 10IU oxytocin plus 0.2mgs methylergonovine with 15 women who had 10IU oxytocin and a placebo of normal saline. Blood samples were taken prior to administration of the medication and at 80-90 minutes following administration. The results showed no significant difference in mean pre-injection serum prolactin levels, but at 80-90 minutes 13 of the 15 control women had raised prolactin levels compared to only 8 of the 14 treatment women $P<0.002$ (Weiss, Klein, Shenkman, Kataoka, & Hollander, 1975). The numbers in this study are too small to draw any clinically significant conclusions but it is possible at least that an effect exists.

A similar study was undertaken in London in 1983 where well women were randomly allocated to one of two groups, a syntocinon treatment group or a syntometrine treatment group. There were only 5 women in each group. Venous blood samples were collected twice in labour, once during the birth and then at 30 minute intervals for the first 5 hours postpartum. Results showed that the women in the syntocinon group had higher prolactin levels than women in the syntometrine group $P<0.005$ (Symes, 1984).

In 1990 Begley conducted a sub-analysis of a study cohort comparing active versus physiological management of the third stage (Begley, 1990b). The study had two research questions one concerning the effect of Ergometrine on prolactin levels at 48 and 72 hours, and the other looking at breastfeeding rates at 4 weeks in the two groups. Women had been randomized into two groups one to receive active management with Ergometrine 0.5mgs intravenously and the other to receive physiological management. Women who had been randomized to receive physiological management and who then received Ergometrine as a treatment ecbolic for postpartum haemorrhage were transferred to the treatment group for analysis. This decision could be interpreted as observer bias, however as the study was designed to look at the effects of Ergometrine it was not possible to include these women in the control group. On reflection it may have been more appropriate to exclude these

women from the analysis altogether. The results of the study showed no significant difference in prolactin levels, however sampling did not occur until day 2 or day 3 and it would have been unusual to see a response at such an interval after administration. There were however some significant differences in breastfeeding rates at 1 week with 15% of women in the Ergometrine group stopping breastfeeding compared to only 7% of the no Ergometrine group (P<0.05), and this continued to be significant but to a lesser extent at 4 weeks. The leading cause of breastfeeding cessation in this group of women was a perception of insufficient milk with 78% of women in the Ergometrine group compared to only 44% in the no Ergometrine group feeling that their milk supply was inadequate (P<0.002) (Begley, 1990b). Begley hypothesized that Ergometrine has a chemical composition similar to that of Bromocriptine and as such has a subtle inhibitory effect on prolactin.

Bromocriptine is the amino acid alkaloid, 2-bromo-α-ergocriptine. It is a brominated ergot derivative which inhibits the synthesis and secretion of prolactin from the anterior pituitary gland by doperminergic stimulation of pituitary prolactin cells (MEDSAFE, 2006a). It has been used in maternity care since the 1970s as a lactation suppressant, primarily for women who have a termination of pregnancy, stillbirth or who opt not to breastfeed (de Groot et al., 1998). However its popularity has declined in recent years as there is an established association with vasospasm, hypertensive crisis and myocardial infarction in susceptible women (Dutt, Wong, & Spurway, 1998). It is however a common treatment for hyperprolactinaemias (Prabhakar & Davis, 2008).

Despite the large numbers of trials evaluating active versus physiological third stage and comparing Syntocinon and Syntometrine, very few have chosen to include breastfeeding as an outcome measure. In 1993 MacDonald conducted a trial to compare Syntocinon with Syntometrine; and included fully breastfeeding at discharge as one of the outcome measures. The study did not reveal a significant difference in the breastfeeding rate between the two groups: 14.7% in the Syntometrine group; compared to 13.6% in the Syntocinon group (OR 1.10 CI 0.90 – 1.33). However the breastfeeding definition was not given and the percentage of women breastfeeding on discharge was extremely low. The short time between birth and discharge and the influence of the hospital staff in maintaining breastfeeding rates during the short

postnatal stay may also have been a significant factor in this result (McDonald et al., 1993).

More recently a small study was conducted in China, where 60 well primiparous women were randomly allocated to receive either Oxytocin 10IU by intramuscular injection or Ergometrine 0.2mgs by intravenous injection. The outcomes measured were time to first lactation (sic) and amount of lactation (sic) in the first 24 hours. Unfortunately there was no description of how these outcomes were assessed. The researchers used Ridit analysis, a statistical method for comparing ordinal-scale responses, to assess the results and showed significantly improved outcomes in both measures for women who received Oxytocin rather than Ergometrine (p=0.001). The researchers concluded that choice of ecbolic should include consideration of effects on breastfeeding (Pei & Zhao, 1996).

Summary

Breastfeeding confers a range of benefits on both the mother and the baby; however rates of breastfeeding in New Zealand continue to remain below Ministry of Health targets. There are a range of factors both social and physiological that effect breastfeeding success. Factors occurring during labour and birth that have been shown to have an effect on breastfeeding include: place of birth; opiate and epidural analgesia; length of second stage of labour; operative birth; and postpartum haemorrhage. Infant factors are equally important with prematurity and low birth weight increasing the likelihood of artificial feeding. The effect of prophylactic ecbolics used to expedite delivery of the placenta and reduce postpartum bleeding have received little attention as a potential source of breastfeeding difficulty despite Syntometrine having pharmacological similarities with Bromocriptine, an effective lactation suppressant. Research by Begley (1990) and more latterly Pei and Zhou (1996) suggest that Ergometrine has a potential to disrupt early breastfeeding through the suppression of prolactin. However the current lack of research evidence confirming an association led to the design of this study. This study used a retrospective cohort methodology to assess for an association between prophylactic ecbolic use in the third stage of labour and exclusive breastfeeding rates at two weeks postpartum.

The following chapter describes the study design and methodology including: choice of methodology; research hypothesis; study setting; participants; inclusion and exclusion criteria; variables; data sources; sample size calculations; cultural and ethical issues considered, and the plan for data management and analysis.

Chapter 3: Research Method and Design

Introduction

The study aimed to compare the effects of prophylactic Syntometrine and Syntocinon with no ecbolic (physiological management) on exclusive breastfeeding at two weeks by selecting a group of well mother and baby dyads who experienced no other medical interventions in labour. This cohort of well women was grouped by prophylactic ecbolic given and analysed after controlling for confounding variables. The study used retrospective data that had been collected and stored electronically as part of the maternity care episode and this information was linked to data collected by the Lead Maternity Carer on breastfeeding status at two weeks and stored by the Ministry of Health. Access to this electronic data created an opportunity for a retrospective cohort study.

In this chapter the research statements and choice of research methodology will be presented. The study setting, sample, sample size calculations, and data sources will be described. The ethical and cultural considerations will be discussed. The variables of interest, confounding variables and the plan for data management and analysis will be described.

Research Statements / Hypotheses

The study aimed to provide answers to the following research statements:

1. Describe the prophylactic ecbolic use for the third stage of labour for a cohort of well mothers

2. Describe the exclusive breastfeeding rate at two weeks postpartum for a cohort of well mother baby dyads

And the following hypotheses

3. Maternal age, parity, ethnicity, and deprivation, type of LMC, and infant birth weight and Apgar score are not associated with exclusive breastfeeding rates at two weeks.

4. Ecbolic use will have no effect on exclusive breastfeeding rates at two weeks:

a) Women receiving syntometrine (compared to no ecbolics) will not be less likely to be exclusively breastfeeding at two weeks

b) Women receiving syntocinon (compared to no ecbolics) will not be less likely to be exclusively breastfeeding at two weeks

c) Ecbolic use is not an independent factor predicting exclusively breastfeeding at two weeks (after controlling for confounding factors)

Research Methodology

To answer these research questions the study was amenable to a quantitative design methodology which follows a deductive research process and involves the collection and analysis of numerical data to identify statistical relationships between variables (Grant & Giddings, 2002). A descriptive methodology was selected because the participants had completed their maternity episode, and no randomization could take place. It would therefore be possible to identify an association between prophylactic ecbolic use and exclusive breastfeeding but not establish causality. The study was amenable to a retrospective cohort methodology (Bruce, Pope, & Stanistreet, 2008) because there was a known designated study cohort (women who had given birth at a Waitemata DHB hospital in the five year period between July 2002 and June 2007), a known intervention (Syntometrine, Syntocinon or physiological management of the third stage of labour), and a discrete timeframe with known outcomes (exclusive breastfeeding at two weeks postpartum).

Study Setting

The study took place at Waitemata District Health Board, which provides health care services for 525,260 people in the northern and western areas of Auckland city and extending up to the Rodney district bordering Northland (Waitemata District Health Board, 2008a). The District Health Board covers a large, mixed urban and rural geographic area (see Appendix 1).

The region has two large maternity units one at North Shore Hospital in Takapuna and one at Waitakere Hospital in Henderson. In 2007 the region had just under 7000 births (3853 at North Shore and 2944 at Waitakere) and a further 207 births in primary birthing units; data for the number of homebirths was not available (Waitemata District Health Board, 2008b). The data for the study was taken from births that occurred in hospital. Births that occurred in primary birthing units and at home were not included in the study.

The two maternity units in this study were both accredited as "Baby Friendly Hospitals" at the end of the study period. North Shore Hospital Maternity Unit was accredited in 2006 and Waitakere Hospital Maternity Unit was accredited in 2007, however the work to achieve "Baby Friendly" status had been ongoing for at least two years prior to accreditation.

Sample

The sample for the study was drawn from the records of all women who had given birth to a live infant at Waitemata DHB between July 2002 and June 2007 (29,815 women). In order to limit the study group to well mother and infant dyads cases were excluded if there had been complications during labour and birth, including women who required a treatment ecbolic for postpartum haemorrhage, and infants who were twins or were premature. Specific exclusion criteria and rationale were:

1. Induction or augmentation of labour with syntocinon.

   Rationale: Use of syntocinon in labour may have a synergistic effect with the prophylactic ecbolics given for active management of the third stage. Augmentation is indicative of a long labour which can contribute to breastfeeding difficulties (Chapman & Perez-Escamilla, 1999; Rajan, 1994)

2. Epidural analgesia.

   Rationale: Fentanyl which is a medication used for epidural anaesthesia has been shown to have a dose related effect on breastfeeding (Beilin et al., 2005; Jordan et al., 2005)

3. Operative birth (Instrumental and caesarean).

   Rationale: Caesarean birth is associated with poorer breastfeeding success (Nissen et al., 1996); instrumental birth either forceps or ventouse is indicative of a prolonged second stage which is also associated with reduced exclusive breastfeeding (Chapman & Perez-Escamilla, 1999).

4. Non-singleton babies, twins or greater multiples.

   Rationale: Multiple births create a very specific set of breastfeeding challenges, and medical interventions such as epidural and syntocinon are common features of multiple births (Damato, Dowling, Standing, & Schuster, 2005).

5. Preterm babies born before 37 weeks gestation.

   Rationale: Premature infants are more likely to be separated from their mother for assessment and treatment and they have a less developed suck, swallow reflex; breastfeeding rates are lower in this group (Rajan, 1994; Yip, Lee, & Sheehy, 1996).

6. Postpartum haemorrhage greater than 500mls.

   Rationale: There is a weak association between postpartum haemorrhage and reduced breastfeeding rates, probably as a result of anaemia (Rioux et al., 2006). Management of postpartum haemorrhage necessitates the use of treatment ecbolics which would have a synergistic effect with the prophylactic ecbolics.

7. Treatment ecbolic used.

   Rationale: Treatment ecbolics are used to manage postpartum haemorrhage and will have a synergistic effect with prophylactic ecbolics. It is not usual to exclude participants from a retrospective study based on characteristics that occur after the treatment decision however in order to avoid compromising the study by including women who had been exposed to an ecbolic as a treatment it was essential to exclude these women from the final cohort.

Sample size

The sample size was calculated to ensure that the results from the study would be meaningful and have clinical significance. The sample size was calculated using draft data produced from "Healthware" the maternity database, and by e-mail communication with the Maternity and Newborn Information system staff at the Ministry of Health. Both system managers reported absent data in some fields, which would necessitate excluding these cases from the analysis.

The WDHB baseline exclusive breastfeeding rate at 2 weeks postpartum was approximately 67% in 2007. Begley (1990) showed a 10% difference in breastfeeding rates at 4 weeks post partum with ergometrine use compared to no ergometrine; however a difference of this magnitude was unlikely in this study. A 5% difference was plausible and this would be ample to be clinically significant.

With an estimated sample size of approximately 3470 women having syntometrine and approximately 580 women having physiological management (reference group) and with a population breastfeeding rate of 67% with 80% power and 95% confidence it would be possible to detect a significant result for ± 6.2%. With a sample size of approximately 1740 women having syntocinon and approximately 580 women having physiological management (reference group) with a population breastfeeding rate of 67% with 80% power and 95% confidence it would be possible to detect a significant result for ± 6.6%. Therefore the available sample would be sufficient to detect a difference in breastfeeding rates of 6% should such as difference exist.

Data Sources

Study data came from two sources: a) Waitemata DHB maternity database "Healthware™"; and b) The Ministry of Health "Maternity and Newborn Information System" (MNIS). Women planning to give birth at Waitemata DHB are required to complete with their lead maternity carer a "Facility Registration" form (Appendix 2). This form collects important social and clinical data. The woman is asked to self

identify her ethnicity and that of her anticipated infant, and to provide other demographic information such as her residential address and date of birth. This data is then recorded onto the DHB maternity database "Healthware" by the clerical staff.

Labour and birth data is summarised immediately after the birth by the Midwife attending the birth and recorded onto a "Labour and birth summary" form (Appendix 3). This information is then recorded onto the DHB maternity database "Healthware" either by a midwife or delegated to the clerical staff.

During the five year study period (July 2002 – June 2007) all lead maternity carers (employed and self-employed) were required by the Ministry of Health to collect breastfeeding status at two weeks postpartum and record this on the "Transfer to Well Child Provider form" (Appendix 4). The LMC then submitted a copy of this form to "HealthPAC" (the Ministry of Health business unit responsible for maternity claims now renamed "Sector Services"). HealthPAC then passed this information to the Maternity and Newborn Information System (MNIS) database. Data showing breastfeeding status at two weeks was available for all neonates in New Zealand until July 2007. From July 2007 the Ministry of Health made a decision to collect this information only from self-employed LMC, District Health Board employed LMCs were no longer required to submit this information, so from July 2007 onwards the data set is incomplete. For this reason it was decided to use a cohort of women who had given birth in the 5 years up to and including June 2007 when a more complete data set was available.

Cultural and Ethical consideration

When conducting research in New Zealand, it is important to consider the Treaty of Waitangi principles of partnership, protection and participation (Health Research Council, 2008). At the outset guidance was sought from the Maori midwives employed at that time in the Te Puna Hauora Maori midwifery team at Waitemata DHB. The Maori midwives consulted were supportive of the study, and the prospect of identifying specific Maori breastfeeding data in the Waitemata community. They offered some thoughts on the reasons why Maori choose to breastfeed and what they

perceived as barriers to exclusive breastfeeding. They also offered ongoing support with the interpretation of the data.

The research proposal was also sent to the Nga Kai Tataki, Maori Research Review Committee at Waitemata DHB. This committee reviewed the research from a Maori perspective and provided approval for the study (Appendix 5).

Of the four main ethical principles: beneficence; non-maleficence; justice and autonomy; autonomy was most compromised by the study design (Barrett & Coleman, 2005). This was because the study involved data from approximately 29,000 births which took place over a 5 year period. To contact each woman individually to request permission to use her data for the study would have been impractical. Extra care in the study protocol was devoted to data management and security to ensure that privacy and anonymity were maintained and data pertinent to the study was abstracted, merged and de-identified from the previously collected data (see Sampling Procedure and Privacy Protection p45).

Approval to undertake the study was gained from Waitemata DHB Knowledge Centre. The study was supported by the General Manager of Child, Woman and Family services. The Ministry of Health Northern X Regional Ethics Committee approved the study protocol based on low ethical risk (expedited review number NTX/09/03/EXP; Appendix 6). Finally approval was gained from Auckland University of Technology Ethics Committee (AUTEC) (Appendix 7).

Variables of interest

Independent variables

The study independent variable was prophylactic ecbolic group with group 1 being physiological third stage, nil given – reference group; group 2 being syntocinon given prophylactically for the third stage of labour; and group 3 being Syntometrine given prophylactically for third stage of labour.

After each birth the lead clinician records the use of prophylactic ecbolics, route, dose and whether any treatment ecbolics have been required and given. This information is captured on the hospital labour and birth summary (Appendix 3).

Dependant variable

The dependant variable was exclusive breastfeeding at two weeks postpartum. Exclusive breastfeeding is recognised as the most advantageous to the infant, and as such is the gold standard for breastfeeding. Step six of the World Health Organisation "Ten steps to successful breastfeeding" advises:

"Give newborn infants no food or drink other than breastmilk, unless medically indicated" (Abalos, 2007; World Health Organisation, 1998, p. 48)

The rationale given is that women who give their babies supplementary feeds with formula or water are more likely to stop breastfeeding earlier than women who exclusively breastfeed, and babies who receive supplements are more likely to suffer diarrhoea and other infections (World Health Organisation, 1998).

The timeframe of two weeks postpartum was selected because this is a point in the early postnatal period after discharge from hospital when breastfeeding has become established. It is also the time that the New Zealand Ministry of Health requires that the lead maternity carer record and report on breastfeeding status.

"A maternity provider must submit health status information in accordance with the claim forms, OMC system or message standard definition for lead maternity care, approved by the Ministry of Health from time to time, including.....

(b)   the baby's breastfeeding status at 2 weeks of age" (Ministry of Health, 2007, p. 1063)

This data is recorded on the Transfer to Well Child Provider Form (Appendix 4) using one of the four New Zealand standard definitions that were adopted by the Ministry of Health in 2002 (Ministry of Health, 2002).

1. **Exclusive Breastfeeding:** The infant has never had any water, infant formula, or other liquid or solid food: only breast milk and prescribed medicines have been given from birth.

2. **Fully Breastfeeding:** Within the past 48 hours, the infant has taken breastmilk only and no other liquids or solids, except a minimal amount of water or prescribed medicines.

3. **Partial Breastfeeding:** The infant has taken some breastmilk and some infant formula or other solid food in the past 48 hours.

4. **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.

Potential confounding variables

Potential confounding variables were identified from the literature as having a potential effect on breastfeeding outcome. The potential confounding variables that were included in this study are described in the data dictionary that appears on the following pages in Table 6.

Table 6: Data Dictionary

Variable	Rationale	Data	Statistical test	Source	Comments
Maternal age	Younger women are less likely to maintain exclusive breastfeeding (Ladomenou, Kafatos, & Galanakis, 2007)	Ordinal	T test	Healthware	Maternal age at time of birth of baby in years was grouped into categories: 19 or less; 20-24; 25 – 29;30 – 34; 35 – 39; 40 or more
Maternal parity	Primigravid women are more likely to experience delayed lactogenesis II (Dewey et al., 2003)	Dichotomous	x^2 test	Healthware	1 = Primiparous 2 = Multiparous
Maternal ethnicity	Maori, Pacific Island and Asian women are less likely to breastfeed exclusively (Ministry of Health, 2008)	Categorical	x^2 test	Healthware	Ethnicity is self selected by the mother when registering for maternity care. The ethnicity was categorized in two ways sub group e.g. Samoan and larger grouping e.g. Pacific Island.
Maternal deprivation	Women from lower socioeconomic groups are less likely to breastfeed exclusively (Jones, West, & Newcombe, 1986).	Categorical	T test	Healthware	NZDep06 scores are established from the mother's residential address. The deprivation scale is from 1-10 with 10 being the most deprived. For the analysis the deciles were combined into 5 pairs 1&2, 3&4, 5&6,7&8, 9&10
Lead Maternity Carer (LMC) type	Midwives have specific and ongoing education in breastfeeding management, care and support (Midwifery Council, 2008), and potentially midwives in different employment settings might have more time to devote to breastfeeding support	Categorical	x^2 test	Healthware	These were categorized into Self-employed midwife; Employed caseload midwife; Employed core midwife; GP; and Obstetrician (see Glossary for definition of different midwife roles)
Infant Birth Weight	There is a perception that larger babies appear hungrier and this affects the confidence of the mother to continue breastfeeding (Glover et al., 2007)	Ordinal	T test	Healthware	Weight measured in grams were grouped into 5 groups: less than 2799g; 2800 – 3199; 3200 – 3599; 3600-3999; 4000 – 4399; 4400 g or more

Table 6 Data Dictionary (continued).

Variable	Rationale	Data	Statistical test	Source	Comments
Infant Apgar Score at 5 minutes of age	Infants with low Apgar scores are more likely to experience separation from their mother for observation or treatment and may be less likely to breastfeed exclusively.	Ordinal	*T* test	Healthware	The clinician present at the birth undertakes an assessment of the baby at one and five minutes and allocates a score from 1-10 based on five key criteria: respiration, heart rate, colour, tone and reflexes. The score indicates how well the infant is adapting to extra uterine life (see Glossary).
Prophylactic Ecbolic	**Independent variable**	Categorical	x^2 test	Healthware	1 = Nil (Physiological), 2 = Syntocinon, 3 = Syntometrine
Breastfeeding at two weeks	**Dependent variable**	Dichotomous	x^2 test	MNIS	Categorized to 1= Exclusive and 0 = Fully, Partial or Artificial.

NOTE: The listed statistical test was used to analyse association between the given variable and the independent and dependent variables.

Sampling procedure and privacy protection

The procedure for data collection is outlined in the sampling procedure flow chart (Figure 2). The Information Manager for the Waitemata DHB Child, Woman and Family Service was asked to generate an excel spreadsheet from Healthware™ the hospital maternity database with the required demographic and clinical data for the time period.

The National Health Index (NHI) number of the mother and of the baby and the date of birth of the baby were then separated from the clinical data. This key identification data was then couriered in an encrypted file to the Maternity and Newborn Information Service (MNIS) in Wellington to be linked with the breastfeeding status at two weeks postpartum. The breastfeeding data was extracted using the infant's NHI as this is unique to each birth, whereas the mother's NHI may have been associated with more than one baby if she gave birth more than once in the 5 year study period.

The breastfeeding data from MNIS was then couriered from Wellington to Auckland and merged with the clinical and demographic data for each birth using the baby's NHI as the common factor. The NHIs for both the mother and the infant were then removed and the records were given a unique identifier which was stored alongside the NHIs in an encrypted file. The records that met the exclusion criteria were excluded. The working file was then screened for missing ecbolic and breastfeeding data. The incomplete records were stored in a separate file so that they could be compared for homogeneity of the potential confounding variables with the final cohort. The total number of women in the final cohort was 5988.

Figure 2: Sampling procedure flow chart
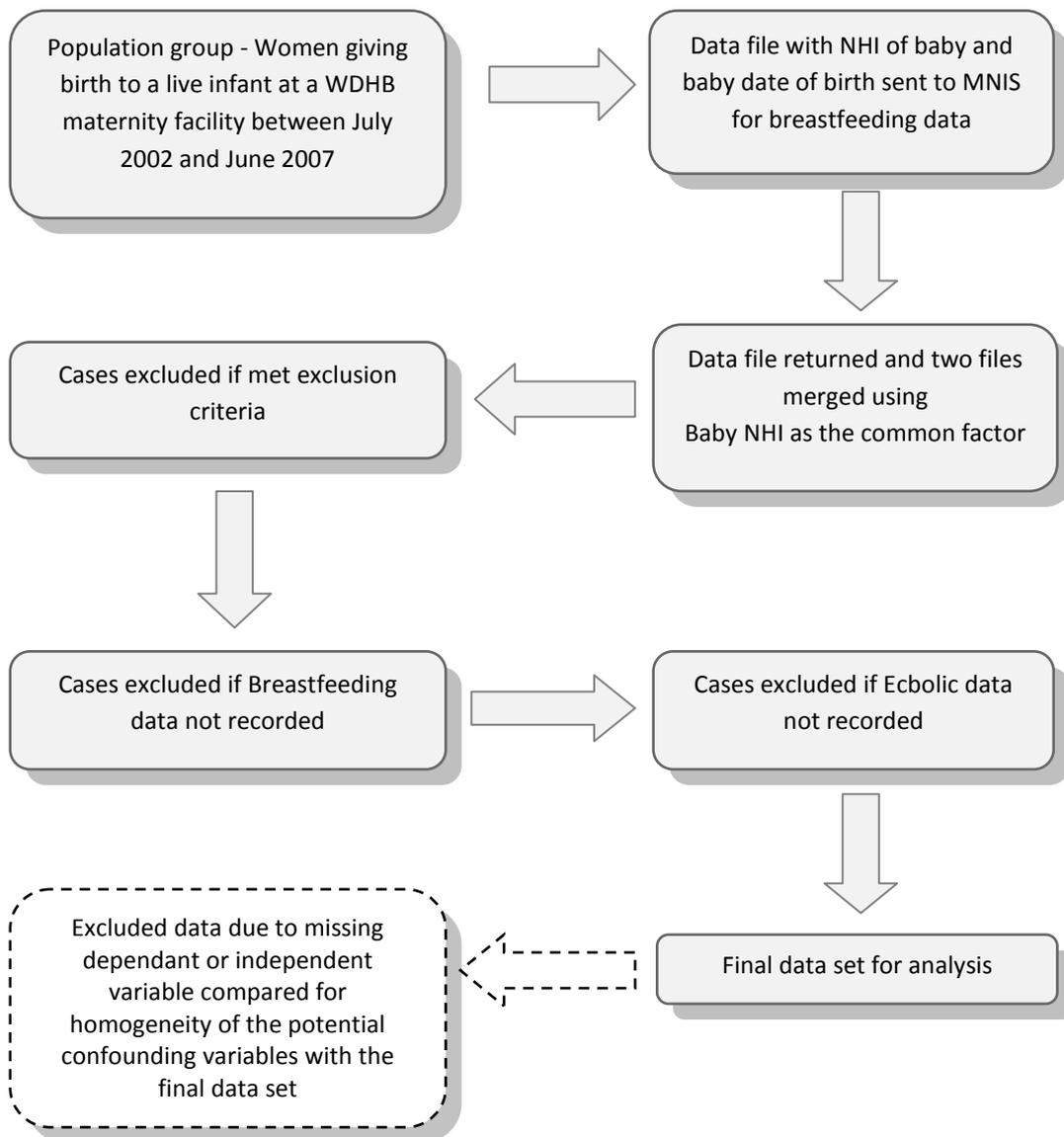
Data management and analysis methods

The data was transferred from excel to a statistical analysis programme, SPSS version 16. The first step in the analysis was to screen the data for missing data, outliers, errors and normality. The data was grouped into meaningful sub groups creating categorical, ordinal and dichotomous data groups (see Table 6) which were then presented as descriptive statistics including the frequency and percentage of the variables.

The two groups excluded due to lack of data (missing ecbolic data and missing breastfeeding data) were compared with the final cohort for homogeneity of the

potential confounding variables (maternal age, parity, ethnicity, deprivation, type of LMC, birth weight of baby; and apgar score of the baby), and the variables of interest (prophylactic ecbolics and exclusive breastfeeding at two weeks).

The descriptive data provided answers to the first two research statements:

1. Describe the prophylactic ecbolic use for the third stage of labour for a cohort of well mothers

2. Describe the exclusive breastfeeding rate at two weeks postpartum for a cohort of well mother baby dyads

Univariate analysis

In order to examine the hypothesis that maternal age, parity, ethnicity, and deprivation, type of LMC, infant birth weight, and Apgar score at 5 minutes are not associated with breastfeeding rates at two weeks, these confounding variables were analysed using binary logistic regression. Results are presented as Odds Ratios (OR) with 95% Confidence Intervals (CI).

Multivariate analysis

Finally multivariate analysis was used to examine the hypothesis that prophylactic ecbolic use will have no effect on exclusive breastfeeding rates at two weeks; after controlling for confounding factors. A binary logistic regression analysis was undertaken with primary ecbolics using a stepwise variable selection process to select the potential confounding variables identified in the univariate analysis that added significantly to the model. Results are presented as Odds Ratios (OR) with 95% Confidence Intervals (CI).

Summary

This study used a retrospective cohort design taking advantage of data that had been routinely collected and stored as part of women's intrapartum and postnatal care. The study merged two data sets: one from Waitemata DHB maternity database; and one from the Ministry of Health maternity database. After exclusions, the final data set consisted of well women giving birth to a normal healthy infant with no medical interventions. Some breastfeeding and ecbolic data was missing from the final

data set and these records were grouped separately and compared for homogeneity with the final cohort. The study aimed to describe the use of prophylactic ecbolics and the breastfeeding rates at two weeks postpartum in a selected group of well mothers. Binary logistic regression analysis was used to evaluate an association between the variables of interest and exclusive breastfeeding at two weeks, and then multivariate analysis was performed with prophylactic ecbolics using a stepwise variable selection process with significant confounding variables identified through the univariate analysis in order to examine the hypothesized relationship between exclusive breastfeeding and prophylactic ecbolics.

The following chapter presents the findings of the study in relation to the research questions.

Chapter Four: Results

This chapter presents the results of the study. A flow diagram showing the exclusion process and final sample will be presented. The reasons, numbers and percentages of the excluded cases will be presented. The descriptive statistics for the final sample will be presented in table format comparing the final cohort with the cases excluded due to missing data. The final cohort characteristics will be described, and then results for prophylactic ecbolic use, breastfeeding at two weeks, and any association between the confounding variables and breastfeeding at two weeks. The binary logistic regression analysis used to evaluate an association between the variables of interest and exclusive breastfeeding at two weeks will be presented as a table. Finally the multivariate analysis performed with prophylactic ecbolics and the significant confounding variables will be presented in a table format.

Sample

In order to limit the study group to well mothers and infants cases were excluded from the analysis if there had been medical interventions during labour and birth (the list of exclusion criteria and the rationale are described in Chapter 3). A total of 29,815 women gave birth at a Waitemata District Health Board maternity facility between July 2002 and June 2007. After exclusions the final cohort for analysis totaled 5988 cases (Figure 3).

The largest percentage of exclusions was due to epidural analgesia (53%); this included women who had epidural for labour and for caesarean birth. Caesarean birth accounted for 26% of women. Postpartum hemorrhage - blood loss greater than 500mls, occurred in 12% of women but treatment ecbolics were recorded as being used in 20% of women; this anomaly is likely to have occurred as a result of a classification error during data input (see Table 7).

Data was missing for both the dependant and independent variables; prophylactic ecbolic data for 12% of the data set, and exclusive breastfeeding data for 24% of the data set. These cases were excluded from the final analysis. The cohorts of excluded cases were compared with the final cohort and were found to be largely

consistent (see Table 8). It would appear that the missing data were missing at random, therefore it was considered reasonable to undertake analysis of the complete cases only. The absence of complete data sets for all of the cases does not appear to be a significant source of bias in the final cohort.

Figure 3: Flow diagram showing exclusions.
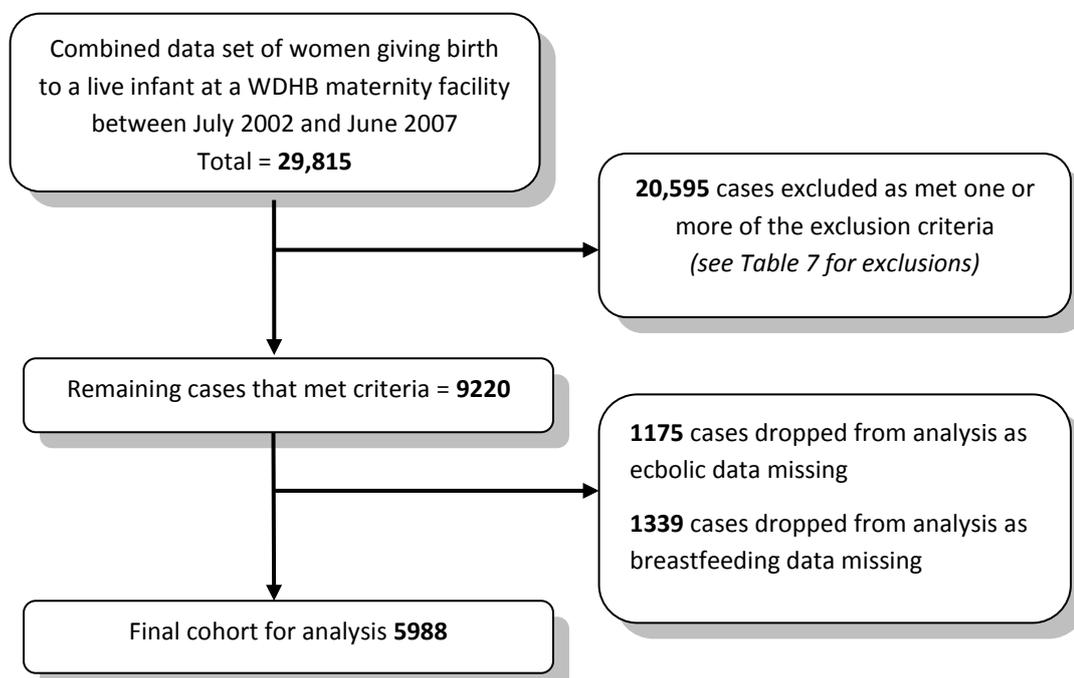
Table 7: Reasons for exclusion, number and percent

Exclusions	Number	Percent
Induction of labour	6261	21%
Augmentation of labour	3046	10%
Epidural for labour or birth	15726	53%
Instrumental births	3041	10%
Caesarean births	7683	26%
Twins (sets)	321	1%
Pre term birth <37weeks	1722	6%
PPH >500mls	3592	12%
Treatment ecbolic	5992	20%
Total number of exclusions	**20,595**	69%

 Note: Groups are not mutually exclusive

Table 8: Descriptive statistics comparing final cohort with excluded cases

Variable categories	Final Cohort		Missing Breastfeeding data		Missing Ecbolic data	
Column frequency (No.) and percents (%)	No.	%	No.	%	No.	%
Total cases	5988	63%	2341	24%	1175	12%
Maternal Age						
19 or less	345	5.8%	151	6.4%	72	6.1%
20-24	995	16.6%	424	18.1%	197	16.8%
25-29	1582	26.4%	612	26.1%	306	26%
30-34	1926	32.2%	761	32.5%	389	33.1%
35-39	996	16.6%	350	15%	198	16.8%
40 or more	144	2.4%	43	1.8%	13	1.1%
Maternal Parity						
Primiparous	1641	27.4%	761	32.5%	368	31.3%
Multiparous	4347	72.6%	1580	67.5%	807	68.7%
Maternal Ethnicity						
European	3160	52.8%	1214	51.9%	709	60.3%
NZ Maori	929	15.5%	369	15.8%	163	13.9%
Pacific Island	882	14.7%	370	15.8%	137	11.7%
Asian	811	13.5%	306	13.1%	141	12%
Other	167	2.8%	68	2.9%	20	1.7%
Missing data	39	0.6%	14	0.6%	5	0.4%
Maternal deprivation						
1 and 2	1146	19.2%	390	16.6%	228	19.3%
3 and 4	1027	17.2%	424	18.1%	243	20.7%
5 and 6	1494	25%	584	24.9%	287	24.4%
7 and 8	2019	33.8%	802	34.3%	344	29.3%
9 and 10	302	5%	122	5.2%	64	5.4%
Infant Birth weight						
Less than 2799g	306	5.1%	123	5.2%	52	4.4%
2800 -3199g	1174	19.6%	458	19.6%	267	22.7%
3200-3599g	2018	33.7%	798	34.1%	422	35.9%
3600-3999g	1647	27.5%	662	28.2%	305	26%
4000-4399g	648	10.8%	245	10.5%	105	8.9%
4400g or greater	195	3.2%	55	2.4%	24	2%
Infant Apgar score						
10	4347	72.6%	1667	71.2%	872	74.2%
9	1451	24.2%	589	25.2%	269	22.9%
8 or less	190	3.2%	78	3.3%	30	2.6%

Variable categories	Final Cohort		Missing Breastfeeding data		Missing Ecbolic data	
Type of LMC *(see glossary for definitions)*						
Self employed midwife	3712	62%	1458	62.3%	839	71.4%
Employed caseload midwife	1243	20.8%	480	20.6%	201	17.1%
Employed core midwife	583	9.7%	255	10.9%	70	6%
General Practitioner	257	4.3%	81	3.5%	43	3.7%
Obstetrician	160	2.7%	50	2.1%	13	1.1%
Missing	33	0.6%	17	0.7%	9	0.8%
Prophylactic ecbolic						
Physiological	821	13.7%	291	14.2%	Missing	
Syntocinon	1636	27.3%	533	25.9%	Missing	
Syntometrine	3531	59%	1231	59.9%	Missing	
Breastfeeding at 2 weeks						
Exclusive	3283	54.8%	Missing		510	60.9%
Fully	995	16.6%	Missing		124	14.8%
Partial	891	14.9%	Missing		109	13%
Artificial	819	13.7%	Missing		94	11.2%

Cohort characteristics

All women in the final cohort had a singleton, term, normal vaginal births, with no induction or augmentation of labour, no epidural pain relief, no postpartum haemorrhage and no treatment ecbolics (see table 7). The women were aged between 14 and 46 years, with the mean maternal age of 29 years; 5.8% were teenagers. The majority of women 73% were having a second or subsequent baby, with the largest number of previous births being 10. European (both NZ European and other European was the dominant ethnicity contributing 53% of the cohort, followed by Maori 15.5%, Pacific Island 14.7% and Asian 13.5%. Women from all deprivation scales were represented but with fewer in the lowest and highest groups (Table 8).

The majority of women (62%) had a self-employed midwife as their Lead Maternity Carer and over 92% of women had a midwife recorded as the lead clinician at the birth (Table 8).

The lowest infant weight was 1700g and the highest weight was 5255g, with the mean birth weight at 3512g. The majority of babies were well and healthy at birth with 97% of babies having an Apgar score of 9 or 10 at five minute.

Prophylactic Ecbolic use for the third stage of labour

"Describe the prophylactic ecbolic use for the third stage of labour for a cohort of well mothers".

Prophylactic ecbolics were given in the majority of births (86%), with Syntometrine (59%) as opposed to Syntocinon (27%) as the medication of choice. Only 14% of women experienced a physiological third stage.

Exclusive Breastfeeding rate at two weeks postpartum

"Describe the exclusive breastfeeding rate at two weeks postpartum for a cohort of well mother baby dyads".

At two weeks postpartum 54.8% of women were exclusively breastfeeding, a further 16.6% were fully breastfeeding, 14.9% were partially breastfeeding and 13.7% were artificially feeding (see Table 8). This presents quite a different picture from the breastfeeding rates at discharge from Waitemata DHB maternity for the same time period with exclusive breastfeeding reducing from 87% to 55% (see figure 5).

Figure 4: Comparison of breastfeeding rates at two weeks and Waitemata DHB breastfeeding rates at discharge from hospital (Waitemata District Health Board, 2008b)
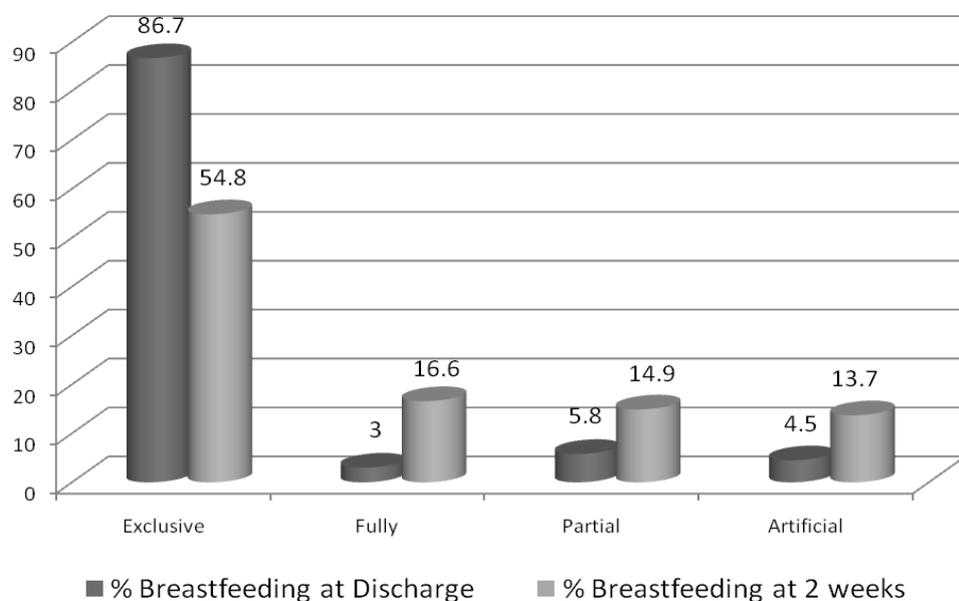
Association between confounding variables and breastfeeding

"Maternal age, parity, ethnicity, and deprivation, type of LMC and infant birth weight and Apgar score are not associated with breastfeeding rates at two weeks."

Each of the confounding variables was analysed using binary logistic regression (see Table 9). Among the potential confounding variables only ethnicity showed a statistically significant difference. Chinese (OR 0.49) and Samoan (OR 0.81) women were statistically less likely to be exclusively breastfeeding at two weeks postpartum than European women.

In addition women over the age of 40 were less likely to be breastfeeding at 2 weeks (OR 0.66) but this trend was not statistically significant. Women who were socially deprived were less likely to breastfeed (54%) than women in the most socially advantaged group (58%); again this did not reach the level of significance. Parity did not appear to be a factor which influenced breastfeeding at two weeks in the cohort, nor did infant condition as measured by birth weight and Apgar score. The LMC type also did not reach statistical significance although women who had a GP LMC appeared to be less likely to be breastfeeding at two weeks (49%) compared to women who had a self-employed midwife LMC (55%). Women who had an obstetrician LMC appeared to be most likely to be breastfeeding at two weeks (61%).

Table 9: Factors affecting exclusive breastfeeding at two weeks: unadjusted analysis

Variable in the equation	Frequency	% Exclusive Breastfeeding	Odds ratio, 95% CI
Maternal age			$P = 0.42$
19 or less (reference)	345	56.8%	1.00
20-24	995	54.0%	0.89 (0.70 – 1.14)
25-29	1582	55.2%	0.94 (0.74 – 1.18)
30-34	1926	55.0%	0.93 (0.74 – 1.17)
35-39	996	55.3%	0.94 (0.74 – 1.21)
40 or more	144	46.5%	*0.66 (0.49 – 0.78)*
Maternal parity			$P = 0.99$
Primiparous (reference)	1641	56.6%	1.00
Multiparous	4347	54.2%	0.99 (0.98 - 1.23)

Variable in the equation	Frequency	% Exclusive Breastfeeding	Odds ratio, 95% CI
Maternal ethnicity			*P = <0.0001*
European (reference)	3160	56.2%	1.00
Maori	929	53.5%	0.90 (0.77 – 1.04)
Samoan	440	50.9%	*0.81 (0.66 – 0.99)*
Tongan	142	55.6%	0.98 (0.70 – 1.37)
Other Pacific Island	300	59.0%	1.12 (0.88 – 1.43)
Chinese	219	38.4%	*0.49 (0.37 – 0.64)*
Indian	215	57.7%	1.06 (0.80 – 1.40)
Other Asian	377	52.5%	0.86 (0.70 – 1.07)
Other	167	61.7%	1.25 (0.91 – 1.73)
Maternal deprivation			*P* = 0.21
1 and 2 (reference)	1146	58.2%	1.00
3 and 4	1027	51.7%	0.77 (0.65 – 0.91)
5 and 6	1494	53.3%	0.82 (0.70 – 0.96)
7 and 8	2019	55.8%	0.91 (0.78 – 1.05)
9 and 10	302	53.6%	0.83 (0.64 – 1.07)
Infant weight			*P* = 0.13
4400g or greater (reference)	195	53.3%	1.00
4000-4399g	648	59.3%	1.27 (0.92 – 1.76)
3600-3999g	1647	55.6%	1.09 (0.81 – 1.47)
3200-3599g	2018	53.8%	1.02 (0.76 – 1.37)
2800 -3199g	1174	54.3%	1.04 (0.77 – 1.41)
Less than 2799g	306	51.0%	0.91 (0.64 – 1.30)
Apgar score			*P* = 0.26
10 (reference)	4347	55.4%	1.00
9	1451	53.5%	0.93 (0.82 - 1.04)
8 or less	190	51.1%	0.84 (0.63 - 1.12)
LMC type *(see glossary for definition*s)			*P* = 0.31
Self employed midwife (reference)	3712	55.3%	1.00
Employed caseload midwife	1243	53.7%	0.94 (0.83 - 1.10)
Employed core midwife	583	54.2%	0.95 (0.80 - 1.34)
GP	257	49.4%	0.79 (0.61 - 1.02)
Obstetrician	160	61.2%	1.28 (0.92 - 1.77)

Association between prophylactic ecbolics and exclusive breastfeeding at two weeks

Ecbolic use will have no effect on exclusive breastfeeding rates at two weeks:

- Women receiving syntometrine (compared to no ecbolics) will not be less likely to be exclusively breastfeeding at two weeks

- Women receiving syntocinon (compared to no ecbolics) will not be less likely to be exclusively breastfeeding at two weeks

- Ecbolic use is not an independent factor predicting exclusively breastfeeding at two weeks (after controlling for confounding factors)

After binary regression analysis was performed with the confounding variables only ethnicity was found to be significant in predicting likelihood of exclusive breastfeeding at two weeks postpartum in the multivariate model (Table 10). The research hypothesis that ecbolic use is not an independent factor predicting exclusive breastfeeding at two weeks after controlling for confounding factors was supported.

Table 10: Exclusive breastfeeding at two weeks: Adjusted analysis

Variable in the equation	Frequency	% Exclusive Breastfeeding	Odds ratio, 95% CI
Maternal ethnicity			*P = <0.0001*
European (reference)	3160	56.2%	1.00
Maori	929	53.5%	0.90 (0.77 - 1.04)
Samoan	440	50.9%	*0.81 (0.66 - 0.99)*
Tongan	142	55.6%	0.98 (0.70 - 1.37)
Other Pacific Island	300	59.0%	1.12 (0.88 - 1.43)
Chinese	219	38.4%	*0.48 (0.37 - 0.64)*
Indian	215	57.7%	1.06 (0.80 - 1.40)
Other Asian	377	52.5%	0.86 (0.70 - 1.07)
Other	167	61.7%	1.25 (0.91 - 1.73)
Prophylactic ecbolic			*P = 0.42*
Physiological (reference)	821	56.3%	1.00
Syntocinon	1636	53.6%	0.90 (0.76 - 1.06)
Syntometrine	3531	55.1%	0.95 (0.82 - 1.11)

Summary

The study selected a cohort of well mother and baby dyads with no medical interventions during labour. The final cohort consisted of 5988 mothers and babies who met the criteria and had complete data available for analysis. The women were predominantly European, having a second or subsequent baby with a self-employed Midwife LMC. Just slightly over half the women 55% were still exclusively breastfeeding at two weeks postpartum. The majority of women (86%) had experienced active management of the third stage with the most common ecbolic being Syntometrine (59%). Univariate analysis revealed that ethnicity was significantly associated with breastfeeding at two weeks postpartum, with both Chinese and Samoan women less likely to be breastfeeding exclusively. Multivariate analysis established that use of prophylactic ecbolics was not an independent factor predicting exclusive breastfeeding at two weeks in this cohort.

The following chapter will discuss these findings, identify some limitations of the study and reflect on possible reasons for the results and the implications for clinical practice, further research and education.

Chapter 5: Discussion

This chapter will discuss the main study findings and review these in light of current knowledge. Study strengths and limitations will be presented along with a discussion about the confidence that can be attributed to the study results. The chapter will conclude with recommendations for education, practice and future research.

Breastfeeding rates

The exclusive breastfeeding rate of 55% at two weeks postpartum in the study cohort of well mothers and babies was well below the government target of 74% at six weeks. When combined with the "fully breastfeeding" rates the total rises to 71%. This percentage is consistent with the Royal New Zealand Plunket Society breastfeeding data which gives a combined exclusive and fully breastfeeding rate at six weeks postpartum of 66% (National Breastfeeding Advisory Committee, 2008b).

There was considerable uniformity in the breastfeeding rates regardless of potential clinical and demographic confounding variables suggesting that there are other factors which are influencing the rate that were not evident in this study.

Exclusive breastfeeding rates dropped 31% in the period from hospital discharge to assessment at two weeks in the community suggesting that this is a key period of adaptation for the mother and infant (see Figure 4). Given that the "Baby Friendly Hospital Initiative" has had a significant inluence on breastfeeding initiation rates in the past few years it is disappointing to note that these gains do not appear to be sustained in the community. This finding supports the need for providing a framework that can deliver ongoing support throughout the breastfeeding continuum for mothers in the community. The Baby Friendly Community initiative is currently being trialed at a number of sites in New Zealand as the vehicle to effect change in this area (National Breastfeeding Advisory Committee, 2008a). The Baby Friendly Community Initiative (BFCI) has seven steps (see Table 11).

Table 11: Baby Friendly Community Initiative Seven Steps (New Zealand Breastfeeding Authority, 2008)

1.	Have a written breastfeeding policy that is routinely communicated to all staff and volunteers.
2.	Train all health care providers in the knowledge and skills necessary to implement the breastfeeding policy.
3.	Inform pregnant women and their families about the benefits and management of breastfeeding.
4.	Support mothers to establish and maintain *exclusive breastfeeding* to six months.
5.	Encourage sustained breastfeeding beyond six months, to two years or more, alongside the introduction of appropriate, adequate and safe complementary foods.
6.	Provide a welcoming atmosphere for breastfeeding families.
7.	Promote collaboration among health services, and between health services and the local community

Breastfeeding rates in different ethnic groups

Ethnicity was identified as a confounding variable and was shown to be statistically significant in predicating the likelihood of exclusive breastfeeding at two weeks postpartum, suggesting that culture may play a part in the decision to stop exclusive breastfeeding particularly after discharge from hospital.

Chinese women were significantly less likely to be exclusively breastfeeding at two weeks than European women (OR 0.48 CI 0.37-0.64). The ethnic composition of the Waitemata DHB population is changing; recent data suggests that the Asian population will grow at a rate of 4% per year from 77,200 people in 2006, to 97,300 people in 2011, to 118,300 people in 2016 (Statistics New Zealand, 2010). Given these demographic changes it is important to ensure that maternity services are culturally appropriate and designed to deliver optimal health outcomes for all, minimizing health inequalities. Lin Li and colleagues in Perth have undertaken a series of studies to examine Chinese immigrant attitudes to breastfeeding and compare these with Australian born women (Li, Zhang, & Binns, 2003; Li, Zhang, Scott, & Binns, 2004, 2005). Most mothers indicated support for breastfeeding (91%). The main indications given for stopping breastfeeding were insufficient milk, and the need to return to work

or study. Higher income families had less preference for breastfeeding and Chinese women were of the view that Australian women formula fed their infants. Factors positively associated with breastfeeding were recommendation from their doctor and support from the father of the baby. In delivering education and support to Chinese women it would therefore be important to include the father of the infant, to ensure medical endorsement is evident in breastfeeding education and to provide guidance around managing breastfeeding and working or studying including information about the legal rights of lactating mothers in the workplace (Payne & James, 2008).

Samoan women were the second ethnic group least likely to be breastfeeding at two weeks (OR 0.81). A study of infant care practices among New Zealand Pacific Island families (Abel, Park, Tipene-Leach, Finau, & Lennan, 2001), raised some important differences between Pakeha and Pacific families regarding infant care including breastfeeding. The role of the family was a key factor in providing support and was very influential in decisions regarding infant feeding. It highlighted that Samoan families had immigrated earlier than other Pacific Islanders and speculated that this may be a reason why they have become more distanced from traditional cultural breastfeeding practices which are prevalent away from the main centres. In a 2004 study looking at reasons why Pacific Island women do not breastfeed exclusively after discharge from hospital a number of important factors emerged (Butler et al., 2004). Samoan women were again the least likely of any of the Pacific Island groups to continue breastfeeding, key factors associated with not breastfeeding were being in New Zealand longer than 10 years; being in current employment; using child care regularly; high parity; use of a pacifier; not sleeping in the same room as the infant, and not receiving a visit from a well child provider.

In delivering education and support to Pacific Island women it would be particularly important to include key family members, encourage rooming in; educate parents around the importance of feeding cues and the effects of pacifiers on infant feeding; provide support and advice about working and breastfeeding; and encourage engagement with well child services.

The New Zealand Ministry of Health has also embarked on a social marketing campaign which features women from both Asian and Pacific cultures to promote the message of breastfeeding for the first six months of life. The influence of this campaign on public views of breastfeeding has been positive (Ministry of Health, 2009)

Currently Waitemata DHB is utilizing funding from the Healthy Eating Healthy Action (HEHA) health promotion budget to provide ethnic specific breastfeeding education. The programme is in its infancy but staff are monitoring breastfeeding initiation and continuance rates amongst these groups to assess whether this type of intervention can improve exclusive breastfeeding amongst Pacific and Asian families specifically.

Despite evidence in other studies suggesting a lower than average breastfeeding rate amongst Maori, the data from this study did not reveal a statistically significant difference, with the exclusive breastfeeding rate at two weeks being 54% compared to 56% in European women. This result is reassuring but overall as the rate is much lower than the recommended 74% there is still much work to be achieved in increasing breastfeeding rates for all groups including Maori.

Effect of ecbolics on breastfeeding

The study revealed that there was a significant preference for active management of the third stage of labour (86%) which was unexpected in this selected low risk cohort. A New Zealand College of Midwives review of 9952 births from a database of Midwifery and Maternity Providers Organization (MMPO) members reflected a different ratio between active and physiological management, with 65% opting for active management and 35% opting for physiological management (New Zealand College of Midwives, 2008). The higher use of prophylactic ecbolics may therefore be unique to Waitemata DHB. The low utilization of physiological management of the third stage (14%) perhaps suggests a lack of confidence with physiological labour, or a preference for adhering to obstetric recommendations regarding management of the third stage, or simply a culture of managing the third stage in a particular way. It is also interesting to note that when opting for active management the medication of choice was Syntometrine (59%) not Syntocinon (27.3%). This is in contrast with international best practice guidelines that recommends syntocinon over syntometrine for most mothers (National Institute for health and clinical excellence (NICE), 2007). It would be interesting to further explore clinician choices around management of the third stage of labour to achieve greater understanding of this phenomenon.

While there is a pharmacological case to indicate that ecbolic medications may contribute in some cases to delayed lactation, this study did not find an association between ecbolic use and exclusive breastfeeding at two weeks; this is reassuring. However given the design of the study it cannot be concluded that prophylactic ecbolics do not affect breastfeeding rates because there may have been factors that were not evident in the study design that masked an effect. It must also be considered possible that an association exists but breastfeeding support practices in place at the time of the study such as midwifery and lactation consultant support to assist women through periods of delayed lactogenesis II may have ameliorated the short term effects of the medications. A recent retrospective cohort study undertaken in Wales, UK (Jordan et al., 2009), demonstrated an association between ecbolic use and breastfeeding at 48 hours, Syntocinon OR 0.75 95% CI (0.61-0.91) and Syntometrine OR 0.77 95% CI (0.65 – 0.91). Clearly a prospective or ideally a sufficiently sized randomized controlled trial with breastfeeding as the key dependant variable should be undertaken to increase knowledge in this area.

Limitations and Strengths of the study

As is often the case for retrospective cohort studies, a key limitation of the study was missing data across the two data sets. Over one thousand (1175, 12%) of the total cases were excluded due to missing ecbolic data and over two thousand (2341, 24%) cases were excluded due to missing breastfeeding data. Although this absence appears to be random, confidence in the results would have been stronger with more complete data sets. Despite breastfeeding data being a mandatory Ministry of Health requirement, it is clear that data collection in the New Zealand Maternity system during the data collection period was far from robust or consistent. This suggests a lack of clinical governance over maternity quality assurance activities. A further design limitation was the lack of information around why decisions regarding ecbolics were made and by whom. It could be argued that women who selected physiological third stage of labour were more confident in their bodies and their ability to both give birth and to breastfeed. As this information was not known it was not possible to include this as a confounding variable. The retrospective cohort design has limitations because it cannot take into account all the possible confounding variables, and therefore

results may be attributable to a different cause that has not been considered, in this case possibly maternal desire to breastfeed for example. A prospective study design may have delivered different results, however all design methodologies have limitations (McCourt, 2005). A strength of the study was the opportunity to merge two large datasets to produce a sufficiently large cohort to conduct the analysis. This is the first time that these two data sets have been bought together in New Zealand.

Implications for education

Undergraduate education of clinicians working in maternity care should include pharmacology in relation to ecbolic medication, and this should be expanded beyond the therapeutic effects and known side effects on the mother to include the potential effects on lactation and breastfeeding. Greater confidence with physiological management of the third stage of labour could be achieved perhaps through greater undergraduate and postgraduate exposure to this practice.

Education of maternity clinicians should also create an opportunity to explore the importance of reducing inequalities in health to ensure that health promoting practices are enjoyed by all. The study revealed that both Chinese and Samoan women were less likely to be providing their infants the benefits accrued by exclusive breastfeeding. Developing an understanding of how culture and ethnicity effects health choices and what practices can assist families to make healthy choices is crucial in optimizing care.

Implications for practice

Clinicians should be aware of the need to provide ethnic sensitive education particularly in relation to Chinese and Samoan women about breastfeeding, not only engaging the woman but the influential people in her life. Ensuring that women are linked with culturally appropriate support may make the difference in continuing or abandoning breastfeeding. Gussler and Briesemeister (1980) found that insufficient milk was often proffered as a reason for stopping breastfeeding although in fact the reason for wanting to stop was largely social not physiological (Gussler & Briesemeister, 1980). Assisting women to understand newborn feeding behavior and

patterns, and helping women to manage their milk supply by nocturnal and frequent effective milk extraction may also assist women to overcome anxiety that their infant is not thriving and requires formula.

Clinicians should be cognizant of the theoretical risks of delayed lactation due to some medications given in labour and consider this when assessing lactation in the first few days after birth. Delayed lactogenesis II is a cause of breastfeeding cessation but with patience and support this delay can often be overcome.

Implications for research

This study raises many opportunities for further research. It would be interesting to understand how women and clinicians make decisions regarding management of the third stage and choice of ecbolics. Further prospective research or a randomized controlled study on ecbolics for the third stage of labour with breastfeeding as a key outcome variable would add to our knowledge around this controversial area. In terms of ethnicity and breastfeeding it would be helpful to research some of the current and proposed interventions to understand what will work in changing the culture towards breastfeeding exclusively for the first 6 months of life for all ethnicities.

Conclusion

This study used a retrospective cohort methodology to assess for an association between prophylactic ecbolic medication for the third stage of labour and exclusive breastfeeding at two weeks postpartum. The study found an association between ethnicity and exclusive breastfeeding for Chinese and Samoan women but did not find an association between ecbolic use and exclusive breastfeeding. Further research is required to increase our understanding of the management of the third stage of labour and the choices that women and maternity clinicians make. Further research is needed to understand why so many women elect to stop breastfeeding exclusively prior to the recommended 6 months and what factors may be successful in influencing changes in behaviour in this regard. Given that Chinese and Samoan women are most likely to

stop exclusive breastfeeding this would be the priority areas for both health interventions and research.

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APPENDIX 1: Map of Waitemata District Health Board Area

Map of Waitemata District Health Board Region from www.moh.govt.nz/dhbmaps

APPENDIX 2: WDHB Facility Registration Form

Page 1

Waitemata District Health Board — *Te Wai Awhina*

Name: _____
Address: _____
Date of birth: _____   NHI: _____

Maternity Facility Registration

EDD: _____   G ___   P ___

Previous last names:	Telephone numbers:
	Home:
You prefer to be called:	Mobile:
Occupation:	Can we leave a message? ☐ Yes ☐ No

Family doctor:
Practice:
Address:
Telephone:

Next of Kin:
Name:
Relationship:
Phone:

Alternative emergency contact:
Name:
Relationship:
Phone:

Planned place for birth:
☐ North Shore
☐ Waitakere
☐ Home
☐ Other

Your ethnic group:
Please mark the spaces that apply to you and your baby E.g, Dutch, Japanese, Tokelauan ; the baby you will be having (maximum 3 choices for each column)

	You	Your Baby
NZ European	☐	☐
Maori	☐	☐
Samoan	☐	☐
Cook Island Maori	☐	☐
Tongan	☐	☐
Niuean	☐	☐
Chinese	☐	☐
Indian	☐	☐

Other - Please specify for yourself and your baby
You _____
Your Baby _____
☐ Eligible for BCG

Eligibility for publicly funded care:
Country of birth:
☐ NZ Citizen
☐ NZ Permanent Resident
☐ Work permit more than 2 years
☐ Other
Payment will be required for non-eligible mothers and babies - see point 3 below

First Language:
Interpreter required: ☐ Yes   ☐ No
Religion:

Lead Maternity Carer:
Name:
Contact:
Back-up:
Contact:

Midwifery care:
If the LMC is an Obstetrician or GP
Labour:
☐ WDHB midwife
☐ Self employed midwife
Postnatal:
☐ WDHB midwife
☐ Self employed midwife
Name of self employed midwife:
Contact:

Completed by Client (Name): _____   Signature: _____   Date: _____

! Please read the important information below regarding the personal information collected on this form:

1. **Ethnicity:** The government requires us to collect information about ethnicity for statistical purposes related to funding for health services. Please also indicate the ethnic group(s) your baby may belong to.
2. **Next of kin / Alternative emergency contacts:** Waitemata District Health Board needs the name and contact details of your next of kin and/or alternative emergency contact person. These contacts do not have to be a family member but it is necessary that the person(s) you list know that you have nominated them. This information allows the hospital to call them to support you, and/or accept interim decision-making in an emergency, and allows us to divert enquiries about your health.
3. **Eligibility:** You will be asked to provide evidence that you are entitled to free maternity care (passport or immigration documentation). see www.moh.govt.nz/moh.nsf/indexmh/eligibility-healthservices-maternity. If you are not eligible for publically funded care, you will be asked to pay for your care. In order to determine eligibility we may disclose to the New Zealand Immigration Service your name, gender and date of birth.
4. **Religion:** This information is made available to our chaplains. Our chaplains provide non-denominational support, friendship and counselling as well as referral to other religious groups.
5. **Training and Quality:** Waitemata District Health Board provides clinical placements for health care trainees and students; you may be asked to have a supervised trainee involved in your care. Your anonymised information may be aggregated and used for quality, audit and research purposes

NB: Waitemata District Health Board may be legally required to provide some of this information to Income Support, the NZ Police, or other authorised Government agencies for audit/research purposes.

5.3.002

Page 2

Waitemata District Health Board — *Te Wai Awhina*

Name: _____
Address: _____
Date of birth: _____   NHI: _____

Maternity Facility Registration – History Summary

Menstrual cycle: *(e.g, 5/28)* ___ / ___
☐ Regular   ☐ Irregular

LMP:
☐ Sure   ☐ Unsure

EDD by dates:

Date of first scan:
Gestation at first scan:

Down syndrome screening: Discussed ☐
1st Trimester ☐   2nd Trimester ☐   Declined ☐

Agreed EDD:

Antenatal blood tests

Blood group: ___   Rh: ___
Red cell antibodies:
Haemoglobin:
HIV: Discussed ☐   Accepted ☐   Declined ☐

Rubella: ___   **Hepatitis B:**
Syphilis:

Clinical examination
Height:
Weight:
Breasts: Heart and lungs:

Pre /Early pregnancy BMI:

Cervical smear history
Last smear results:
AN smear   ☐ Yes   ☐ No
Next smear due:

Swabs taken:
Results:

Medical / Surgical / Mental Health History
☐ No history

Family History
☐ No history

Smokefree status
☐ Always smokefree
☐ Now smokefree
☐ Just smokefree < 4 weeks
☐ Partner smokefree
☐ Household smokefree
☐ NOT Smokefree ___ cigs/day
Smokefree service referral date: ___

Medications
☐ Nil

Allergies
☐ Nil

Alcohol and recreational drugs

SFV: Y☐ N☐ D☐ Ref Y☐ N☐

Obstetric History: G ___   P ___

Place, Month + Year	Duration in weeks	Pregnancy complications	Labour Duration in Hours	Birth Outcome	Postpartum Complications	Infant		
						Sex and Name	B/F	Birth weight

Completed by LMC _____   Date _____

5.3.002

APPENDIX 3: WDHB Labour and Birth Summary Form

APPENDIX 4: Transfer to well child provider form

Referral to Well Child Provider and Notification to GP

This form is to be sent to both the Well Child Provider and the GP in order to fulfil clauses C4.5.4 & C4.5.5

MINISTRY OF HEALTH
MANATŪ HAUORA

Mother

Family name: ....

Given names: ....

Birth Date: .... NHI number: ....

Address: ....

....

Daytime phone: .... Alternative Contact: ....

Parity: ....

Baby

Family name: ....

Given names: ....

Birth Date: .... NHI number: ....

Gender: Male   Female

Baby Summary

Gestation: .... Weeks

Significant birth/postnatal event(s) (e.g. apgar score, birth weight)

....

....

Vitamin K   Guthrie test

Feeding at time of referral to Well Child Provider

Exclusive Breastfeeding   Fully Breastfeeding   Partial Breastfeeding   Artificial feeding

Comment ....

....

Summary of ongoing needs identified at time of referral (e.g. referral to Family Start, Multiple Birth Society):

....

....

Date referral/notification sent to Well Child Provider and GP: ....

Planned date of discharge from LMC: ....

Name of LMC: ....

LMC Contact details: ....

WHITE - **CLIENT COPY**   PINK - **WELL CHILD PROVIDER COPY**   BLUE - **GENERAL PRACTITIONER COPY**   YELLOW - **LEAD MATERNITY CARER COPY**

MOH008
REORDER NO 61287
03/03

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APPENDIX 5: Support letter from WDHB Maori Research Committee

Waitemata
District Health Board

Te Wai Awhina

Nga Kai Tataki
Maori Research Review
Committee
Private Bag 93503
Takapuna Auckland 9
Telephone: 09 4861491
Facsimile:094498171

20 April 2009

Emma Farmer
5 Tainui Road
Devonport
Auckland

Tena koe Emma,

A comparison of exclusive breastfeeding rates at 2 weeks postpartum in woman who have received prophylactic syntocinon, syntometrine or no ecbolic for the third stage of labour.

This letter is to advise that your application was discussed at the last meeting of the Nga Kai Tataki Maori Research Review Committee. We are pleased to advise that your application was approved.

Please send us a copy of the completed report once your research is finished.

Noho ora mai ra

Tanekaha Rosieur   Te Aniwa Tutara
Chairperson   **General Manager**
Nga Kai Tataki   **Maori Health**

C:\Users\Farmer\Desktop\Thesis\Syntometrine\Appendices\Maori Research support letter.doc

APPENDIX 6: Ethics approval from Northern X Region Ethics Committee

Health and Disability Ethics Committees

email: cheh_chua@moh.govt.nz

Northern X Regional Ethics Committee
Ministry of Health
Private Bag 92522
Wellesley Street, Auckland 1141
Phone: (09) 580 9063
Fax: (09) 580 9001

20 March 2009

Ms Emma Farmer
5 Tainui Rd
Devonport
North Shore City **Auckland 0624**

Dear Emma

NTX/09/30/EXP   **A comparison of exclusive breastfeeding rates at 2 weeks postpartum in women who have received prophylactic syntocinon, syntometrine or no ecbolic for the third stage of labour**

Principal Investigator: Ms Emma Farmer

Thank you for your application received 19 March 2009.   The above study has been given ethical approval by the Deputy Chairperson of the **Northern X Regional** Ethics Committee under delegated authority.

Approved Documents
- Protocol (undated but received 19/03/09)

Accreditation
The Committee involved in the approval of this study is accredited by the Health Research Council and is constituted and operates in accordance with the Operational Standard for Ethics Committees, April 2006.

Final Report
The study is approved until **23 December 2009**. A final report is required at the end of the study and a form to assist with this is available at http://www.ethicscommittees.health.govt.nz. If the study will not be completed as advised, please forward a progress report and an application for extension of ethical approval one month before the above date.

Amendments
It is also a condition of approval that the Committee is advised of any adverse events, if the study does not commence, or the study is altered in any way, including all documentation eg advertisements, letters to prospective participants.

Please quote the above ethics committee reference number in all correspondence.

It should be noted that Ethics Committee approval does not imply any resource commitment or administrative facilitation by any healthcare provider within whose facility the research is to be carried out. Where applicable, authority for this must be obtained separately from the appropriate manager within the organisation.

Yours sincerely

Cheh Chua(Ms)
Assistant Administrator
Northern X Regional Ethics Committee

cc: Waitemata DHB

Administered by the Ministry of Health   Approved by the Health Research Council   http://www.ethicscommittees.health.govt.nz

APPENDIX 7: Approval from AUT Ethics Committee AUTEC

AUT
UNIVERSITY

MEMORANDUM
Auckland University of Technology Ethics Committee (AUTEC)

To:	Jackie Gunn
From:	**Madeline Banda** Executive Secretary, AUTEC
Date:	20 May 2009
Subject:	Ethics Application Number 09/99 **A comparison of exclusive breastfeeding rates at 2 weeks postpartum in women who have received prophylactic Syntocinon, Syntometrine or no ecbolic for the third stage of labour.**

Dear Jackie

I am pleased to advise that the Auckland University of Technology Ethics Committee (AUTEC) approved your ethics application at their meeting on 11 May 2009. Your application is now approved for a period of three years until 11 May 2012.

I advise that as part of the ethics approval process, you are required to submit to AUTEC the following:

- A brief annual progress report using form EA2, which is available online through *http://www.aut.ac.nz/about/ethics*. When necessary this form may also be used to request an extension of the approval at least one month prior to its expiry on 11 May 2012;

- A brief report on the status of the project using form EA3, which is available online through *http://www.aut.ac.nz/about/ethics*. This report is to be submitted either when the approval expires on 11 May 2012 or on completion of the project, whichever comes sooner;

It is a condition of approval that AUTEC is notified of any adverse events or if the research does not commence. AUTEC approval needs to be sought for any alteration to the research, including any alteration of or addition to any documents that are provided to participants. You are reminded that, as applicant, you are responsible for ensuring that research undertaken under this approval occurs within the parameters outlined in the approved application.

Please note that AUTEC grants ethical approval only. If you require management approval from an institution or organisation for your research, then you will need to make the arrangements necessary to obtain this. Also, if your research is undertaken within a jurisdiction outside New Zealand, you will need to make the arrangements necessary to meet the legal and ethical requirements that apply within that jurisdiction.

When communicating with us about this application, we ask that you use the application number and study title to enable us to provide you with prompt service. Should you have any further enquiries regarding this matter, you are welcome to contact Charles Grinter, Ethics Coordinator, by email at *charles.grinter@aut.ac.nz* or by telephone on 921 9999 at extension 8860.

On behalf of the AUTEC and myself, I wish you success with your research and look forward to reading about it in your reports.

Yours sincerely

Madeline Banda
Executive Secretary
Auckland University of Technology Ethics Committee

Cc: Emma Farmer emma.farmer@waitematedhb.govt.nz

From the desk of …	Private Bag 92006, Auckland 1142	Tel: 64 9 921 9999
Madeline Banda	New Zealand	ext 8044
Executive Secretary	E-mail: madeline.banda@aut.ac.nz	Fax: 64 9 921 9925
AUTEC		page 1 of 1