Timing of cord clamping (TOCC): an observational study of cord clamping practice in a New Zealand maternity hospital

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A thesis submitted in fulfilment of the degree Master of Midwifery at Otago Polytechnic, Dunedin, New Zealand

Submission Date: 9 December 2019
Declaration

Declaration concerning thesis presented for the degree of Master of Midwifery

I,

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solemnly and sincerely declare, in relation to the thesis entitled

Timing of cord clamping (TOCC): an observational study of cord clamping practice in a New Zealand maternity hospital

that

(a) the work was done by me, personally

and

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

Signature:

On 9 December 2019
Abstract

Title

Timing of cord clamping (TOCC): an observational study of cord clamping practice in a New Zealand maternity hospital

Background

When an umbilical cord is left unclamped after birth, a significant proportion of the blood from the placenta flows into the newborn, contributing to approximately one-quarter of total potential blood volume. The routine intervention of immediate cord clamping was introduced as part of active management of the third stage of labour over half a century ago. It has become a growing cause for concern due to the potential harm of preventing the newborn access to its placental blood and subsequent reduction in iron levels. Despite the evidence of potential harm from immediate cord clamping, a study in Canada found that over half of the infants observed in 2006/7 had their cord clamped within 15 seconds of birth (Hutton, Stoll, & Taha, 2013).

Aim

The aim of the TOCC study was to investigate cord clamping practice for term vaginal births in a New Zealand tertiary hospital, where the majority of births have a midwife as lead practitioner.

Methods

A stopwatch was used to time the cord clamping interval at 55 term vaginal births in a tertiary maternity hospital. The stopwatch was pressed once at the time of the birth and once when the first clamp was applied to the umbilical cord. Mode of birth (spontaneous or instrumental), maternal position for birth and whether midwives and/or doctors and neonatal practitioner were involved in the birth was documented alongside the cord clamping timing.
Results

Cord clamping timing ranged from a minimum of 14 seconds to a maximum of 34 minutes. The median umbilical cord clamping time for all births in the study was 3.5 minutes. The median cord clamping time was likely to be longer when the woman had a spontaneous vaginal birth rather than an instrumental birth; when she birthed in a side-lying or upright position rather than a seated position; when a midwife facilitated the birth rather than a doctor and when there was no neonatal team present at the birth.

Conclusions

The median cord clamping time of 3.5 minutes is aligned with current local, national and international guidelines. Midwives are likely to facilitate longer cord clamping times as they are more likely than doctors to attend spontaneous uncomplicated births which do not warrant immediate separation of mother and baby for preventative or resuscitative measures. Further discussion is warranted on how longer cord clamping times fit with active management of placental birth and how we can achieve optimal cord clamping when newborn resuscitation is indicated.
Acknowledgements

This study would not have been possible without the participation of the women who agreed to have their births observed as part of the TOCC study. I would like to thank every woman and every member of her whanau who took time to read the information leaflet, discuss the study and then consent to take part.

The midwives and doctors, both in the community and the hospital, were a huge contribution to the successful recruitment for the TOCC study. I have thanked many of them individually but acknowledge them again in the writing up of this thesis. The TOCC study took place at an exceptionally busy time in our region and I am grateful for the additional workload that they embraced for the purpose of this research. I also thank the management team and the research office at the TOCC study hospital for supporting this project.

I sincerely thank Otago Polytechnic for supporting me through this Masters journey. My primary supervisor Dr Sally Baddock has provided endless hours of wisdom and support through the four-year duration of this project. I have particularly valued her expertise in quantitative data analysis and her help in mastering the TOCC Excel spreadsheets. My secondary supervisor Dr Jean Patterson has been the midwifery voice on the TOCC study. They have both challenged me to deepen my thinking. Thank you to the rest of the Otago Polytechnic team for the background support and for providing me with an outstanding pair of supervisors.

To everyone who has listened patiently while I talk incessantly about cord clamping, I wish I could thank you all individually but I hope you know who you are. You are all a part of this project and your help is much appreciated.

Lastly but most importantly thank you to my husband John and daughter India who have tolerated my physical and mental absences from family life while I have been on this Masters journey. I am looking forward to the end as much as you are.
## Glossary and Abbreviations

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td>Cord Clamping time</td>
<td>The interval between birth of the baby and time that the first clamp was applied to the umbilical cord</td>
</tr>
<tr>
<td>DHB</td>
<td>District Health Board</td>
</tr>
<tr>
<td>Hospital-employed midwife (or core midwife)</td>
<td>A midwife who works in a maternity facility and provides support for LMCs</td>
</tr>
<tr>
<td>Kaitohutohu</td>
<td>An advisor on the Otago Polytechnic leadership office with responsibility for overseeing the incorporation of the principles of Te Tiriti o Waitangi in day-to-day operations at the institute.</td>
</tr>
<tr>
<td>LMC</td>
<td>Lead Maternity Carer. A midwife, general practitioner or obstetrician who has been selected by a woman to provide and coordinate care throughout the duration of her pregnancy and for up to six weeks after the birth.</td>
</tr>
<tr>
<td>Placental transfusion</td>
<td>Blood transferred from the placenta to the newborn via the umbilical cord during and after the birth.</td>
</tr>
<tr>
<td>Primary maternity facility</td>
<td>Facilities providing care for low-risk pregnancy and birth, usually staffed by midwives. Epidural analgesia or operative birth services are not available on site.</td>
</tr>
<tr>
<td>Tangata whenua</td>
<td>The indigenous or first people of the land known as Aotearoa or New Zealand (NZ)</td>
</tr>
<tr>
<td>Tertiary maternity facility</td>
<td>Hospital that provides care by specialised multidisciplinary teams for women with high-risk, complex pregnancies, with obstetric and neonatal services available on site 24 hours a day</td>
</tr>
<tr>
<td>Te Tiriti o Waitangi</td>
<td>An agreement signed by the representatives for the British Crown and Māori chiefs in 1840 declaring British sovereignty over New Zealand. The English and Māori versions held different meanings and there are challenges in interpreting the different expectations of the Treaty.</td>
</tr>
<tr>
<td>TOCC</td>
<td>Timing of Cord Clamping</td>
</tr>
<tr>
<td>Whānau</td>
<td>Māori term for extended family or community of related families. In the modern context the term is sometimes used to include friends who may not have any kinship ties to other members.</td>
</tr>
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Chapter 1: Introduction

Since its introduction as one of the first ever interventions in childbirth, umbilical cord clamping has been the topic of ongoing historical debate, physiological speculation and a multitude of experimental studies. As with many childbirth interventions, cord clamping does not stand alone but is instinctively linked with other interventions such as active management of the third stage of labour and newborn resuscitation. With the rapidly growing evidence around the harms of immediate cord clamping, in particular a reduction in blood volume leading to low iron stores for infants at three to six months of age (McDonald, Middleton, Dowswell, & Morris, 2013), I have been driven to discover what is current practice in New Zealand and what factors may influence our choices on when and whether to clamp the cord.

When a cord is left attached to the placenta after birth, a significant proportion of the blood will flow from the placenta to the newborn contributing to between one-third and one-quarter of total potential blood volume at birth (Farrar et al., 2011; Yao, Moinian, & Lind, 1969). The routine intervention of immediate cord clamping, along with the administration of uterotonic medication and controlled cord traction, was widely adopted in the 1960’s to manage placental birth and reduce maternal blood loss. Over the past two decades a growing number of maternity practitioners have begun to question the practice of immediate cord clamping and consider a more physiological transition achieved by leaving the cord intact. Most national and international guidelines on intrapartum care have been updated to recommend a delay between birth and cord clamping for any baby that does not need resuscitation (NICE, 2015; NZCOM, 2013; RANZCOG, 2017b; WHO, 2012b, 2012a, 2013).

As a result of this change in guidance on active management of the third stage of labour and newborn resuscitation, the first two decades of the 21st century have seen an evolutionary progression in immediate post-birth care. Observational data on these significant practice changes is limited. The studies which have actually timed cord clamping practice either recorded observations
over ten years ago (Airey, Farrar, & Duley, 2008; Hutton et al., 2013) or recorded observations in low-resource maternity hospitals (Ersdal, Linde, Mduma, Auestad, & Perlman, 2014; Nelin, KC, Andersson, Rana, & Målqvist, 2018). One of these observational studies, set in a Canadian tertiary hospital, found that over half of the infants observed during 2006 and 2007 had their cord clamped within 15 seconds of birth despite mounting evidence at the time that supported leaving the cord intact for at least 2 minutes (Hutton et al., 2013). Of the 89 practitioners observed in this study, 39 were obstetricians, 37 were family physicians and only 13 were midwives. The majority (93%) of women giving birth in Canada have a an obstetrician or family physician (General Practitioner) as their lead maternity carer (Guliani, 2015) whereas in New Zealand the majority (94.2%) of women have a midwife (Ministry of Health (Manatū Hauora), 2019). There have not been any published observational studies on cord clamping in the New Zealand maternity system. The Timing of Cord Clamping (TOCC) study was devised to accurately measure what is currently happening for these New Zealand women and their newborns.

Background to the Research

Personal Background

As a midwife I developed a specialist interest in the topic of placental birth from very early on in my career. As a direct-entry midwifery student at Portsmouth University in the UK in the 1990’s, a major project in my third undergraduate year was on physiological third stage of labour, which involves a “hands-off” approach while waiting for the placenta to birth spontaneously with the aid of gravity or maternal effort (Begley et al., 2019). I have continued to practice this watchful waiting approach to placental birth while supporting women as a midwife. As physiological third stage ideally involves leaving the umbilical cord intact until after the placenta is birthed, my interest around the topic of cord clamping timing evolved.

I moved to New Zealand in 2004 and have worked as a midwife in Wellington and Christchurch. In my current role as a midwifery educator at Canterbury District Health Board (CDHB), I have been instructing on the Zealand Resuscitation Council Newborn Life Support (NLS) course since 2006. In recent
simulation teaching for newborn life support I have included a demonstration of intact cord resuscitation as a response to midwives who report using this method in primary settings. We discuss the practicalities of resuscitation with intact cord and how this practice involves rapid decision making to ensure best possible outcomes for both the woman and her newborn baby.

In 2014 I was part of a committee of midwives, obstetricians and neonatologists who created a guideline for umbilical cord clamping at CDHB maternity units. This guideline combined the evidence from three different professional bodies (Australian and New Zealand Committee on Resuscitation, 2017; New Zealand College of Midwives, 2013; Royal Australian and New Zealand College of Obstetricians and Gynaecologists, 2017b) into one resource for all healthcare professionals attending births in the CDHB region. The recommendation was to leave the cord intact for 3 minutes for term babies born vaginally that did not require resuscitation.

I completed an extensive literature search on cord clamping practices as part of my postgraduate diploma in Midwifery in 2013 and continued with a keen interest in this topic as I ventured into this research project for my Master of Midwifery thesis. My particular area of interest is how birth practice has evolved in New Zealand in response to the growing evidence of benefits for a prolonged cord clamping time.

The New Zealand context
The maternity model of care in New Zealand at the time of the TOCC study was one of fully funded continuity of care for all eligible women. Women choose a Lead Maternity Carer (LMC) who provides and coordinates care throughout the duration of their pregnancy and for up to six weeks after the birth. For the women who registered with an LMC in 2017, 94.2% chose a midwife, 5.6% chose an obstetrician and 0.2% chose a General Practitioner (Ministry of Health (Manatū Hauora), 2019). Women who choose a midwife or General Practitioner to provide primary maternity services have their care funded by the Ministry of Health. Women may choose a private obstetrician as their LMC for primary maternity care and there is usually a payment for this option. In some instances, either through choice or through a lack of
availability of an LMC, women receive primary maternity care from their local District Health Board (DHB). Women are less likely to receive continuity of care when primary maternity services are provided by DHB than they are with an LMC.

LMC’s are on call for the births of the women on their caseload. They usually work in group practices where, if they take time off call, a member of their group practice will attend births as their backup. Private obstetricians who work as LMC’s usually sub-contract some aspects of a woman’s labour and postnatal care to a midwife. Where the birth takes place in the tertiary hospital, LMC’s are assisted by hospital-employed (otherwise known as “core”) midwives. If complications ensue, assistance is provided by these hospital-employed midwives as well as on-call obstetric, anaesthetic and/or neonatal teams. If women birth at a training hospital, some births will also be attended by trainee doctors and student midwives.

The TOCC study took place in a large tertiary maternity hospital in New Zealand run by the Canterbury District Health Board (CDHB). The New Zealand definition of a tertiary maternity facility is a hospital that provides care by specialised multidisciplinary teams for women with high-risk, complex pregnancies, with obstetric and neonatal services available on site 24 hours a day (Ministry of Health (Manatū Hauora), 2012).

A tertiary location was chosen as the setting for the TOCC study for a number of reasons. Firstly, it was more likely to provide an accurate comparison to the study data produced in a previous observational study of cord clamping in Canada where births were facilitated by a variety of birth practitioners (Hutton et al., 2013). In a tertiary setting in New Zealand, births are facilitated by both doctors and midwives whereas in a primary setting the vast majority of births are conducted by midwives, and only very occasionally by a GP or private obstetrician. Secondly, the complexity of births in a tertiary facility is more likely to produce variable data on the type of health professional conducting the birth and the need for neonatal resuscitation, two factors known to influence cord clamping timing. Lastly, the timing of cord clamping is likely to vary more widely in a tertiary facility due to the type of third stage
management required at complex births. If the study had been carried out in a primary facility, more births would have been followed by a physiological birth of the placenta therefore cord clamping timing would be less variable. New Zealand data from 2004 to 2008 showed that 57.8% of births were followed by a physiological placental birth in a primary unit, compared to only 34.1% physiological in a tertiary unit (Dixon et al., 2009).

The population served by the CDHB is in the Canterbury region in the South Island of New Zealand. At the time of the study (2017/2018), there were 563,200 people living in the CDHB region which is 11.5% of the nation’s total population (Statistics NZ (Tatauranga Aotearoa), 2019). Of the women giving birth in the CDHB region during the time that data collection took place, the two most common ethnicities were European (44.6%) and Māori (25%) (Ministry of Health (Manatū Hauora), 2019).

Māori are tangata whenua, the first people of the land of Aotearoa New Zealand. Historians examining prehistoric remains, estimate that Māori settled here from approximately 1150. The original settlers arrived on voyages of exploration from Polynesia and their numbers are thought to have reached around 100,000 before the first contact was made from European explorers. Following the arrival of the first British settlers in the 1700’s, the signing of the Te Tiriti o Waitangi/Treaty of Waitangi in 1840 recognised the principles of partnership, participation and active protection between the two nations (King, 2003). The TOCC study is set in the context of the bicultural country of Aotearoa New Zealand, and this is discussed in more detail in the ethics section later in this chapter.

The CDHB has one tertiary maternity hospital and multiple primary maternity units with an overall number of 6,418 births in 2016 (CDHB, 2018). There were 5,259 births at the tertiary hospital where the TOCC data was collected, which was 82% of the total of births in the Canterbury District Health Board region, with the remaining 12.8% of babies being born in primary units and 5% at home. In New Zealand, women who have an uncomplicated pregnancy, with no medical or obstetric complications, are encouraged to birth at a primary unit but many choose to birth at the tertiary hospital. The vaginal birth rate for the
Canterbury District Health Board (the combined facilities which include tertiary and primary facilities) in 2016 was 85.7%. Of these vaginal births, 81% were spontaneous and the remaining 19% were assisted by forceps or ventouse. The percentage of babies born before 37 weeks in 2016 was 7.5%, therefore term births accounted for 92.5% of all births at the CDHB. Knowing these statistics will provide a comparison to determine whether the TOCC data is an accurate representation of births at the tertiary maternity unit as a whole.

Aims and Objectives

The aim of the TOCC study was to investigate cord clamping practice for term vaginal births in a New Zealand tertiary hospital, where the majority of births have a midwife as lead practitioner.

The objectives of this research were to:
- accurately record birth to cord-clamping interval at 100 term vaginal births
- identify influences on cord clamping practices
- compare the above findings with a similar study in Canada where 89 births were measured in 2006-7 (Hutton et al., 2013)
- discuss the findings in relation to local, national and international guidelines.
- identify any implications for further national and international research.

Summary

This first chapter has introduced the TOCC research study and explained the background of the author as well as the New Zealand context.

The second chapter will summarise what is already known about umbilical cord clamping, including the history of the intervention, the physiology of placental transfusion and the outcomes for women and babies. Major findings will be analysed and critiqued, with an aim of identifying any knowledge gaps.

Chapter Three will outline the methodology and research method for the TOCC study, including the reasons for selecting the study design, the choice of participants and the processes involved in collecting and recording data.
The results of the study will be presented in Chapter Four and examined using descriptive statistics. A variety of tables and figures will be used to illustrate the data.

The discussion in Chapter Five considers the implications of the study findings and how these relate to the literature reviewed in Chapter Two.

The sixth and final chapter will conclude the study, review whether the study aim has been met and suggest recommendations for future practice.
Chapter 2: Literature Review

The purpose of this literature review was to identify and critically evaluate research on umbilical cord clamping and to discover any gaps in this research that may lead to a new and relevant area of study.

An electronic search of the CINAHL, Medline, EBSCO, PubMed, Google Scholar and Cochrane databases was undertaken using combinations of these key words and phrases:
- Umbilical cord clamping; immediate, early, deferred, delayed, optimal cord clamping; timing of cord clamping; term birth; term infant; birth practice; observational study; clinical guidelines; interprofessional practice; placental transfusion; placental birth; third stage of labour; intact cord resuscitation; neonatal resuscitation.

Literature was also sourced from the Mendeley Reference Manager and the Otago Polytechnic thesis repository. Reference lists from significant articles were used to locate additional literature.

In the process of gathering the literature various themes were identified and this literature review has been sorted accordingly under the following subheadings:

- History of cord clamping
- Physiology: Redistribution of blood between placenta and newborn
- Timing of cord clamping and maternal outcomes
- Timing of cord clamping and neonatal outcomes
- Cord clamping and newborn resuscitation
- National and International guidance on cord clamping
- Surveys on cord clamping practice
- Observational studies on cord clamping practice
History of cord clamping

Historical texts written by the Greek medical physicians Hippocrates and Galen over 2,000 years ago have described the role of umbilical blood in fetal nutrition but do not mention how long after the birth babies were separated from their mothers by biting or cutting of the cord (Downey & Bewley, 2012). The first records of cutting the cord before the birth of the placenta were found in 17th century (Inch, 1985). The practice of cord cutting by birth attendants began to be regularly documented in the 18th century, linked with the rise in medicalization of childbirth, particularly amongst more affluent families. As “medical men” began to attend births instead of the more traditional female midwives, they brought more tools and intervention to birthing practice around the world (Drife, 2002; Edwards & Wickham, 2018; Stojanovic, 2012). Around this time, in order to better “observe” childbirth, women changed from birthing in upright positions to semi-recumbent or seated positions on beds and it has been suggested that the practice of tying the cord before cutting was necessary to avoid the placental end of the cord bleeding and soiling the bed linen (Inch, 1985). Over the last four centuries, medicine has developed its place as the dominant ideology over midwifery and this has had a decisive impact on birthing practice including the decision about when to separate the mother and baby by cutting the cord. One of the recognised differences between obstetrics and midwifery is the medical assumption that birth is an unreliable process that can be improved upon (Murphy-Lawless, 1998).

Not all practitioners were advocates of early placental separation, as indicated by this well-known quote by the physician Erasmus Darwin whose early ideas on the functioning of the human body were later developed into a theory of evolution by his grandson Charles Darwin:

“Another thing very injurious to the child, is the tying and cutting of the navel string too soon; which should always be left till the child has not only repeatedly breathed, but till all pulsation in the cord ceases. As otherwise the child is much weaker than it ought to be, a portion of the blood being left in the placenta, which ought to have been in the child” (Darwin, 1801, cited in Dunn, 2003, p.F347)
Along similar lines, in 1891, an obstetrician in London produced a midwifery textbook that warned against immediate cord ligation, stating that “it is equivalent to bleeding the child to the amount of three ounces, a bleeding that would correspond to about 60 ounces in an adult” (Galabin, cited in Stojanovic, 2012, p.99). In metric measurements, three ounces equates to 89mls and 60 ounces is 1,774mls.

In New Zealand the passing of the Midwives Act in 1904 brought with it the introduction of formal training schools for midwives and increasing regulation of the profession by medical doctors. Birth moved rapidly from home to hospital over the first half of the 20th century. The difference between place of birth for different ethnic groups was marked, with statistics from 1938 showing 17% of Maori women giving birth in hospital compared to 87% of European women (Stojanovic, 2012). Despite the increasing medicalization of childbirth across the Western world, during the early 1900s textbooks continued to advocate waiting 5-10 minutes, and/or for the cessation of pulsations, prior to tying and cutting the cord. It was not until 1937 that midwifery textbooks first recommended earlier clamping, explaining that it would encourage the newborn to establish its own respiratory efforts and would assist in prevention of hypothermia (Stojanovic, 2012).

One reason suggested for the widespread adoption of the early cord clamping in the middle of the last century was the increased use of narcotic analgesia in labour (Downey & Bewley, 2012). The potency of these narcotics, as they crossed the placenta, caused more respiratory depression in the newborn and increased the need for early clamping and transfer for resuscitation.

There have been other medications which, when their use increased across birthing practice, caused dramatic changes to the timing of umbilical cord clamping. The development of uterotonic drugs included Ergometrine in 1932, Syntocinon in the 1950’s and later a combination of the two in the form of Syntometrine (Edwards & Wickham, 2018; Stojanovic, 2012). The use of ergot, which is derived from a fungus on rye, had been used for stimulation of uterine contractions since the 16th century but it was the development of the synthetic and injectable forms of uterotonics which prompted them to be used as a
prophylaxis for postpartum haemorrhage. Immediate cord clamping became normal practice by the 1960s when active management of the third stage of labour was first introduced, alongside hospitalization for over 90% of women in New Zealand, both Maori and European (Stojanovic, 2012). The triad of interventions involved in active management vary from country to country but a Cochrane Review describes the three common elements as:

- administration of a uterotonic;
- clamping of the cord immediately;
- controlled cord traction for the birth of the placenta (Begley et al., 2019).

The three interventions of active management, including their effectiveness in reducing postpartum haemorrhage, will be discussed in more depth under the section below on maternal outcomes.

Later in the 20th century, the maternity system in New Zealand again underwent considerable changes. In 1990, with the Nurses Amendment Act, midwives regained autonomous practice and no longer required the supervision of a medical practitioner when caring for women with normal labour, birth and puerperium (Guilliland & Pairman, 2010). With changes to midwifery care provision, consumer choice and consent regained their importance and midwives relearned their skills for physiological placental birth, where the umbilical cord is left intact until it stops pulsating and/or until after the placenta has been born (NZCOM, 2013).

**Physiology: Redistribution of blood between placenta and newborn**

Knowledge of neonatal physiology, and the redistribution of blood between the placenta and the newborn, has directed birth practice over the course of history. The first few minutes after birth are a time when we undergo more physiological changes than at any other time in our lives (Polglase & Stark, 2018). In utero, gas exchange occurs in the placenta, sometimes referred to as the “fetal lung”, and consequently only around 10% of cardiac output is
required for fetal pulmonary circulation (Katheria, Lakshminrusimha, Rabe, McAdams, & Mercer, 2017). Ex utero, this pulmonary circulation increases to over 50% of total cardiac output as the lungs fill with air and take over gas exchange from the placenta. Leaving the cord intact for an extended period after birth leads to a gradual increase in neonatal circulatory volume with the corresponding reduction in placental circulatory volume. After birth the umbilical arteries constrict, often within 45 seconds, reducing the blood flow from baby to placenta, whereas the umbilical vein remains patent resulting in a net flow of blood from placenta to baby (Yao & Lind, 1974). The high red cell mass of this blood is broken down and the haemoglobin releases iron, which is laid down as iron stores (Farrar et al., 2011; Van Rheenen, 2011).

In utero, around one third to one half of the fetal-placental blood is in the placenta (Farrar et al., 2011; Yao et al., 1969). Access to this placental blood post-birth provides the increase in cardiac output for the newborn that facilitates a smoother transition from intrauterine to extrauterine life (Bhatt et al., 2013; Ersdal et al., 2014; Hooper et al., 2015; Mercer & Skovgaard, 2002; Niermeyer & Velaphi, 2013). Some practitioners refer to the intact cord providing ongoing oxygenation to the newborn infant after the birth. It is likely that ongoing oxygenation is limited when the maternal vessels supplying the placental circulation have contracted due to the reduction in size of the uterus immediately after the birth (Palethorpe, Farrar, & Duley, 2010). However, the extra blood volume associated with longer cord clamping intervals will bring additional red blood cells to the newborn, increasing transport of oxygen around the body, regardless of whether ongoing oxygenation from maternal circulation has ceased.

Umbilical blood flow between the placenta and the newborn is not the same at every birth but is dependent on a variety of factors including gestation, mode of birth, contractions (with or without uterotonic effects), cord pulsations, the position of the infant at birth, and newborn breathing patterns (Ghirardello et al., 2018; Hooper et al., 2015; Katheria et al., 2017). Each of these factors will be considered below to further expand on the topic of redistribution of blood as part of neonatal physiological transition.
Gestation
The first factor to be considered in this review of neonatal physiological transition is gestation. At earlier gestations (under 30 weeks), blood volume is equally distributed, with around half in the fetus and half in the placenta (Linderkamp, 1982). Whereas, at term gestation, around a third of the blood is in the placenta and two-thirds in the fetus. This may explain why the advantages for preterm infants of sustained umbilical circulation post Birth are greater than those for term infants as there is relatively more blood available in the preterm placenta to assist with transition. A systematic review of the literature in 2010 demonstrated the detrimental effects of interrupting placental transfusion for preterm infants, with increases in intraventricular haemorrhage, lower blood pressures and increases in the need for blood transfusions in the babies who had early clamping (under 30 seconds) compared to delayed clamping (30 seconds or more) (Rabe, Reynolds, & Diaz-Rossello, 2010). More recently, with the addition of evidence from several recent large-scale randomised controlled trials, more dramatic benefits have been recognised. An updated meta-analysis showed that preterm babies who had 30-60 seconds of placental transfusion post birth were more likely to survive beyond the early neonatal period (Fogarty et al., 2018).

Mode of birth
The second factor to be discussed here in relation to umbilical blood flow post birth is mode of birth. The Cochrane review on the effects of cord clamping timing for term infants included both caesarean and vaginal births but did not report on whether the outcomes differed between these two groups (McDonald et al., 2013). Physiological speculation leads some to propose that the absence of contractions after a caesarean section results in less blood flowing from placenta to newborn (Katheria et al., 2017). However, the results of a historical cohort control study found that infants who had a 30-second delay in cord clamping after an elective caesarean section had a comparable 4-month ferritin level to infants born after a three-minute delay after a vaginal birth and significantly higher ferritin levels than infants who had immediate cord clamping (Andersson, Hellström-Westas, & Domellöf, 2016). One possible theory for the results of this study is that, during labour, extra blood circulates in the placenta with the effect of providing extra oxygen to the fetus during the
potentially hypoxic effect of contractions (Knol et al., 2018). After a vaginal birth blood moves more readily from this placental circulation to the newly-born baby, whereas at elective caesarean (in the absence of labour) the blood is more evenly distributed between the placenta and the newborn and therefore blood redistribution may be faster, as explained by 30 seconds of deferred cord clamping at elective caesarean being equivalent to three minutes at vaginal births.

**Uterine contractions**

Transfer of blood from the placenta to the neonate will speed up in the presence of uterine contractions (Yao, Hirvensalo, & Lind, 1968; Yao & Lind, 1974). In an early study by a Scandinavian paediatric team, blood volumes of term babies born vaginally were measured to determine how uterine contractions affect placental transfusion (Yao et al., 1968). They discussed how the uterine contraction that occurs during the birth of the baby squeezes the placenta and forces blood through the umbilical vein into the baby’s inferior vena cava, which is at a lower pressure than the placenta. In contrast, flow from baby to placenta in the umbilical artery is restricted during contractions due to high pressure in the placenta. The next contraction after the “birth contraction” occurs at an average time of 2 minutes after the birth (Dunn, 1966, cited in Yao et al., 1968, p.382).

For active management of the third stage of labour, contractions and placental transfusion will be affected by the choice of uterotonic medication and its route and dose. In the 1968 study by Yao et al. peak placental transfusion was reached at 1 minute in the group where the woman was given intravenous ergometrine at 10-15 seconds after the birth, compared to 3 minutes in the group without ergometrine. In a study of the use of intramuscular oxytocin prior to cord clamping, net transfer of blood to the newborn did not increase when compared to when this uterotonic was given after cord clamping (measured by baby weight in the first 5 minutes post birth) (Farrar et al., 2011). In studies of preterm lambs, uterine contractions induced by oxytocin administration were more vigorous than those where a placebo was given and resulted in disturbances to cardiovascular stability and to oxygenation of the newborns (Stenning et al., 2015). Although these studies are small and further
research is warranted, some guidelines are cautious when advocating for uterotonic administration while the newborn is still attached to the placenta with an unclamped cord (CDHB, 2014; NZCOM, 2013).

Cord pulsations

Studies on cord clamping often describe the cessation of cord pulsations as a measurement of late clamping (McDonald et al., 2013). It is likely that palpation of pulsations does not necessarily equate to actual blood flow as ultrasound measurement of umbilical cords after birth showed that flow was still present after pulsations had ceased (Boere et al., 2015). Pulsations are felt in the umbilical arteries rather than the vein and will therefore be indicative of the blood that is travelling away from the newborn rather than towards the newborn. It is surprising that these pulsations are used as an indication of when the newborn has received its full quota of placental blood when they in fact measure blood flow away from the newborn. When measuring the cord pulsations using palpation it is important not to put too much pressure on the cord as this may cause the vessels to spasm and affect the umbilical blood flow (Katheria et al., 2017).

Position of the infant

The position of the infant in the first few minutes after the birth, in particular whether it rests above or below the level of the placenta for the duration of ongoing umbilical circulation, may also have an effect on transfer of blood. In an early experiment which studied the effect of gravity at term vaginal births, neonates held 50-60cm above the estimated level of the placenta for 3 minutes had significantly higher blood volumes than if they were held 40cm below the placenta (Yao & Lind, 1969). Outside of experimental conditions such as these, babies are not held above and below the woman at such an extreme distance but are most likely to be placed on the maternal abdomen (in seated and supine positions), or on the birth surface if the woman gives birth in a kneeling or side-lying position. A more recent randomised controlled trial looked at the difference when babies were held either on the maternal abdomen or at the level of the vagina during 2 minutes of ongoing umbilical circulation (Vain et al., 2014). Mean neonatal weight gain after 2 minutes was 56g (Standard Deviation (SD): 47; 95% Confidence Interval (CI): 50-63) for the 197 babies held
at the vagina and 53g (SD:45; 95% CI: 46-59) for the 194 babies held on the abdomen, indicating that gravity does not influence the volume of placental transfusion as much as was previously believed. The authors discussed how this finding may increase compliance with a longer cord clamping time as holding the baby below the vagina, as was previously recommended, hindered early skin to skin contact and bonding and was likely to be uncomfortable for the birth practitioner.

Newborn breathing patterns
Data from experimental physiology has shown the flow of blood moving to and from the placenta is affected by newborn breathing patterns. When cord blood flow was measured using ultrasound post birth, the venous flow away from the placenta and towards the baby increased markedly during large breaths and reversed during crying (Boere et al., 2015). A well-known physiological model described in 2002 as “a new paradigm” proposed, through an extensive synthesis of the literature, that uninterrupted umbilical circulation aids respiratory effort in the newborn by increasing blood flow to the lungs, creating more erect alveoli and an increased absorption of pulmonary fluid (Mercer & Skovgaard, 2002). More recent examinations of cord clamping timing and the newborn physiological response suggests that if the cord is clamped before the newly born infant has taken a first breath there is a decrease in the amount of blood entering the heart (also known as preload) and consequently a reduction in cardiac output (Bhatt et al., 2013; Ersdal et al., 2014; Hooper et al., 2015; Niermeyer & Velaphi, 2013). In a study on 12 preterm lambs, there was a drop of 65% in right ventricular output (RVO) for those that had their cords clamped before ventilation (from 114.6 ± 14.4 to 38.8 ± 9.7 millilitres per minute per kilogram) compared to a 22% drop in RVO for those who were ventilated with an intact cord (from 153.5 ± 3.8 to 119.2 ± 10.6 millilitres per minute per kilogram) (Bhatt et al., 2013). There was a drop in the mean heart rate immediately after cord clamping (171.0 ± 11.9 beats per minute (bpm) to 102 ± 7.0 bpm) for the 6 lambs who had their cords clamped before they were ventilated. For the 6 lambs who were ventilated first, the mean heart rate remained unchanged after cord clamping (165.2 ± 15.5 bpm to 164.8 ± 17.0 bpm). The Bhatt et al. study postulates that it is not the immediate cord
clamping itself that is harmful but the failure to wait for lung expansion and the resulting improvements in haemodynamic stabilisation.

Beyond animal studies, a large observational study of 15,563 babies born in a rural referral hospital in Tanzania examined the relationship between onset of spontaneous respirations and timing of cord clamping (Ersdal et al., 2014). Infants who had their cords clamped before they initiated spontaneous breathing were more likely to die or require admission to the neonatal unit than their counterparts (Odds Ratio (OR): 4.53; 95% CI: 1.92-9.58). The risk of death or admission to a neonatal unit decreased the longer the time difference between spontaneous respirations to cord clamping up to two minutes. As this study is set in a low-resource country, there may be differences in the personnel, equipment and practice when compared to births in high-resource countries.

Although there are limited studies, data taken from human and experimental animal studies shows that deferring cord clamping until after the first breath results in higher pulmonary blood flow and a more stable cardiovascular transition in the newborn.

Summary

Reviewing the factors that influence the redistribution of blood between the placenta and the newborn has emphasized the complexity of newborn physiological transition and has led some practitioners to advocate for an individualised approach to each birth rather than the use of a specific measure of time (Katheria et al., 2017; Knol et al., 2018; Niermeyer, 2015).

Timing of cord clamping and maternal outcomes

The majority (65.7%) of women in New Zealand who have a normal birth (spontaneous onset of labour after 37 completed weeks of pregnancy with a cephalic presentation of a single live baby) in a tertiary centre will have active management of the third stage of labour according to a study of over 33,000 women in 2004-2008 (Dixon et al., 2009). As mentioned in the history section, active third stage was introduced in the 1960’s to reduce maternal harm from
postpartum haemorrhage. Active management involves immediate administration of a uterotonic, early cord clamping and controlled cord traction (Begley et al., 2019). The routine intervention of early cord clamping as part of active management of placental birth was introduced without rigorous evaluation (RCOG, 2015). In contrast to this interventionist approach, the main requirement of a physiological placental birth, otherwise known as physiological or expectant management, is ‘watchful waiting’. This method usually involves leaving the cord unclamped and attached to the baby until after placental birth (Begley et al., 2019; Dixon, Fullerton, Begley, Powell Kennedy, & Guilliland, 2011). In the most extreme version of physiological placental birth, known as Lotus birth, there is no cutting or clamping of the cord and the placenta is left attached to the baby until after natural separation occurs after around 3-7 days (Eichenbaum-Pikser & Zasloff, 2009; Niermeyer, 2015).

Obstetric haemorrhage remains in the top five leading causes of direct maternal death in New Zealand (PMMRC, 2018). Although it has previously been widely believed that active management of the third stage of labour reduces the postpartum haemorrhage rate, a recent meta-analysis has re-examined the evidence and found that this reduction is not evident for all women in high resource countries (Begley et al., 2019). From a review of 3 studies (4636 women) within this meta-analysis, there was evidence of a reduced risk of severe haemorrhage (1,000 mls or more) with active management and there was a higher incidence of uterotonic side effects including raised blood pressure, vomiting and afterpains. However, the authors describe the level of evidence as poor and thus they were conservative in their conclusions. Although this meta-analysis found a lower haemoglobin in women who had expectant management of the third stage compared to active management, the difference was only around 0.5 g/dl blood lower which is unlikely to be clinically significant as it is similar to the fall in haemoglobin levels observed following a routine blood donation (0.6 g/dl).

When 33,752 births were analysed as part of a retrospective cohort study in New Zealand, women who had a normal birth were equally as likely to have active third stage management (51.9%) as a physiological placental birth (48.1%).
(Dixon et al., 2013). The median estimated blood loss for physiological placental birth was 200mls compared to 250mls for the women who had active management. These outcomes do not align with the majority of randomised controlled trials, which show a higher blood loss for physiological placental birth than for active management, even when complex births are excluded (Begley et al., 2019). As the midwives in the Dixon et al. study were equally as likely to practice physiological placental birth as active management it is possible that they have retained the skills associated with this method of watchful waiting and this may explain the lower rates of postpartum bleeding. As midwives in New Zealand continue to consider physiological placental birth as an option for “low-risk” women, with favourable outcomes for reducing blood loss, longer cord clamping times will be a part of practice data for normal births.

When active management is used at births, babies have a lower birthweight, indicative of a reduction in transfer of placental blood equivalent to approximately 80 mls less than if expectant management was used (Begley et al., 2019). Active management traditionally includes immediate cord clamping and controlled cord traction, as well as uterotonic administration, but more recently the combination of these interventions has been questioned. If active management is adapted to include deferred cord clamping then the damaging effects of reduced newborn blood volume may be mitigated. The majority of studies that measured maternal outcomes when deferred cord clamping was used as part of active management of the third stage of labour found that women did not have an increase in postpartum haemorrhage rates and had similar postnatal haemoglobin levels to those women who had active management with immediate cord clamping (McDonald et al., 2013). Studies on the use of controlled cord traction with active management found no reduction in haemorrhage compared to when the placenta was born by maternal effort alone (Gülmuzoglu et al., 2012; Hofmeyr, Mshweshwe, & Gülmezoglu, 2015). It is therefore likely that it is the administration of the uterotonic alone, and not the early cord clamping and controlled cord traction that reduce maternal haemorrhage rates.
Leaving the cord intact for an extended period after the birth will leave the baby with the extra blood volume and the placenta with a reduced blood volume. This may facilitate the third stage of labour as a smaller placenta is likely to birth more easily. A technique called “placental cord drainage” can be used after immediate cord clamping. This practice involves releasing the clamp on the placental end of the cord to allow the blood to drain into a container, creating a more compact placenta (Gyte, 2006). Some studies report that placental cord drainage result in a third stage of labour which is an average of 2.85 minutes shorter (95% CI: -4.04 to -1.66) than when the clamp is left attached to the placental end of the cord (Soltani, Pouluse, & Hutchon, 2011). The authors of this Cochrane review suggest that, although clamping and then unclamping the cord for drainage is an intervention, it has similar maternal outcomes as for placental transfusion during physiological third stage.

As the research into benefits to newborns of leaving the umbilical cord intact become incorporated into practice, new versions of management of the third stage of labour are developed. When there is a delay of all three interventions until after cord pulsation ceases, this is described as “delayed active management” (Gyte, 2006). Other versions of third stage management with variations in timing of uterotonic, variations in timing of cord clamping and sometimes excluding controlled cord traction are sometimes referred to as “mixed”, “combined” or “piecemeal” management (Begley et al., 2019).

Maternal outcomes of delayed cord clamping at complex births is of interest as part of this literature review. One study indicated that there were no increases in maternal blood loss when a 30 second delay in cord clamping was introduced for multiple pregnancies (Ruangkit et al., 2018). Another study showed there was no increase in maternal blood loss where a two minutes delay in cord clamping was introduced at caesarean section births (Chantry, Blanton, Taché, Finta, & Tancredi, 2018).

Some authors postulate that deferred cord clamping enhances the positive effects of skin-to-skin contact at birth. Uninterrupted skin-to-skin contact between mother and newborn post birth has been shown to promote thermoregulation and prolonged breastfeeding (Gabriel et al., 2010; Moore,
Bergman, Anderson, & Medley, 2016). Eichenbaum-Pikser & Zasloff (2009) suggest that prolonged intervals between birth and cord clamping encourage a physical closeness between the mother and the baby which may, in turn aid immediate bonding. Hastie & Fahy (2009) describe how the rush to clamp the cord and interfere with physiology may impact on the post-birth hormonal balance which, in turn, may affect maternal bleeding, neonatal transition and breastfeeding outcomes. A systematic review of cord clamping trials examined data on breastfeeding rate at discharge from nine studies with a total of 2,950 babies (McDonald et al., 2013). Breastfeeding rates at various time points, from one month to six months post birth, did not vary significantly between the early and deferred cord clamping groups. Further research into cord clamping timing and its effects on breastfeeding and bonding may uncover ways in which we can improve short and long term maternal and infant outcomes.

Timing of cord clamping and neonatal outcomes

For the past two decades, evidence has been mounting that facilitating placental transfusion through a prolonged cord clamping time improves both long and short-term outcomes for infants (Hutton & Hassan, 2007; MacDonald et al., 2013). Two conclusive benefits to emerge from the meta analyses of Hutton and Hassan (2007) and MacDonald et al. (2013) are that deferred cord clamping results in increased haemoglobin levels at 24-48 hours post-birth and higher ferritin levels in term infants at three to six months of age. The increase in birthweight in infants whose mothers had a physiological placental birth rather than active management of the third stage is evidence that more blood volume is received by babies who have longer birth-to-cord clamping intervals (Begley et al., 2019).

There are variable definitions of deferred cord clamping across the multiple studies that measured neonatal outcomes for term infants (Hutton & Hassan, 2007; McDonald et al., 2013). Some studies used a time value such as one, two, three or five minutes post birth. In other studies, deferred cord clamping was defined as the cord being clamped after pulsations ceased and/or after placental birth. Early cord clamping had more consistency in definition, with the majority of clamping being 0-15 seconds post-birth, although occasionally
up to one minute post-birth. One of the most robust randomized controlled trials included in the 2013 meta-analysis randomised cord clamping of 382 births in Sweden (Andersson, Hellström-Westas, Andersson, & Domellöf, 2011). The researchers found a 45% higher mean serum ferritin (95% CI: 23% to 71%) at four months of age in babies who had their cords clamped three minutes after birth compared to those who had immediate cord clamping. In a more recent study, set in Nepal, the positive effects of two minutes or more of delayed cord clamping showed a decrease in iron deficiency even later in infancy, and up to 12 months of age (Kc et al., 2017). A later observational cohort study measured ferritin levels for babies at four months of age and found similar levels in those who had three minutes of placental transfusion compared to only one minute (in both groups the baby was held at a level about 20cm below the vulva for 30 seconds and then placed on the mother’s abdomen) (Askelöf et al., 2017). There is still no definite answer as to how long a baby needs to be connected to its umbilical circulation in order to have the full benefits of increased iron stores.

There have been inconsistent results on the possible association between deferred cord clamping and rates of jaundice in the neonate. As mentioned in the physiology section above, the increase in blood transferred to the baby as a result of deferred cord clamping results in high levels of haemoglobin in the fetal circulation. As the haemoglobin is broken down to release iron, one of the by-products is bilirubin. Most bilirubin is easily excreted in the faeces following conjugation in the liver but if transport through the gut is slow then some bilirubin may be deconjugated, reabsorbed and deposited in the skin and sclera of the eyes, becoming visible as a yellow discolouration known as jaundice (Rankin, 2017). For most neonates jaundice is a normal transitional occurrence which resolves without treatment.

Two major meta-analyses on cord clamping differed in their findings about whether there is an increase in jaundice levels with longer intervals between birth and clamping (Hutton & Hassan, 2007; McDonald et al., 2013). The first found no significant difference in mean serum bilirubin levels in 1009 infants randomised between early and late cord clamping but they did find a non-significant rise in babies with polycythaemia (Hutton & Hassan, 2007). In the
larger Cochrane meta-analysis, data from 2,324 infants found 2.74% infants in the early cord clamping group required phototherapy for jaundice compared to 4.36% in the late clamping group (RR 0.62, 95% CI 0.41 to 0.96) (McDonald et al., 2013). One critique of the Cochrane review is that it included one trial with 1,000 participants, which was from a PhD thesis but never published in a peer reviewed journal publication (Mercer et al., 2018).

Studies released since the 2007 and 2013 reviews continue to have conflicting results with some finding a rise in jaundice levels for infants who have delay of over 2 minutes of cord clamping (Ranjit et al., 2015) and some finding no such link (Carvalho et al., 2018; Fawzy et al., 2015). In a meta-analysis of outcomes for preterm infants a 3% rise in polycythaemia and an increase in peak bilirubin levels was shown for infants who had 30-120 seconds of delayed cord clamping but these outcomes were not associated with increased morbidity (Fogarty et al., 2018). A Cochrane analysis that looked at the difference between active management of the third stage of labour, where the cord is clamped immediately, and expectant management, where the cord is left to pulsate, found little or no differences between the two groups in the rates of neonatal jaundice requiring phototherapy (Begley et al., 2019).

It is likely that the fear of an increased jaundice rate continues to be a barrier to the worldwide implementation of placental transfusion strategies (Anton, Jordan, & Rabe, 2018). Although the majority of cases of neonatal jaundice resolve spontaneously or with phototherapy, in extreme cases the condition can lead to the requirement for an exchange transfusion, or, if left untreated, kernicterus, a bilirubin-induced brain dysfunction. There is a reliance on the advocates of deferred cord clamping to demonstrate that leaving the cord intact confers benefits that outweigh the risks of jaundice and polycythaemia. Although physiological jaundice is a common condition which is relatively easy to treat with phototherapy, this treatment does often involve separation of mother and infant and a disturbance to breastfeeding. Evolving evidence suggests that the antibacterial properties of bilirubin may even be protective against early-onset neonatal sepsis, particularly from Group B Streptococcus (GBS) (Hansen et al., 2018). An in vitro laboratory experiment by Hansen et al. evaluated the growth of GBS isolates cultured in varying concentrations of
bilirubin. They found a reduction in GBS growth when the bilirubin concentration was over 100 micromoles/litre when compared to GBS growth in the absence of bilirubin. Future clinical studies randomising neonates at risk of developing sepsis to high and low tolerance thresholds for hyperbilirubinaemia may be able to evaluate the subsequent rates of sepsis and the ongoing impact of any illnesses.

Iron deficiency in infancy even without anaemia is linked with impaired neurodevelopment (Carter et al., 2010; Lozoff et al., 2013). Immediate cord clamping is linked with iron deficiency in infancy (McDonald et al., 2013) and further research has looked at longer term outcomes for infants depending on the length of time they spent with ongoing umbilical circulation post-birth. For example, a Swedish study where 189 babies had their cords clamped early (less than 10 seconds post-birth) and 193 babies had their cords left intact for at least three minutes followed up the children at age four (Andersson et al., 2015). 263 children returned for follow up and had tests for various neurodevelopment outcomes, including an assessment by a psychologist and measurement against several developmental questionnaires. Those who had their cords left intact for three minutes had improved performance in motor function demonstrated in a bicycle trail test and a pencil-grip test. This group also had higher scores in parent-reported test on social behaviour. Interestingly, the improvement in neurodevelopment was more marked in the boys than in the girls. The researchers discuss how this is consistent with previous results that show higher rates of iron deficiency in male infants. Boys would therefore benefit more from increased iron stores after delayed cord clamping.

In countries where there is a high prevalence of iron-deficiency anaemia, the improvement in neurodevelopment may be even more pronounced. A Nepalese study compared outcomes of term infants who had greater than three minutes of cord clamping compared to under one minute (Rana, Kc, Målqvist, Subedi, & Andersson, 2019). The Ages and Stages Questionnaire (ASQ), measuring communication, gross-motor and social skills, which was also used in the study of Swedish infants (Andersson et al., 2015), assessed neurodevelopment in 332 of these Nepalese infants at one year of age. It found that fewer infants in the deferred cord clamping group (7.8%) had low scores in
the ASQ (indicating a risk of affected neurodevelopment) than infants in the early cord clamping group (18.1%) (OR: 0.43; 95% CI: 0.26-0.71).

Iron is required for brain development in infancy, in particular for the development of the myelin sheath that coats the nerve fibres allowing electrical impulses to transmit quickly and effectively (Snaidero & Simons, 2014). A study on how this brain development is affected by cord clamping timing found that, of the 44 infants who had an MRI at around 4 months of age, the group that had a minimum of five minutes of placental transfusion had a greater myelin content in the internal capsule than the group that had 20 seconds or less placental transfusion (Mercer et al., 2018). The study is a small-scale experiment postulating that a low-tech, no-cost approach such as delayed cord clamping, by facilitating a transfer of iron-rich blood from the placenta, may have a positive impact on childhood neurodevelopment.

As we move away from a universal policy of immediate cord clamping, other benefits for newborn infants require further investigation. For example, whether prolonged cord clamping times increase the transfusion of umbilical cord blood stem cells which may improve the development in a variety of organ systems (Tolosa et al., 2010) and reduce the levels of oxidative stress which may have a protective effect on our future health (Moustafa et al., 2017).

Delayed cord clamping has been described as a simple procedure that costs nothing. In term babies it has a potential to improve ferritin stores and neurodevelopmental outcomes (Andersson et al., 2015; Mercer et al., 2018). In the preterm population it has an even more dramatic outcome of the reduction in hospital mortality. In a meta-analysis of 18 randomised controlled trials (2,834 preterm infants) it was found that, for every 33 babies who have their cords clamped 30-120 seconds after birth, there will be one extra baby who survives to hospital discharge when compared to the previous intervention of immediate cord clamping (Fogarty et al., 2018).
Cord clamping and newborn resuscitation

The majority of studies examining outcomes for term infants of early versus delayed cord clamping excluded any infant that needed resuscitation (McDonald et al., 2013; Rabe et al., 2010). Most term babies will take their first spontaneous breath within the first minute of life and, for the majority of these babies, crucial circulatory and respiratory transition occurs successfully without intervention (Niermeyer, 2015). If a baby has not taken its first breath during this “golden minute” resuscitation guidelines direct practitioners to commence Intermittent Positive Pressure Ventilation (IPPV) at 60 seconds (ANZCOR, 2017). For birthing rooms which have a distant resuscitation table, this requires cutting and clamping of the cord at around 45 seconds to enable prompt transfer to IPPV equipment. A review of the literature on “redistribution of blood” as described above suggests that placental transfusion requires at least one minute, preferably over 3 minutes, and is dependent on factors such as uterine contractions, maternal/infant positioning and newborn breathing efforts. Therefore, the ability to resuscitate a baby with an intact cord will prolong the time available for placental transfusion and improve the success of the newborn’s transition to extraterine life. Intact cord resuscitation is an area of active current research which will be discussed in this section of the literature review.

Many midwives who practice at home births and at midwifery-led units are not new to intact cord resuscitation. In a cross-sectional descriptive study of experiences of midwives in Canada, 69% of 82 participants reported that they had resuscitated infants with an intact cord and were much more likely to utilize this technique at home rather than at hospital births (Fulton, Stoll, & Thordarson, 2016). These midwives were aware that there are no randomised controlled trials to demonstrate the risks or benefits of intact cord resuscitation but, on consideration of the available evidence, they incorporate it into their practice with the intent of improving physiologic benefits for the newborn and keeping the mothers and babies together.

Although there are no randomised controlled trials, several experimental studies have demonstrated that cord clamping is harmful when done before the
onset of respirations (Bhatt et al., 2013; Ersdal et al., 2014; Gruneberg & Crozier, 2015; Hooper et al., 2016). Cord clamping prior to spontaneous breathing exacerbates a reflex bradycardia that may increase the need for resuscitative measures that would otherwise have not been necessary if placental transfusion had been given time to stabilize. The babies that are most likely to have their cords cut before they take their first breath may be the ones who would most benefit from placental transfusion (O’Donnell, 2017). When practitioners cut and clamp the cord early and then discover that a baby has a low heart rate and does not breathe, this may confirm for them that prompt transfer to the resuscitation table was warranted when in fact, it may have been the early clamping and cutting itself that caused the bradycardia and delay in respirations. This circular argument has been described by Niermeyer & Velaphi (2013) using some case examples of a birth of a baby born at 29 weeks gestation. With placental transfusion being established as a vital part of adaptation to extra uterine life, the ability to wait for an asphyxiated newborn to take its first breath can be difficult, especially “waiting without action for a process that is largely invisible and incompletely understood” (Niermeyer, 2015, p.10). One method which may give some babies more time with intact cord is to auscultate the newborn heart rate within the first minute and only clamp and cut if the heart rate is below 60 beats per minute, regardless of breathing efforts (NICE, 2015).

Initial drying and stimulation of a newborn baby can be done with an intact cord on the maternal abdomen. If a baby needs intermittent positive pressure ventilation (IPPV), a flat surface, out of the birth fluids, with access to ventilation equipment is ideal to maintain newborn temperature, open the airway and to establish respiratory support. Ideas on how to provide this surface have been described according to whether existing equipment is used, or whether a mobile trolley designed for bedside resuscitation is available (Batey, Yoxall, Fawke, Duley, & Dorling, 2017). Homebirth midwives describe using a “cookie tray” covered with a towel and access to a bag and mask (Fulton et al., 2016). In the TOCC hospital the newborn resuscitation tables are fixed to the wall and therefore cannot be moved to provide intact cord resuscitation, although it has been suggested that, if anticipating a compromised baby, an alternative method would be raising and moving the
birthing bed adjacent to the resuscitation table (Batey et al., 2017) or providing IPPV with the baby remaining on the birth surface (Van Rheenen, 2011). The more specialised versions of mobile resuscitation platforms have been evaluated in multiple trials and found to be acceptable both to the parents, who will be in close contact with their baby while it is being resuscitated, and to the clinicians (Duley et al., 2018; Katheria, Sorkhi, Hassen, Faksh, & Ghorishi, 2018; Knol et al., 2018; Thomas, Yoxall, Weeks, & Duley, 2014; Weeks et al., 2015; Yoxall et al., 2015).

Cord milking is a method for speeding up placental transfusion as an alternative to deferred cord clamping. Cord milking involves pinching the umbilical cord and squeezing it along its length several times to push the blood towards the newborn infant (Katheria, 2018). The action can be achieved in a matter of seconds, although care has to be taken to untwist the cord prior to milking as the vessel spirals may obstruct flow of blood (Niermeyer, 2015). There are two variations, either “intact cord milking” where the cord remains attached to the placenta or “cut cord milking” where a long section of cord is left on the newborn and then milked when the baby reaches the resuscitation table. Cord milking is popular at premature births, caesarean births and for compromised babies where there is often a desire to transfer babies early to the resuscitation table (Rabe, Diaz-Rossello, Duley, & Dowswell, 2019). Although a meta-analysis of seven randomised controlled trials demonstrated that milking improved infant haemoglobin levels (Al-Wassia & Shah, 2015), there is ongoing concern that the large swings in volume movement caused by milking may cause haemodynamic disturbances that would otherwise not be present when the umbilical circulation is left undisturbed to reach its own equilibrium (Knol et al., 2018; Niermeyer, 2015).

**National and International guidance on cord clamping**

As a result of the growing evidence from cord clamping studies (the history, the physiology, the maternal and the neonatal outcomes) health organisations, committees and councils around the world have produced guidelines for best
practice for birth practitioners. This next part of this review will look at these guidelines and how they may have influenced practice in the TOCC hospital during this study.

Internationally, immediate cord clamping was removed from the recommendations for active management of placental birth in 2006 as part of a joint statement released by the International Confederation of Midwives (ICM) and the International Federation of Gynaecologists and Obstetricians (FIGO) (Anton et al., 2018; Weeks, 2007). The World Health Organisation currently has a clear directive in three of its guidelines for a minimum of one minute, and preferably up to three minutes, of intact cord time for all babies unless there are concerns the neonate required positive-pressure ventilation (WHO, 2012b, 2012a, 2013).

Various organisations around the world vary in their recommendations on an optimal time for cord clamping and, for the purposes of a comparison for this literature review, these have been presented in a table in Appendix one.

In New Zealand midwives are guided by their College of Midwives (NZCOM) consensus statements. In September 2013 the NZCOM published a new consensus statement on placental birth with recommendations for a delay of at least three minutes between birth and cord clamping for active management of the third stage of labour alongside administration of the uterotonic after cord clamping (NZCOM, 2013). This was a significant change to the previous NZCOM practice guideline released in 2006 which advocated for administration of the uterotonic as soon as possible after the birth of the baby’s anterior shoulder and cord clamping as soon as possible after the birth of the baby (NZCOM, 2006). Both versions of this consensus statement propose that physiological placental birth is a safe option for women who have had a physiological labour and birth, with cord clamping delayed for “several minutes”, in accordance with the woman’s wishes and, in some cases, left intact until after the placenta is birthed.

The obstetric profession in New Zealand is guided by the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG). Their
guidelines on intrapartum care and on the management of postpartum haemorrhage recommend active management of the third stage for all women, citing evidence for a two-fold increase in postpartum haemorrhage with the practice of physiological third stage (RANZCOG, 2017b, 2017a). This is in contrast to the previously mentioned NZCOM consensus statement which states that physiological placental birth is a safe option following uncomplicated labour and birth (NZCOM, 2013) and brings to discussion the interprofessional differences which lead to variations in interpretation of the evidence. In light of the recent evidence on benefits of prolonged placental transfusion, despite continuing to recommend active management for all, the RANZCOG guideline does address the issue of immediate clamping. The intrapartum care guideline now states that, for active management of the third stage of labour “there should be no urgency to cut the umbilical cord and this can be done in an appropriate time frame” (RANZCOG, 2017, p.11). In its review of the evidence it places an emphasis on the position of the baby in relation to the mother for placental transfusion, stating that transfusion time will be complete in one minute if the baby is held 40cm below the placenta compared to 3 minutes for positions 10cm above the placenta. This is a based on study from the 1960s (Yao & Lind, 1969) and does not take into account a more recent finding that gravity does not in fact play a large part in the redistribution of blood between placenta to newborn (Vain et al., 2014).

Midwives, obstetricians and neonatal staff in New Zealand are guided by the New Zealand Resuscitation Council (NZRC), which publishes a five-yearly update on newborn resuscitation guidelines in collaboration with the Australian Resuscitation Council (ARC) and based on evidence reviewed by the International Liaison Committee on Resuscitation (ILCOR). The most recent version of this guideline states that the evidence for deferred cord clamping for term infants, from 30 seconds until cessation of cord pulsations, demonstrates improved iron status but an increase in jaundice requiring phototherapy (ANZCOR, 2017). The guideline goes on to recommend delayed cord clamping (time not specified) for preterm infants who do not require resuscitation but does not make a statement for term babies who do not require resuscitation. However, for all gestations it suggests that the placenta cannot be relied upon to provide compensatory gas exchange in non-breathing infants and does not
find adequate evidence to recommend an optimal time for cord clamping for the compromised newborn. In contrast, the European Committee on Resuscitation (ERC) who published guidelines based on the same ILCOR evidence, specifies a birth to cord clamping interval of one minute for term and preterm infants not requiring resuscitation (Wyllie et al., 2015). For babies who are not breathing or crying, the ERC recommends prompt resuscitation after the cord has been clamped and cut. The American Heart Association (AHA), again looking at the same ILCOR evidence, does not make any statements on cord clamping timing for term infants, only for preterm infants (Perlman et al., 2015). As with the discrepancies in recommendations for physiological placental birth, again we see variations in interpretation of the same evidence but this time not according to profession but related to world regions, with Europe adopting delayed cord clamping for compromised neonates before Australasia and the United States of America.

For a complex birth at a tertiary unit the obstetric, midwifery and neonatal teams are expected to make fast collaborative decisions on cord clamping, often in high-stress situations. When national guidelines demonstrate discrepancies in how the different professional organisations and different world regions interpret the evidence, a local guideline with clear definitions, timings and exclusion criteria can be vital for successful implementation of a change in practice (Anton et al., 2018). In the Netherlands, only 19% of the 500 caregivers who responded to a survey confirmed that a cord clamping protocol existed in their practice area (Boere et al., 2015), and in Italy only 21% of 86 tertiary-care delivery wards reported having an obstetric-neonatal guideline on cord clamping (Perrone & Ghirardello, 2017). The local guideline for the TOCC study hospital recommended, for term vaginal birth, that the cord be left unclamped for at least three minutes unless the neonatal team were present and considered it necessary to clamp sooner for the purposes of resuscitation (CDHB, 2014).

Surveys on cord clamping practice

Surveys that have asked midwives, obstetricians and other maternity care professionals about their cord clamping habits reveal that the evidence for
benefits of prolonged placental transfusion times is not always being translated into practice (Jelin, Kuppermann, Erickson, Clyman, & Schulkin, 2014; Ononeze & Hutchon, 2009; Stoll & Hutton, 2012). The surveys of healthcare practitioners will be described in this section, alongside an examination of consumer’s views on cord clamping.

Two surveys asked midwives to define delayed cord clamping according to a time value. Of the 82 midwives from British Colombia in Canada who responded in 2014 there was a wide variation in how delayed cord clamping was defined. Four percent defined it as a minimum of 60 seconds, 32% a minimum of 2 minutes, 47% as waiting until after the cord has stopped pulsating and 5% waiting until after the placenta has been delivered (Fulton et al., 2016). In a similar question answered by 153 Irish midwives (date of survey not specified), 1.3% defined delayed cord clamping as 30-60 seconds, 13.8% as 1-3 minutes, 10.6% as 3-5 minutes and the remaining 74.3% as after the cessation of cord placental transfusion (by palpation or visual estimation) (Devin & Larkin, 2018).

Some surveys asked questions of different members of the maternity healthcare team to elicit any interprofessional differences in self-reported cord clamping practice. In a study where practitioners from Canada were questioned in 2005, 77.9% of obstetricians favoured early clamping compared to only 2.2% of midwives (Tan, Klein, Saxell, Shirkoohy, & Asrat, 2008). This was similar to the results a slightly later survey sent in 2006/7, also in Canada, in which 77.9% of obstetricians reported immediate cord clamping, compared to only 9.8% of midwives (Fulton et al., 2016). A large postal survey sent in 2008 in the UK had replies from 1194 obstetricians and 1702 midwives. For active management of third stage of labour at term births 89% of midwives and 97% of obstetricians clamp the cord before 60 seconds (Farrar, Tuffnell, Airey, & Duley, 2010).

With regard to the practice of physiological third stage, only half (51.2%) of the 47 midwives in a Canadian survey agreed with the national guideline which recommends active management for all births, compared to almost all (95.2%) of the 77 obstetricians (Tan et al., 2008). In a survey sent to midwives in New Zealand in 2008, 96% of the 257 midwives who responded reported practicing
planned physiological third stage (Richards, 2009). In this New Zealand study, 86% of the midwives reported leaving the cord intact for at least three minutes during a physiological third stage, whereas only 16% would do the same during an active third stage.

With regard to type of workplace, more midwives report using early cord clamping in a tertiary hospital than in a primary maternity setting in order to comply with hospital policy and to fit in with the culture of the unit (Fulton et al., 2016; Mercer, Nelson, Skovgaard, & Chern-Hughes, 2000; Richards, 2009; Stoll & Hutton, 2012). This finding aligns with a New Zealand study which observed from clinical records that midwives caring for a caseload of low-risk first-time mothers are more likely to use evidence-based care associated with physiological labour and birth when caring for these women at a home than in a tertiary hospital (Miller & Skinner, 2012). In this study, the evidence for supporting physiological birth included supporting an upright maternal position in labour, avoiding artificial rupture of membranes as well as delaying cord clamping. Another reason for a preference for early cord clamping when working in a tertiary facility, which was cited by 15% of 153 midwives in an Irish survey, was time pressure due to the busyness of the unit (Devin & Larkin, 2018).

In surveys of Canadian and Irish maternity care providers reasons for early clamping were described as resuscitation of the newborn infant; reduction in maternal bleeding; concern over maternal deterioration and parental request (Devin & Larkin, 2018; Fulton et al., 2016). For midwives in New Zealand decisions around cord clamping timing were most strongly influenced by parent’s choice, the need for active management of the third stage, birth in water, the need to support newborn transition to extra uterine life and the desire not to separate mother and baby (Richards, 2009). For some surveys one of the reasons for clamping early was to collect cord blood for stem cells (Mercer et al., 2000; Tan et al., 2008). Cord blood banking may conflict with delayed cord clamping because of the requirement for a large volume of umbilical blood to ensure the harvesting of sufficient stem cells (Eichenbaum-Pikser & Zasloff, 2009).
One of the primary reasons for early clamping is to facilitate newborn resuscitation. Of the 157 midwives who responded to a survey in Canada in 1998, 84.1% reported early clamping to facilitate resuscitation (Mercer et al., 2000). In a similar survey sent to midwives in New Zealand a decade later in 2008, 79% of the 257 midwives also cited newborn resuscitation as a reason for early clamping (Richards, 2009). Those who chose to delay clamping time even when babies appeared to require resuscitation described the practice of drying and stimulating the baby with intact cord to maximise placental transfusion prior to moving to the resuscitation table (Richards, 2009) and a belief that the baby continues to receive oxygen from the mother while the cord is intact (Mercer et al., 2000).

Maternity clinicians appear to be slow to implement the evidence on cord clamping into practice, although surveys from the last five years are showing longer self-reported cord clamping intervals (Boere et al., 2015). A comparison of midwifery practice over the past two decades, as reported in surveys from European countries, demonstrates a move from immediate to deferred clamping. In the mid-2000’s UK midwives reported a cord clamping time of less than one minute for 89-92% of births (Airey et al., 2008; Diane Farrar et al., 2010). By the mid-2010’s midwives in Ireland reported a cord clamping time of less than one minute at only 36% births (Devin & Larkin, 2018) and midwives in the Netherlands at only 14% of births (Boere et al., 2015). Surveys from obstetricians would also indicate that they have been adopting a later time to clamp and cut the umbilical cord. In the late 2010’s 67% of the 185 obstetricians in the United States of America who responded to a survey were using delayed cord clamping (Leslie, Greene, Schulkin, & Jelin, 2018) compared to only 7.8% of the 74 obstetricians in Canada who responded to a survey in the mid-2000’s (Stoll & Hutton, 2012). However, comparisons must be treated with caution due to the potential differences in data collection and the differences in practice between different countries.

No research was found in peer-reviewed journals on the views of women, parents and family members on the topic of cord clamping. Through contact with the author, results from an unpublished consumer survey were obtained (Hill, M., personal communication, 1/8/18). Over 3,500 responses were
received from an online survey which asked parents about umbilical cord clamping at births from 2015-2017. The majority (3249/3530) had heard of delayed/optimal cord clamping. Almost half (1,497/3482) reported that their baby’s cord had been cut within 2 minutes of the birth, despite the fact that two thirds of these parents (2315/3530) had requested delayed/optimal cord clamping in their birth plan. Listed below are some of the statements collated in the section which asked for the reasons for not receiving delayed/optimal cord clamping:

- It wasn’t cut straight away but sooner than I would have liked. No reason stated they just cut it.
- Baby was born quickly and shocked so midwife panicked and clamped cord. I was on all fours with my back turned so couldn’t stop her.
- I did not know about it. I have 4 children and have never ever had this offered or explained to me.
- Midwife didn’t give me the option. I would have said yes if given the option.

The results of this survey highlight that, of those parents who replied, there was a lack of consent and explanation to women, their partners and their whānau when the umbilical cord is clamped and cut at birth. Although the large sample size and the inclusion of both quantitative and qualitative data give an insight into an otherwise unpublished area of cord clamping research, the results should be viewed with caution as it is possible that only participants with particular views completed the survey, providing a potentially biased sample.

This review of surveys on cord clamping has shown that self-reported practice varies considerably according to year of survey, profession, country and primary/tertiary workplace. It also highlights a lack of published research on the views of women and their whānau.

**Observational studies on cord clamping practice**

Observational studies use epidemiological and clinical observation to discover how best to protect and improve healthcare practices (National Ethics Advisory
Committee, 2012). They have an advantage over surveys as they avoid the discrepancies that may arise between self-reported practice and objective measurement (Hutton et al., 2013). An observational study can provide evidence on whether placental transfusion is being implemented into practice by accurately recording the time of birth and the time the cord is clamped.

An observational study in Canada reported a median cord clamping time of 12 seconds at 89 term vaginal births, with over half of the babies having their umbilical blood flow stopped within 15 seconds of the birth (Hutton et al., 2013). A wide variation in cord clamping practice was observed between the three practitioner groups, with median time being 12 seconds for obstetricians (39/89 births), 19 seconds for family physicians (37/89 births) and 81 seconds for midwives (13/89 births). In the analysis of this data the authors discuss how the differences in cord clamping times for the different practitioner groups may have been influenced by the risk profile and personal preferences of women who are cared for by obstetricians, family physicians and midwives. The median cord clamping times in this study were longer if the birth was spontaneous (19 seconds vs 7 seconds for instrumental), with no cord blood gas collection (22 seconds vs 9 seconds when cord blood gas was collected) and when there was no neonatal intervention after the birth (20 seconds vs 8 seconds for neonatal intervention). The data was gathered from an additional researcher who was present at each birth with a stopwatch and the authors suggest that practice was affected by the knowledge that they were being observed, although in light of the generally short cord clamping intervals it is unlikely that it had a significant effect.

The only other observational study to be found in a high-resource country was from the UK where 100 births (96 term and 4 preterm) were observed in 2006 and 2007 and cord clamping was timed with a stopwatch (Farrar et al., 2010). The study recorded that 85% of cords were clamped under 30 seconds, a further 11% between 30-60 seconds and 4% between 61 and 100 seconds. The position of the baby was recorded during the time that the cord was intact and was found to be most likely on the bed (78%), with only 22% on the woman’s abdomen. As this observational study ran concurrently with a survey of
midwives’ practice, the authors concluded that observation and self-reported practice do not always look the same.

A later larger study in a low-resource country that observed 15,563 births (term and preterm) from 2009 to 2013 found a median cord clamping time of 54 seconds (Ersdal et al., 2014). In this hospital in Tanzania births are usually facilitated by midwives, with doctors on call for complexities. The hospital has a guideline which follows the WHO direction to leave the umbilical cord intact for one to three minutes if the baby is breathing (WHO, 2012a, 2012b, 2014). As part of an ongoing descriptive study looked at cord clamping in relation to spontaneous breathing, a researcher timed every birth with a stopwatch. Results showed that neonatal outcomes were better when there was a minimum of 2 minutes between initiation of breathing and clamping of the cord. The authors speculate that this is due to a smoother cardiovascular transition and haemodynamic stability, which would correspond with physiological considerations covered earlier in this review under the section on “redistribution of blood between placenta and newborn”.

In Nepal, another observational study in a tertiary-level hospital timed 128 vaginal births (term and preterm) in 2013 with a stopwatch and recorded a median cord clamping time of 1.07 mins (Nelin et al., 2018). Overall, 48% of babies received placental transfusion over one minute, as per the WHO guidelines (WHO, 2012a, 2012b, 2014). Interestingly there was a higher likelihood of delayed cord clamping where there were labour/delivery complications such as breech presentations, fetal distress and meconium-stained liquor. Correspondence with one of the study authors provided the explanation that, in his experience of attending births, midwives in this hospital are more likely to do early cord clamping when they are in control of the birth as this is more familiar to them, whereas when there are complications there may be hierarchical issues leading to a longer cord clamping issues (personal correspondence via email from Mats Malqvist 13/8/9). A further significant finding of this study was that the risk of neonatal death or admission to the neonatal unit decreased by 20% for every 10-second delay between cord clamping after initiation of breathing.
Summary

The decision on how to study New Zealand cord clamping practice first required a review of the current evidence around the history, physiology and outcomes as well as how these fit with the New Zealand context. Having reviewed the evidence it is clear that multiple maternal, neonatal and practitioner factors affect the choice of when and whether to clamp and cut the umbilical cord. Despite significant positive benefits of extending the period of placental transfusion, there are a wide variety of opinions around when to clamp and cut the umbilical cord and often an inability to reach consensus about best practice, particularly in relation to the compromised baby.

As a result of my exploration of the literature, I found a lack of observational data on cord clamping practice in New Zealand. Choosing an observational method of research provides an objective measurement of practice, allowing an insight into cord clamping timing in this era of ongoing debate on the risks and benefits of extending placental transfusion.

It is anticipated that an observational study will contribute to the following gaps in our knowledge on cord clamping:

- How long are umbilical cords left intact after birth in a New Zealand tertiary hospital?
- What factors influence cord clamping practice?
- How does New Zealand practice compare to other evidence from overseas maternity units?

This chapter has provided a detailed review of the literature around cord clamping practice. The following chapter “Methodology” will look at the design, development and implementation of the study.
Chapter 3: Methodology

After performing an extensive literature review it became evident that, despite a dramatic change in guidance for practitioners around when to clamp the cord, little evidence existed on whether this guidance was being implemented into practice in the current maternity system in NZ. In response to this gap in knowledge, the Timing of Cord Clamping (TOCC) study was devised to measure actual timings and some of the influences on current practice.

The aim of the TOCC study was to observe the interval between birth and cord clamping at term vaginal births in a New Zealand tertiary maternity hospital and to investigate how certain circumstances, such as the birthing position of the mother or the presence of a neonatal practitioner, affects cord clamping timing.

This chapter outlines the methodology and research method for the TOCC study, including the reasons for selecting the study design, the choice of participants and the processes involved in collecting and recording data.

Methodology

The TOCC study is a descriptive observational study of cord clamping practice at term vaginal births in a tertiary maternity hospital.

Quantitative research methodology was chosen because the aim was to quantify practice, i.e. to accurately measure the time interval between birth and cord clamping. A question that lends itself to numerical measurement is best resolved from a positivist paradigm, in an objective and observable way, using quantitative methodology (Dyson & Norrie, 2013). A relatively large data set can be analysed when a quantitative methodology is used. When these data are examined using statistical techniques, a summary of trends and underlying patterns in clinical practice can be produced. Although the TOCC study answered important questions around the actual timing of cord clamping it did not provide us with an in-depth insight on how the individuals involved
perceived or interpreted the situation. Further research from a qualitative perspective would be a useful follow up to the TOCC study to allow us to describe personal experiences of the women and the practitioners at the time of birth.

The research involved an observational study of cord clamping practice. In an observational study, information is collected first hand by a researcher based on how people are seen to behave or interact in certain situations (Rees, 2011). The investigator has no control over study variables and merely observes outcomes. This has less risk involved than an interventional study, in which changing an aspect of clinical practice may have a detrimental impact on healthcare (National Ethics Advisory Committee, 2012). Overt participant observation has the advantage over questionnaires and interviews as it is more likely to record accurate data, by avoiding the significant discrepancies that may exist between self-reported estimations and objective measurement (Hutton et al., 2013). People are not always able to accurately describe or articulate their own actions. Unlike surveys, observation does not rely on memory, and therefore data is likely to be more accurate (Rees, 2011).

The data obtained from this observational study was examined using descriptive statistics to identify any relationships between umbilical cord clamping timing and the circumstances of each birth. The term “descriptive”, when used in relation to statistics, indicates that data will be described and summarised rather than using inferential statistics which are more able to be generalised to the wider population (Dyson & Norrie, 2013).

One of the aims of the TOCC study was to compare New Zealand birth data collected from July 2017 to April 2018 to data collected ten years earlier in a Canadian study where births were observed from October 2006 to April 2007 (Hutton et al., 2013). The research design and population sample of the TOCC study was informed by this Canadian study. In both studies, the context was a large tertiary hospital where births are conducted by both doctors and midwives. Of particular interest is the change in cord clamping practice over the ten years between studies. In addition, a comparison is made between two different maternity systems: a New Zealand system where the majority of
women (94.2%) choose a midwife as their lead maternity carer (Ministry of Health (Manatū Hauora), 2019) and a Canadian system where the majority women (93%) have an obstetrician or family physician (General Practitioner) as their lead maternity carer (Guliani, 2015).

Study Methods

This study was informed by an observational study of cord clamping practice in a Canadian tertiary maternity hospital (Hutton et al., 2013). The TOCC study observed term vaginal births, both spontaneous and instrumental, in order to provide a data set comparable to the Hutton et al. study.

Health practitioners working in a birthing suite in a New Zealand tertiary hospital were asked to use a stopwatch to time the interval between the birth of a baby and the time when the first clamp was applied to the cord. No extra research person was at the birth in the TOCC study: the stopwatch duty was allocated to a member of staff who would otherwise have been present in the birthing room. This differed from the Hutton et al. study, which used researchers as additional attendees at the birth. Where the research role is allocated to a midwife who attends to assist the LMC at a birth, they are in an ideal role to act as overt participant observer as they are familiar with the environment and thus have the insider’s perspective. Another crucial advantage of using the hospital midwives as participant observers is that it negates the need for a separate researcher to be in the room (in addition to the existing birth attendants) which may have a negative influence on the birth ‘territory’ (Hastie & Fahy, 2009).

It is conceivable that this observational study would add stress to women at time of their birth, an outcome that the investigator was keen to avoid. However, as the study was observing the health practitioner and not directly the woman, it was anticipated that this stress would be minimised. Practitioner participants in the TOCC study were advised that, if there was an emergency procedure at the time of birth, TOCC study requirements would cease if they were likely to have an impact on normal management of the birth. The aim was
to mitigate any risks by informing the assisting midwife that the stopwatch was never to take precedence over any usual care.

Women and healthcare practitioners who met the criteria for the TOCC study (see below in “Participants” section) were provided with information leaflets and consent forms (see Appendices two and three). When a woman had consented and progressed to a vaginal birth at term, a health practitioner present at the birth was available to accurately record birth and cord clamping times using a stopwatch. The health practitioners were instructed to press the start switch on the stopwatch following birth of the entire baby and to stop the timing as the first clamp was applied. The stopwatch recorded this time in minutes:seconds:centiseconds. If the cord was clamped before the birth of the entire baby, the time was to be recorded as 0 minutes. If the cord was clamped after 10 minutes, often associated with a physiological placental birth or if the cord was not clamped at all, as for a lotus birth, this was recorded as an interval of >10 minutes. If the stopwatch was not used, for any reason (e.g. emergencies) then that birth was excluded from the study.

The stopwatch data was recorded in a TOCC study notebook along with the following information:

- Mode of birth
- Maternal position for birth
- Who facilitated birth and who clamped the cord i.e. midwife, doctor, student, support person, etc. (professional group only, not individual names)
- Whether a neonatal team member was present at the birth

The template from the study notebooks, designed to collect the data on cord clamping and birth circumstances, is included in Appendix four. It included similar data fields to the study by Hutton et al. (2013) in order to compare results in a similar environment. The study notebooks were completed by the LMC or hospital midwife.
It is recognized that many other factors could have been included in this study that may have an influence on cord clamping timing. As described in the Locality section below, the initial data collection table was more extensive but the table was restricted to make it more manageable for the health practitioners recording data for the study (see Appendix nine). Rees (2011) suggests that the number of activities recorded as part of observational studies needs to be limited so that observers are not overwhelmed when events unfold quickly, as they do during a birth.

The study notebooks were stored in the birthing suite workroom in an accessible place for all healthcare practitioners who were involved in data collection. The birthing suite workroom is where clinical notes are located for the duration of a woman’s stay and is considered a secure location as it is accessed only by LMCs and CDHB staff.

No data that could identify the woman was collected in this notebook to comply with privacy legislation. The women and their birth partners were informed that, if they consented to take part, the hospital midwife would record anonymous data that would be used in a study to look at current practice in the timing of umbilical cord clamping.

The leaflets and forms were clearly worded to ensure that women were under no obligation to participate and the LMC’s were advised to make this clear to the women in their discussions.

All participants had the opportunity, as described in the consent form (see Appendices two and three), to withdraw from the study at any time during the process, up until the time that data was being analysed. Women and healthcare professionals who agreed to have their birth data used in the study were advised to keep a copy of the information leaflet and to phone or email the investigator if they wished to know the study results.

Participants were not remunerated in any way for their participation in the TOCC study and were advised that their care/practice would not be affected by their involvement in the study.
Participants

I approached two groups of participants to take part in the TOCC study:

1. Pregnant women who planned to give birth in a tertiary hospital
2. Maternity healthcare practitioners who work in the birthing suite of this hospital.

All participants, both pregnant women and maternity healthcare professionals were provided with information on the study. Information leaflets and consent forms were designed as part of the ethics application. Copies of this supporting documentation is included in Appendices two and three.

In order to compare findings to a previous observational study of cord clamping (Hutton et al., 2013) I aimed for a sample size of 100 term vaginal births at the chosen tertiary maternity hospital.

The healthcare practitioners selected to take part in the TOCC study were LMCs, DHB-employed midwives working on birthing suite and obstetric doctors. This participant group were most likely to lead the decision as to when the cord will be clamped and cut. If a practitioner who was conducting the birth was not consented at the time of the women’s admission to hospital then practitioner consent was sought at that time or following the birth. The lead practitioner making the decision as to timing of cord clamping was the one who was approached to provide consent to being observed. If a student or birth support person clamped the cord, this would be under the supervision of the lead practitioner.

In order to conduct a high-quality ethical study, I was keen to avoid approaching women for recruitment while they were in active labour, when they would be potentially vulnerable. The National Ethics Advisory Committee (2012) defines one aspect of vulnerability as being when people have a restricted ability to make independent decisions about their participation in a study due to their health status or their altered physical or mental capacity. Women in labour are often in pain and/or may be in a state of high anxiety or fear and are potentially a vulnerable population. In this study, LMCs were
asked to approach women in their third trimester of pregnancy rather than when they were already in labour. Women can be vulnerable at any stage of their pregnancy, labour or birth and practitioners were reminded as part of their consent process for the TOCC study to be mindful of the fact that, if any concern existed around a woman’s ability to consent, it was essential that she be excluded from the study. Any LMC who consented to take part in the study was supplied with information leaflets/consent forms to pass on to women and given instructions on the eligibility criteria and the recruitment process. If a woman was not consented at time of admission to hospital for labour care and the lead practitioner caring for her considered it appropriate for her to consent at that time (i.e. if she was not unduly distressed and not in a circumstance where the discussion may have impacted on her ability to cope with labour), participation in the study was offered at this time. For example, women could be approached to take part in the TOCC study if they were admitted at term with pre-labour rupture of membranes and/or admitted at term for induction of labour. This recruitment was initially proposed to be by either the LMC or by the hospital-employed midwives. As described below, the added workload of TOCC recruitment for hospital-employed midwives was considered to be a risk to care provision on birthing suite, and therefore the option for recruitment by hospital-employed midwives was removed following Locality Authorisation process.

Exclusion and inclusion criteria
Women who birthed breech babies, multiple babies, who birthed prior to 37 weeks and/or who birthed outside of the tertiary unit were excluded from this study as these situations affect the decision-making around cord clamping. Women who birthed vaginally assisted by ventouse (suction) and/or forceps were included in the study but not births that progressed to caesarean section. Variations in cord clamping timing do exist at caesarean section and indeed, at the time of the study the local guideline recommended an interval of 2 minutes for operative birth (CDHB, 2018). However, caesarean births were excluded from the TOCC study to further attempt to provide an accurate comparison to a previous cord clamping observational study (Hutton et al., 2013). It is likely that results may have been quite different if the sample had included caesarean
and preterm births or had the study been conducted in a primary midwifery-led setting.

Consultation and ethical approval

Once I had devised a methodology and study methods for the TOCC study, I submitted a proposal to the Midwifery Postgraduate Committee at Otago Polytechnic School of Midwifery for review. On 25 January 2017 the Committee approved the study, with unanimous support to progress to an ethics application.

Cultural considerations

This research impacts on women from all ethnicities including Māori who are tangata whenua of Aotearoa New Zealand. All health researchers should commit to the principles of Te Tiriti o Waitangi (The Treaty of Waitangi) to ensure that Māori individual and collective rights are respected and protected (National Ethics Advisory Committee, 2012). As I am of English and French descent it was important that I collaborated with Māori health advocates to ensure that key Māori cultural issues were being met throughout this project. I consulted the guidelines for researchers on health research involving Māori to ensure that the principles of Te Tiriti o Waitangi (The Treaty of Waitangi) were being upheld throughout the study process (Health Research Council of New Zealand, 2010; Hudson, Milne, Reynolds, Russell, & Smith, 2010).

Consultation occurred with the Otago Polytechnic Kaitohutohu’s office and a response was received on 27 January 2017 in support of an ethics application.

Consultation was then initiated with Te Komiti Whakarite (CDHB Research Consultation with Māori). Their reply on 28 March 2017 included several comments for consideration (see Appendix five). In response to the suggestions from Te Komiti Whakarite, I consulted with the CDHB Kaiawhina Whaea me Nga Peepi (Women’s and Children’s Māori Health Worker) and made the following changes to the information leaflet/consent form for pregnant women:
• the inclusion of contact details for the Kaiawhina Whaea me Nga Peepi so that women had the opportunity to discuss tikanga/customs in relation to Hauora Māori/Māori Health;
• the inclusion of an offer to participants of a support person or whānau member to accompany them during the consent process, in keeping with the values of manaaki/caring and tautako/support;
• a statement reassuring all participants that no identifying data would be used in publications of the TOCC study, and that they were able to withdraw from the study without any adverse effect on their maternity care.

One further suggestion from Te Komiti Whakarite was that collection of ethnicity data as part of the TOCC study would further expand our understanding of experiences that specifically relate to Māori tikanga/customs. Ethnicity is a measure of cultural affiliation as opposed to race, ancestry, nationality or citizenship. Having considered the collection of ethnicity data, and after deliberation and discussion, the suggestion was declined, with an explanation that no demographics were being collected as part of the TOCC study to keep the data simple and manageable and to further protect the anonymity of the participants.

However, it was recognised that as there are significant tikanga/customs related to the care of the pito/cord and whenua/placenta for Māori, the impact on birth practices as a result of this study was likely to be of particular relevance to tangata whenua. Although no data was collected on women’s ethnic background, due to the TOCC study being on a small scale as part of a Masters project, the impact on health outcomes for both Māori and non-Māori families was likely to be positive as an increased interval between birth and cord clamping leads to increased infant iron stores, amongst other numerous benefits. Following completion of the TOCC study, a final report will be submitted to Te Komiti Whakarite, in response to their request and as a way of building relationships between researchers with the hopes of improving Māori health outcomes.

Further cultural considerations were addressed in response to suggestions from the Health and Disability Ethics Committee application as described below.
Health and Disability Ethics Committee (HDEC)

Ethical approval for the TOCC study was sought from the Health and Disability Ethics Committee (HDEC). Ethical approval is required for all research involving human participants in order to safeguard the participants and to promote high-quality research for the well-being of society (National Ethics Advisory Committee, 2012). Despite harm being possible with any research, the potential harms from observational studies are considered to be less than for studies which involve intrusive intervention. The only changes to clinical care for women recruited to the TOCC study were the use of a stopwatch to time birth and cord clamping and the retrospective collection of TOCC-specific data by one of practitioners at the birth.

For the TOCC study, risk was minimised by avoiding recruitment while a woman was in labour and by avoiding the need for an extra person (i.e. a dedicated researcher) in the birthing room. The main potential harm of this study was breach of confidentiality and therefore all efforts were made to de-identify both birthing women and health practitioners.

All resources including information leaflets/consent forms, flyers and data collection tables were submitted as part of the application to HDEC. These resources went through multiple changes until the final versions (see Appendices two and three) were approved.

The design of the initial information leaflet/consent form was based on a HDEC proforma, supplied as part of the application process. Community representatives were involved in the planning of the content of the information leaflet/consent form, as recommended by the National Ethics Advisory Committee (2012). Five women who had given birth within the last eight years were approached to review the draft version of the information leaflet/consent form for pregnant women. This group of women included one who identified as Māori and one for whom English was a second language. Edits were made as a result of their feedback. The final version was checked using the Flesch Reading Ease Score as suggested by HDEC. While there are no precise rules for the readability of information sheets, a Flesch Reading Ease score of 65 or above
usually indicates that a document is written in plain English. The score of the for the initial version of the information leaflet/consent form for pregnant women submitted to HDEC was 69.

Two midwives and one doctor reviewed the information leaflet/consent form for health practitioners. Again, edits were made as a result of their feedback.

After initial submission, the application was reviewed by the Northern B Health and Disability Ethics Committee and provisionally approved pending receipt of further information. The reply from the Committee is included in Appendix six. The request for further information was addressed by replying to each of the ten concerns as listed in Appendix seven.

Following changes to the information leaflet/consent form for pregnant women the Flesch Reading Score was 66.8, which remained acceptable for readability (>65). The new versions of the study material were sent to HDEC on 10 May 2017 along with a letter responding to their concerns.

Following this second submission, approval was received from the HDEC on 19 May 2017 (Reference 17/NTB/82) (see Appendix eight). Two conditions were outlined. Firstly, a standard condition that approval must be sought from the study’s locality (i.e. the tertiary maternity facility). Secondly a non-standard condition that an email address (in addition to a telephone number) be added to the information leaflet/consent forms to allow participants to contact the investigator for a summary of the results. The email address was added to all study material (see appendices two and three) and the locality authorisation process is described below.

Locality Authorisation
Locality Authorisation is required as a prior condition of HDEC approval and must be obtained prior to commencement of a study. The TOCC study was presented to key members of the CDHB Women and Children’s Health Division, including maternity, obstetric and neonatal managers as well as the CDHB Research Office.
One change suggested and implemented was to remove the option of hospital-employed midwives recruiting women to the TOCC study at the time of admission to birthing suite. This was considered to be a risk to maternity care provision as it had the potential to reduce the time that hospital-employed midwives would have for non-research activities. As data collection was likely to take longer when recruitment was reliant solely on LMCs, the study period was extended from 3 to 6 months.

A further change suggested and implemented was a reduction in the number of fields for data collection. This was to reduce research requirements for midwives who already had a considerable workload in the birthing suite. Following discussion with the Director of Midwifery I refined the data collection table from 12 influences to 5 (see Appendix nine).

Following the edits as described above, the Locality Authorisation was signed by key members of the CDHB Women and Children’s Health Division on 22 June 2017 and was submitted to HDEC.

A post approval submission was made to HDEC and approval to proceed was granted on 29 June 2017. The Locality Authorisation and HDEC approval letter was shared with the CDHB Research Office.

Recruitment

Recruitment for the TOCC study commenced in July 2017 following completion of Māori consultation, the ethics application process and locality authorisation. Information leaflets were distributed to practitioners who facilitated births at the study hospital. Each practitioner was asked to sign a form to consent to being observed. As I was employed as a midwifery educator in the study hospital it was possible to have regular contact with LMC midwives and maternity healthcare professionals working on the birthing suite.

Various methods of advertising to LMC midwives and hospital-employed staff were employed, including the use of posters around the maternity unit, information posted via email and social media, articles in the local maternity
unit newsletter and presentation at a regional meeting of the NZ College of Midwives.

LMC’s were provided with copies of the pregnant woman information leaflet/consent form. They were asked to discuss the study with women at a third trimester antenatal visit and if appropriate, ask the woman to sign a consent to being observed.

Pregnant women were also recruited independently via posters and copies of the information leaflet/consent form distributed around antenatal clinics in the study hospital and in community settings.

Women were eligible for recruitment to the TOCC study at point of admission to the birthing suite if:

- Both the woman and her LMC had consented to take part in the study
- The woman was:
  - ≥37 weeks pregnant with a singleton cephalic fetus
  - In labour at the study hospital
  - Not identified as planning to birth by caesarean section or where this was likely due to complications

Data Collection and Analysis

The initial aim was for hospital midwives to be trained as participant observers, and to collect specific data at births attended as a ‘second midwife’. However, due to the acknowledgement that very little training is needed to use a stopwatch, during data collection the most appropriate member of staff present at the birth did the timings. This was often the hospital midwife, but may also have been the LMC or a delegated student (midwifery or medical). The stopwatch was pressed once at the time that the entire baby was born and then again when the first clamp was applied to the cord.
When the stopwatch was successfully used to record the birth to cord clamping interval, one of the health professionals (usually the LMC or hospital midwife) at the birth recorded the time in the notebook along with other TOCC study data. I checked the notebook on a weekly basis and if there was any missing data, I contacted the midwife for clarification. Photographs were taken of the completed pages of the study notebook on a regular basis as a safety measure in case the notebook went missing.

Cord clamping times were recorded from the stopwatch into the study notebook as minutes:seconds:centiseconds. For the purpose of analysis, times have been converted to minutes (e.g. 4 minutes 38 seconds = 4.63 minutes).

Data from the notebook were transferred to an Excel spreadsheet. Excel can be used as an option for relatively straightforward data analysis, such as that collected by the TOCC study (Steen & Roberts, 2011). Summary statistics were calculated. A statistician was consulted for clarification as needed. The sample size was insufficient for statistical analysis and the study was not designed to control for confounding factors.

The cord clamping times were listed in numerical order, representing the range, and the median was calculated to represent the middle data point. The median is a good indicator of the central tendency of data as it is less affected by outliers. In contrast, the mean cord clamping time for the TOCC study is a figure significantly skewed by the births where cord clamping time was within one minute or over ten minutes. Further to this, for cord clamping times over 10 minutes the precise time was not always recorded and thus could not be included in a calculation of the mean. Mean values are more representative when the data is symmetrically distributed (Whitley & Ball, 2002) which is not the case with this TOCC data set.

Interquartile range (IQR) was also used as a descriptor for the TOCC data. When the range of cord clamping times were listed, the middle 50% of the data represents the IQR. As with the median, this gives an indicator of the most likely cord clamping times, excluding the outliers.
Cord clamping times were arranged into categories to explore the data according to frequency distribution. Categories identified were: Less than 1 minute, 1 - 2.99 minutes, 3 - 4.99 minutes, 5 - 9.99 minutes and over 10 minutes. Frequency distributions illustrated the impact on cord clamping times of the different factors investigated (mode of birth, maternal position for birth, practitioners involved in the birth). Pivot tables were used to combine more than one factor and to demonstrate how these combinations impacted the cord clamping times. Results were presented in both tables and figures including bar graphs, box and whisker plots and pivot tables.

**Dissemination of Results**

Once the study was complete, information about the study findings was distributed as follows:

- Verbally and in writing to LMCs and to core midwives and doctors working at the study hospital.

- A summary to any pregnant women who participated in the study and requested a copy.

- A final report to Te Komiti Whakarite and HDEC following examination of thesis.

**Summary**

The TOCC study was successfully completed in compliance with ethical standards and according to protocols outlined above.

The data were analysed using descriptive statistics and are reported in the following results chapter.
Chapter 4: Results

Introduction

The TOCC study was designed to collect data from women who gave birth vaginally at term in a tertiary maternity hospital where a stopwatch was used to time the interval between birth of the baby and time that the first clamp was applied to the umbilical cord (referred to as “cord clamping time” in this analysis). As well as the cord clamping time, data was also collected on the position of the woman at the time of birth, the mode of birth (i.e. spontaneous or instrumental) and the healthcare practitioners involved. In this chapter the results of the TOCC study births are presented and examined using descriptive statistics. The first section describes the overall data. Subsequent sections describe each of the potential influences on cord clamping in turn.

General data

The TOCC study ran from July 2017 to April 2018. Recruitment for the TOCC was slower than anticipated despite efforts to promote the study to LMCS and directly to pregnant women. At the beginning of December 2017, after five months of recruitment, 30 births had been recorded in the study notebook and therefore recruitment was extended for a further 4 months until the end of March 2018 in order to allow more time for the full quota of 100 births.

The first birth to have data recorded was on the 14 August 2017 and the last birth was recorded on 7 April 2018. Data on 56 term vaginal births were collected. There were no twin births in the TOCC study data.

Of the 36 healthcare practitioners who consented to have information collected from births that they facilitated, 31 were midwives and eight were doctors. Most of the practitioners had one birth timed as part of the TOCC study. One midwife had 22 births timed, another midwife had nine births timed, two midwives each had two births timed. The information in the TOCC notebooks
was collected by LMC midwives or hospital midwives, including for births where a doctor was facilitating. In view of the fact that one midwife collected 22/56 births this data has been reviewed in a sub-analysis to determine the level of bias her practice may have had on the overall results.

Consent forms were collected for the 56 women who had their births recorded as part of the TOCC study. It is not known how many women consented to the study and then were not included in data collection (for example, if they birthed by caesarean section or before 37 weeks) as these consent forms were not collected.

Exclusion
One birth was excluded from the data analysis. The words “36 weeker” were documented in the comments box. This was outside the TOCC study criteria of 37 or more weeks gestation. With this birth excluded, the final number of births included for analysis was 55.

Table 1: Exclusions

<table>
<thead>
<tr>
<th></th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Births where consent obtained and data collected</td>
<td>56</td>
</tr>
<tr>
<td>Exclusions (36 week gestation)</td>
<td>1</td>
</tr>
<tr>
<td>Births for analysis</td>
<td>55</td>
</tr>
</tbody>
</table>

Cord clamping times of all study participants

The median umbilical cord clamping time for all births in the TOCC study was 3.5 minutes. For the purpose of analysis, times have been converted from stopwatch display of minutes:seconds:centiseconds to minutes to two decimal places (e.g. 3 minutes 30 seconds = 3.5 minutes).

The range of umbilical cord clamping times in the TOCC data set was from 0.23 minutes to 34 minutes. The interquartile range (IQR) describes the middle 50% of these times. The 25th centile for the TOCC data is 2.18 minutes and the 75th
centile is 5.68 minutes. Therefore, the IQR is 2.18 - 5.68. The IQR can also be represented as a calculated range, i.e. 5.68 – 2.18 = 3.5 minutes.

Table 2 summarises the range, median and IQR for the TOCC data set.

Table 2: Cord clamping time for all study participants (range, median and interquartile range)

<table>
<thead>
<tr>
<th></th>
<th>Cord clamping time (minutes)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Range</strong></td>
<td>0.23 - 34.00</td>
</tr>
<tr>
<td><em><em>Median (IQR</em>)</em>*</td>
<td>3.50 (2.18 - 5.68)</td>
</tr>
</tbody>
</table>

*Interquartile range (25th to 75th centile)

Frequency distribution of cord clamping times

Four babies had their cords clamped less than one minute after their birth and seven babies had their cords clamped over ten minutes after their birth. The majority of babies (64%) had their cords clamped between one and five minutes. This data is outlined in Table 3 below and represented in figure 1.

Table 3: Frequency distribution of cord clamping times

<table>
<thead>
<tr>
<th>Cord clamping time (minutes)</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 1</td>
<td>4 (7%)</td>
</tr>
<tr>
<td>1-2.99</td>
<td>16 (29%)</td>
</tr>
<tr>
<td>3-4.99</td>
<td>19 (35%)</td>
</tr>
<tr>
<td>5-9.99</td>
<td>9 (16%)</td>
</tr>
<tr>
<td>More than 10</td>
<td>7 (13%)</td>
</tr>
<tr>
<td>Total</td>
<td>55</td>
</tr>
</tbody>
</table>
Figure 1: Frequency distribution of cord clamping times

Where the interval between baby’s birth and placental birth was longer than 10 minutes, birth practitioners were asked to record >10 in the study notebook. The reason for not requesting a precise figure was because, in planning for the study, it was anticipated that data collection would usually be done by a hospital-employed midwife and that she or he was unlikely to be able to stay beyond ten minutes to stop the time on the stopwatch due to other birthing suite demands. In reality, it was often the Lead Maternity Carer midwife who used the stopwatch and who was then present beyond the birth of the placenta. When results were analysed, seven births had a cord clamping time of more than ten minutes. Of these seven births, four midwives chose to document the precise time and three midwives chose to document the time as “>10”. As the majority of this data was known, I chose to add actual times to the data set. In the four cases where precise times were recorded, the cord clamping time ranged from 11.85 minutes to 34 minutes. In the three cases where cord clamping time was recorded without an actual number (as >10 minutes), a figure of 11 minutes was used as a code for data analysis.
Where the cord was clamped before the full birth of the baby’s body, e.g. when the cord was wrapped tightly around the baby’s neck, healthcare practitioners were asked to document this as 0 minutes. No births in the TOCC study were recorded as 0 minutes.

**Mode of birth and cord clamping times**

Of the 55 births in the TOCC study, 45 (81.8%) were spontaneous not in water, one (1.8%) birth was spontaneous in water and nine (16.4%) births were instrumental (ventouse or forceps). Mode of birth is represented in Figure 2. Due to the low number of waterbirths, the results for spontaneous births both in and out of water have been combined.

![Figure 2: Mode of birth](image)

The median cord clamping time for a spontaneous birth (3.71 minutes) was longer than for an instrumental birth (2.08 minutes). The IQR for a spontaneous birth (2.67 - 6.23) was wider than for an instrumental birth (0.55 - 2.30), indicating that there was more variation in the cord clamping practice at spontaneous births. The maximum time that a cord was left intact at an instrumental birth was 4.15 minutes, whereas for a spontaneous birth the maximum time was 34 minutes. This data is included in table 4.
Table 4: Cord clamping times according to mode of birth (range, median and interquartile range)

<table>
<thead>
<tr>
<th>Mode of birth</th>
<th>n (%)</th>
<th>Range</th>
<th>Median (IQR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spontaneous (in or out of water)</td>
<td>46 (83.6%)</td>
<td>0.33 - 34.00</td>
<td>3.71 (2.67 – 6.23)</td>
</tr>
<tr>
<td>Instrumental (ventouse or forceps)</td>
<td>9 (16.4%)</td>
<td>0.23 - 4.15</td>
<td>2.08 (0.55 - 2.30)</td>
</tr>
</tbody>
</table>

Spontaneous births were most likely (29/46: 63%) to be followed by a cord clamping time of between 1 and 5 minutes. Instrumental births were most likely (7/9: 78%) to be followed by a cord clamping time of between 0 and 3 minutes. None of the births in the instrumental group had a cord clamping time of over 5 minutes whereas 35% of the births in the spontaneous group had a cord clamping time of over 5 minutes. This data is represented in table 5 and figure 3.

Table 5: Frequency distribution of cord clamping times according to mode of birth

<table>
<thead>
<tr>
<th>Cord clamping time category (minutes)</th>
<th>Spontaneous n (%)</th>
<th>Instrumental n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 1</td>
<td>1 (2%)</td>
<td>3 (33%)</td>
</tr>
<tr>
<td>1- 2.99</td>
<td>12 (26%)</td>
<td>4 (45%)</td>
</tr>
<tr>
<td>3- 4.99</td>
<td>17 (37%)</td>
<td>2 (22%)</td>
</tr>
<tr>
<td>5-9.99</td>
<td>9 (20%)</td>
<td>0</td>
</tr>
<tr>
<td>More than 10</td>
<td>7 (15%)</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>46</td>
<td>9</td>
</tr>
</tbody>
</table>
Figure 3: Frequency distribution of cord clamping times according to mode of birth

Maternal position for birth and cord clamping times

The woman at the time of birth was most likely to be in a semi recumbent position (22/55; 40%) and least likely to be standing (2/55; 4%). See figure 3 for the frequency distribution of birth positions.
Maternal birthing positions that are most similar were combined to further analyse cord clamping times: semi-recumbent combined with seated upright; kneeling combined with standing.

When birth positions are combined, the seated position (either seated upright or semi-recumbent) accounts for almost half (47%) of all births in the TOCC study. The birth position with the highest median cord clamping time of 6.37 minutes was side lying. There was a similar median cord clamping time for women who birthed in kneeling/standing positions (3.93 minutes) and seated upright/semi-recumbent positions (3.47 minutes). The IQR was wider for kneeling/standing (3.27 - 9.17) than for seated upright/semi-recumbent (2.43 - 4.82). The babies born to mothers who were in lithotomy position had the lowest median cord clamping time of 2.24 minutes and a narrow IQR of 1.87 - 3.50. Table 6 details the median and quartile analysis for these four categories of birth positions.
Table 6: Cord clamping times according to maternal position for birth (range, median and interquartile range)

<table>
<thead>
<tr>
<th>Maternal position for birth</th>
<th>n (%)</th>
<th>Range</th>
<th>Median (IQR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Seated (Upright or recumbent)</td>
<td>26 (47%)</td>
<td>0.55 - 11.85</td>
<td>3.47 (2.43 - 4.82)</td>
</tr>
<tr>
<td>Lithotomy</td>
<td>12 (22%)</td>
<td>0.23 - 12.27</td>
<td>2.24 (1.87 - 3.50)</td>
</tr>
<tr>
<td>Kneeling or Standing</td>
<td>10 (18%)</td>
<td>1.47 - 34.00</td>
<td>3.93 (3.27 - 9.17)</td>
</tr>
<tr>
<td>Side-lying</td>
<td>7 (13%)</td>
<td>0.33 - 33.63</td>
<td>6.37 (4.15 - 9.48)</td>
</tr>
</tbody>
</table>

Of the four babies who had their cords clamped before one minute, three were in seated or lithotomy groups and one was in the side-lying group. No babies in the kneeling/standing group had their cords clamped before one minute. In all of the birth positions, there is at least one birth where the cord was left intact for over 10 minutes.

A large percentage (87%) of births in the side lying position had a cord clamping time of over 3 minutes, as well as 80% in the kneeling/standing group. Whereas a lower percentage (41%) of births in the lithotomy group had a cord clamping time of over 3 minutes. It is interesting to note that, despite lithotomy being mostly used for complicated births, one of these babies had a cord left intact for an extended time of 12.27 minutes.

Table 7 and figure 5 illustrate frequency data for maternal birth position.
Table 7: Frequency distribution of cord clamping times according to maternal position for birth

<table>
<thead>
<tr>
<th>Cord clamping time category (minutes)</th>
<th>Seated n (%)</th>
<th>Lithotomy n (%)</th>
<th>Kneeling or Standing n (%)</th>
<th>Side-lying n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 1</td>
<td>1 (4%)</td>
<td>2 (17%)</td>
<td>0</td>
<td>1 (14%)</td>
</tr>
<tr>
<td>1- 2.99</td>
<td>9 (35%)</td>
<td>5 (42%)</td>
<td>2 (20%)</td>
<td>0</td>
</tr>
<tr>
<td>3- 4.99</td>
<td>10 (38%)</td>
<td>3 (25%)</td>
<td>4 (40%)</td>
<td>2 (29%)</td>
</tr>
<tr>
<td>5-9.99</td>
<td>4 (15%)</td>
<td>1 (8%)</td>
<td>2 (20%)</td>
<td>2 (29%)</td>
</tr>
<tr>
<td>More than 10</td>
<td>2 (8%)</td>
<td>1 (8%)</td>
<td>2 (20%)</td>
<td>2 (29%)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>26</strong></td>
<td><strong>12</strong></td>
<td><strong>10</strong></td>
<td><strong>7</strong></td>
</tr>
</tbody>
</table>

Figure 5: Frequency distribution of cord clamping times according to maternal position for birth
Birthing practitioner and cord clamping times

The majority of births (40/55: 73%) in the TOCC study were facilitated by a midwife. Doctors facilitated 14/55 (25%) of the births. One birth was facilitated by a midwifery or medical student under the supervision of a registered practitioner. Birth practitioner numbers are illustrated in figure 6.

![Practitioner facilitating birth](image)

**Figure 6: Practitioner facilitating birth**

In the majority of births (48/55: 87%) the practitioner who clamped the cord was the same as the practitioner who facilitated the birth. The seven cases where there was a change of practitioner between birth and cord clamping have been recorded in table 8.

<table>
<thead>
<tr>
<th>Was the cord clamped by the same practitioner than practitioner who clamped cord.</th>
<th>n (%)</th>
<th>Birth facilitator and cord clamper</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>48 (87%)</td>
<td>Midwife then midwife</td>
<td>35</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Doctor then doctor</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Student then student</td>
<td>1</td>
</tr>
<tr>
<td>No</td>
<td>7 (13%)</td>
<td>Doctor then midwife</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Midwife then doctor</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Midwife then student</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Midwife then partner</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>55 (100%)</td>
<td></td>
<td>55</td>
</tr>
</tbody>
</table>
As it is normal practice for the practitioner who facilitated the birth to be the one who led the decision as to when to clamp the cord, further analysis of cord clamping timing is presented according to the practitioner who facilitated the birth and not the one who clamped the cord.

Midwives had a median cord clamping time of 4.06 minutes (IQR: 2.68 - 6.65) and doctors had a median cord clamping time of 2.13 minutes (IQR: 1.48 - 3.28). Table 9 outlines the range, median and IQR for different practitioner groups.

Table 9: Cord clamping times according to the practitioner who facilitated the birth (range, median and interquartile range).

<table>
<thead>
<tr>
<th>Practitioner</th>
<th>n (%)</th>
<th>Range</th>
<th>Median (IQR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Midwife</td>
<td>40 (73%)</td>
<td>0.33 - 34.00</td>
<td>4.06 (2.68 – 6.65)</td>
</tr>
<tr>
<td>Doctor</td>
<td>14 (25%)</td>
<td>0.23 - 12.27</td>
<td>2.13 (1.48 - 3.28)</td>
</tr>
<tr>
<td>Student</td>
<td>1 (2%)</td>
<td>N/A</td>
<td></td>
</tr>
</tbody>
</table>

Three of the births facilitated by a doctor had a cord clamping time of under one minute whereas only one birth facilitated by a midwife had this degree of early cord clamping. Six of the births facilitated by a midwife had a cord clamping time of over ten minutes, whereas only one of the births facilitated by a doctor had this degree of extended cord clamping time. Midwives were most likely (35%) to clamp the cord in the 3-4.99 minute category, whereas doctors were most likely (43%) to clamp the cord in the 1-2.99 minute category. Table 10 and figure 7 show how cord clamping time categories for different practitioner groups.
Table 10: Frequency distribution of umbilical cord clamping times, according to the practitioner who facilitated the birth

<table>
<thead>
<tr>
<th>Cord clamping time (minutes)</th>
<th>Midwife n (%)</th>
<th>Doctor n (%)</th>
<th>Student n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 1</td>
<td>1 (2.5%)</td>
<td>3 (21%)</td>
<td></td>
</tr>
<tr>
<td>1- 2.99</td>
<td>10 (25%)</td>
<td>6 (43%)</td>
<td></td>
</tr>
<tr>
<td>3- 4.99</td>
<td>14 (35%)</td>
<td>4 (29%)</td>
<td></td>
</tr>
<tr>
<td>5-9.99</td>
<td>9 (23%)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>More than 10</td>
<td>6 (15%)</td>
<td>1 (7%)</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>40</td>
<td>14</td>
<td>1</td>
</tr>
</tbody>
</table>

Figure 7: Frequency distribution of cord clamping times according to practitioner who facilitated the birth (not including one birth facilitated by a student)
A sub-analysis was made of the cord clamping times for the one midwife who consented women for 22/55 of the TOCC births. This midwife was not necessarily the practitioner who facilitated every one of these 22 births. Care would have been handed over to an obstetric doctor if there were complications and/or the neonatal team may have been present and directed earlier cord clamping. This midwife recorded that 6/22 (27%) of the births where she had obtained consent from the woman were facilitated by a doctor and 16/22 (73%) by a midwife. This is a similar proportion to the figures in Table 9. The median cord clamping time for the 22 births recorded by this midwife was 3.55 minutes (IQR: 2.50-5.68) which resembles the median (IQR) for the 34 births which were not recorded by this midwife of 3.49 minutes (2.10-5.47).

A box and whisker plot (see figure 8) highlights interprofessional and intraprofessional variation in the timing of cord clamping. The box outlines the upper (75th) and lower (25th) centiles of cord clamping timings and the line across the middle of the box represents the median. The lines extending vertically from each box are the whiskers and these extend to the minimum and maximum times of cord clamping for each of the professional groups, excluding outliers. The Excel software has represented extreme outliers as dots and therefore the median and centile data represented by the boxes are slightly different to that presented in table 10. By excluding the outliers, the box and whisker plot provides a better representation of usual practice.

This box and whisker plot shows that midwives clamped cords later and with more variation than doctors. Both practitioner groups had similar minimum values for cord clamping timing (represented by the lower end of the whisker) but the midwives had significantly higher upper value (represented by the upper end of the whisker).
Neonatal team at birth and cord clamping times

The neonatal team was recorded as being present at the birth or within the first five minutes. At 20/55 (36.4%) births the neonatal team were present. This is represented in figure 9.

Figure 8: Box and whisker plot of cord clamping times according to practitioner who facilitated the birth

Figure 9: Neonatal team presence at the birth or within five minutes
The median cord clamping time for births where the neonatal team were not present was 4.73 minutes whereas for births where they were present the median was lower at 2.13 minutes. The IQR for births where the neonatal team were not present (IQR: 3.32 - 8.26) was wider than for those where they were present (IQR: 1.28 - 3.27). The differences between births where the neonatal team were present or not present are described in table 11 according to range, median and IQR.

Table 11: Cord clamping times according to neonatal team presence (range, median and interquartile range)

<table>
<thead>
<tr>
<th>Neonatal Team</th>
<th>n (%)</th>
<th>Range</th>
<th>Median (IQR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neonatal team not present</td>
<td>35 (63.6%)</td>
<td>1.47 - 34.00</td>
<td>4.73 (3.32 - 8.26)</td>
</tr>
<tr>
<td>Neonatal team present</td>
<td>20 (36.4%)</td>
<td>0.23 - 5.68</td>
<td>2.13 (1.28 - 3.27)</td>
</tr>
</tbody>
</table>

All of the births where the cord was clamped before one minute were in cases where the neonatal team were present. All of the births where the cord was clamped over ten minutes after the birth were in cases where the neonatal team were not present. Where the neonatal team were not present at the birth, 70% of the babies had their cords left intact for over 3 minutes. For babies where the neonatal team were present at the birth, 30% of the babies had their cords left intact for over 3 minutes. This data is illustrated in table 12 and figure 10.
Table 12: Frequency distribution of cord clamping times according to neonatal team presence

<table>
<thead>
<tr>
<th>Cord clamping time (minutes)</th>
<th>Neonatal team not present</th>
<th>Neonatal team present</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 1</td>
<td>0</td>
<td>4 (20%)</td>
</tr>
<tr>
<td>1- 2.99</td>
<td>6 (17%)</td>
<td>10 (50%)</td>
</tr>
<tr>
<td>3- 4.99</td>
<td>14 (40%)</td>
<td>5 (25%)</td>
</tr>
<tr>
<td>5-9.99</td>
<td>8 (23%)</td>
<td>1 (5%)</td>
</tr>
<tr>
<td>More than 10</td>
<td>7 (7%)</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>35</strong></td>
<td><strong>20</strong></td>
</tr>
</tbody>
</table>

Figure 10: Frequency distribution of cord clamping times according to neonatal team presence
A box and whisker plot (Figure 11) shows that the variation in cord clamping times for births where the neonatal team was not present is wider than when they were present, with the orange “no” box being much larger than the blue “yes” box. The orange box representing the IQR “neonatal team not present” (excluding the dot point for extreme outliers) rests above the blue box for births where neonatal team were present as the cord clamping times for these births were longer. Also, of note, there is no dot point for the blue “neonatal team present” box as there were no outliers, the upper limit of the range is represented by the top of the whisker at 5.68 minutes.

![Box and whisker plot of cord clamping times according to neonatal team presence](image)

**Figure 11: Box and whisker plot of cord clamping times according to neonatal team presence**

**Further Comparisons**

Pivot tables allow the TOCC data to be explored in more depth, combining more than one influence on the cord clamping times.

When looking at mode of birth and neonatal team presence, the neonatal team were present at 100% of instrumental births. They were present at 11/46 (24%) of the spontaneous births. At instrumental births, with the neonatal team present, the cord clamping time was most likely (4/9; 44%) to be in the 1-3
minute category. When the neonatal team were present at a spontaneous birth, the cord clamping time was also most likely (6/11; 54%) to be in the 1-3 minute category. When the neonatal team were not present at a spontaneous birth, the cord clamping time was most likely (14/35; 40%) to be in the 3-5 minute category. Table 13 presents the total number of births when mode of birth and NICU presence are included.

Table 13: Number of births in each time category according to mode of birth and neonatal team presence

<table>
<thead>
<tr>
<th></th>
<th>Cord clamping time (minutes)</th>
<th>Less than 1</th>
<th>1-2.99</th>
<th>3-4.99</th>
<th>5-9.99</th>
<th>More than 10</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Instrumental</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>9</td>
</tr>
<tr>
<td>Neonatal team present</td>
<td></td>
<td>3</td>
<td>4</td>
<td>2</td>
<td></td>
<td></td>
<td>9</td>
</tr>
<tr>
<td><strong>Spontaneous</strong></td>
<td></td>
<td>1</td>
<td>12</td>
<td>17</td>
<td>9</td>
<td>7</td>
<td>46</td>
</tr>
<tr>
<td>Neonatal team not present</td>
<td></td>
<td>6</td>
<td>14</td>
<td>8</td>
<td>7</td>
<td></td>
<td>35</td>
</tr>
<tr>
<td>Neonatal team present</td>
<td></td>
<td>1</td>
<td>6</td>
<td>3</td>
<td>1</td>
<td></td>
<td>11</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td>4</td>
<td>16</td>
<td>19</td>
<td>9</td>
<td>7</td>
<td>55</td>
</tr>
</tbody>
</table>

Births facilitated by a doctor had a neonatal team member present in 11/14 (79%) of cases. Births facilitated by a midwife had a neonatal team member present in 9/40 (23%) of cases.

With a doctor facilitating the birth and a neonatal team member present, the cord clamping time was most likely (5/11; 45%) to be in the 1-3 minute category and there were no births with a cord clamping time over 5 minutes. With a midwife facilitating the birth and a neonatal team member present, the cord clamping time was also most likely (5/9; 56%) to be in the 1-3 minute category and there was only one birth with a cord clamping time over 5 minutes.
However, when a midwife was facilitating the birth and the neonatal team were not present, the cord clamping time was most likely (12/31; 39%) to be in the 3-5 minute category and there were 14/31 (45%) births where the cord clamping time was over 5 minutes. Table 14 outlines the number of births in each time category according to neonatal presence and birth practitioner.

Table 14: Number of births in each time category according to practitioner who facilitated the birth and neonatal team presence

<table>
<thead>
<tr>
<th>Cord clamping time (minutes)</th>
<th>Less than 1</th>
<th>1-2.99</th>
<th>3-4.99</th>
<th>5-9.99</th>
<th>More than 10</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doctor</td>
<td>3</td>
<td>6</td>
<td>4</td>
<td>1</td>
<td>14</td>
<td>1</td>
</tr>
<tr>
<td>Neonatal team not present</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Neonatal team present</td>
<td>3</td>
<td>5</td>
<td>3</td>
<td>1</td>
<td>11</td>
<td>1</td>
</tr>
<tr>
<td>Midwife</td>
<td>1</td>
<td>10</td>
<td>14</td>
<td>9</td>
<td>6</td>
<td>40</td>
</tr>
<tr>
<td>Neonatal team not present</td>
<td>5</td>
<td>12</td>
<td>8</td>
<td>6</td>
<td>31</td>
<td>1</td>
</tr>
<tr>
<td>Neonatal team present</td>
<td>1</td>
<td>5</td>
<td>2</td>
<td>1</td>
<td>9</td>
<td>1</td>
</tr>
<tr>
<td>Student</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>4</td>
<td>16</td>
<td>19</td>
<td>9</td>
<td>7</td>
<td>55</td>
</tr>
</tbody>
</table>

Overall, the median cord clamping time was likely to be longer when the woman had a spontaneous vaginal birth rather than an instrumental birth; when she birthed in a side-lying or upright position rather than a seated position; when a midwife facilitated the birth rather than a doctor and when there was no neonatal team present at the birth. This is represented in table 15 below.
Table 15: Comparison Table of median and range of cord clamping times by subgroups

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>%</th>
<th>Median</th>
<th>IQR</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mode of Birth</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spontaneous (including in water)</td>
<td>9</td>
<td>16</td>
<td>3.71</td>
<td>2.67-6.23</td>
</tr>
<tr>
<td>Instrumental (ventouse and forceps)</td>
<td>46</td>
<td>84</td>
<td>2.08</td>
<td>0.55-2.30</td>
</tr>
<tr>
<td><strong>Birth Position</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kneeling or Standing</td>
<td>10</td>
<td>18</td>
<td>3.93</td>
<td>3.27 - 9.17</td>
</tr>
<tr>
<td>Side-lying</td>
<td>7</td>
<td>13</td>
<td>6.37</td>
<td>4.15-9.48</td>
</tr>
<tr>
<td>Seated (upright or recumbent)</td>
<td>26</td>
<td>47</td>
<td>3.47</td>
<td>2.43-4.82</td>
</tr>
<tr>
<td>Lithotomy</td>
<td>12</td>
<td>22</td>
<td>2.24</td>
<td>1.87-3.50</td>
</tr>
<tr>
<td><strong>Birth facilitated by</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Midwife</td>
<td>40</td>
<td>73</td>
<td>4.06</td>
<td>2.68 – 6.65</td>
</tr>
<tr>
<td>Doctor</td>
<td>14</td>
<td>25</td>
<td>2.13</td>
<td>1.48 - 3.28</td>
</tr>
<tr>
<td>Student</td>
<td>1</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Neonatal team present</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>35</td>
<td>63.6</td>
<td>4.73</td>
<td>3.32 - 8.26</td>
</tr>
<tr>
<td>Yes</td>
<td>20</td>
<td>36.4</td>
<td>2.13</td>
<td>1.28 - 3.27</td>
</tr>
</tbody>
</table>

Summary

Cord clamping timing varied significantly in the TOCC study from a minimum of 14 seconds to a maximum of 34 minutes. The overall median cord clamping time for the 55 births where a stopwatch was used was 3.5 minutes and the IQR was 2.18 - 5.68. The median cord clamping time was likely to be longer when the woman had a spontaneous vaginal birth rather than an instrumental birth; when she birthed in a side-lying or upright position rather than a seated position; when a midwife facilitated the birth rather than a doctor and when there was no neonatal team present at the birth.
This chapter has described cord clamping times at 55 term vaginal births in a tertiary New Zealand hospital and explored which factors may have an influence on birthing practice. In the following chapter, the results will be discussed in relation to the wider literature on cord clamping, with a consideration of the implications for practice and for future research.
Chapter 5: Discussion

Introduction

This chapter will discuss the TOCC study findings in relation to the existing literature on umbilical cord clamping, along with implications for further research.

Cord clamping was one of the earliest interventions to be introduced to birthing practice. Immediate clamping became widely adopted in the 1960’s as part of active management of the third stage of labour, introduced to reduce adverse outcomes from postpartum haemorrhage. However, the review of the literature in chapter two demonstrated multiple benefits for infants who have deferred cord clamping without an increase in maternal haemorrhage rates.

In the TOCC study we were able to accurately record the interval between birth and cord clamping at 55 term vaginal births in a tertiary New Zealand hospital. The median was 3.5 minutes and the IQR was 2.18 - 5.68 minutes, while the shortest cord clamping time was 0.23 minutes and the longest was 34 minutes. These results are indicative of a move towards longer cord clamping times in practice. Newborns in the TOCC study were more likely to receive a prolonged period of cord clamping if their mother birthed in an upright or side-lying position rather than seated position, when the birth was spontaneous rather than assisted by forceps or ventouse, where the birth was facilitated by a midwife rather than a doctor and where there was no neonatal team in attendance. Some reasons as to why cord clamping times differ according to mode of birth, maternal position and practitioner will be examined in this discussion chapter.

Aside from the factors that were measured, cord clamping practice is entwined in many other aspects of birth practice, including:

- Adherence to policies and guidelines
- The need for newborn resuscitation
The presence of a nuchal cord requiring pre-birth cord clamping
- Gestational age at time of birth
- The position of the baby immediately after the birth
- Choice of active or physiological placental birth
- Interprofessional teamwork

This chapter will discuss cord clamping times in the 55 births in the TOCC study with reference firstly to optimal time for clamping, as suggested in the literature search, and then in relation to each of the measured influences plus the factors listed above. The discussion will include an exploration of the ways in which practice within the New Zealand tertiary setting may differ from practice elsewhere.

Optimal cord clamping times

The median cord clamping time in this study was 3.5 minutes which demonstrates a move away from immediate cord clamping. However, the optimal time for cord clamping is unknown. Blood continues to flow through the cord after the birth accounting for approximately one-quarter to one-third of potential total blood volume in term babies (Farrar et al., 2011; Yao et al., 1968). Most studies define immediate cord clamping as within the first 15 seconds of birth, with delayed/deferred cord clamping ranging from one to five minutes post birth (if a time value was used) or sometimes defined as the cord being clamped after pulsations ceased and/or after placental birth (Hutton & Hassan, 2007; McDonald et al., 2013).

It is still not clear whether the optimal time for cord clamping should be an actual time point, such as one minute or five minutes, or whether it should be related to other factors such as neonatal breathing efforts. Physiological studies on humans and animals demonstrate that placental transfusion is dependent on a number of factors and therefore a “time value” for optimal cord clamping is individual for each newborn. There is a move to use terminology such as “Wait for White”, to recommend waiting until the cord is flaccid and empty of blood (Burleigh, 2016), “Aerate-Breathe-Clamp” or “Physiological-Based Cord Clamping” to recommend individualised practice according to the newborn response to extra-uterine transition (Knol et al., 2019).
Even the terminology has changed over time, with the word “late” being replaced by delayed or deferred clamping and, more recently, optimal clamping. This terminology was examined as part of a survey of UK midwives and obstetricians (Farrar et al., 2010). The authors referenced the Oxford English Dictionary which defines “late” as “after the proper time”. As this may have negative connotations they suggested that the term “deferred” is more neutral in tone. Even the terminology “optimal” has been questioned as it lacks definition (Edwards & Wickham, 2018).

A 1960's study which measured the residual blood volume in the placenta following cord clamping times ranging from five to 180 seconds, found that the majority of blood is transferred to the newborn in the first minute after birth and that placental transfusion is completed in most cases by three minutes (Yao et al., 1969). More recently though, an ultrasound study showed that blood may continue to move through the cord, both in arteries and the vein, up to and beyond five minutes post-birth (Boere et al., 2015).

The largest randomised controlled trial on cord clamping for term babies used a three minute cut off to show increased infant iron stores at four months and improved childhood neurodevelopmental outcomes at four years (Andersson et al., 2011, 2015). Another small randomised controlled study examined an even longer birth to cord clamping interval and demonstrated improved brain myelination at 4 months of age for term babies that had over 5 minutes of placental transfusion (Mercer et al., 2018). Many other studies looked at the outcomes following shorter periods of placental transfusion of 60 seconds, particularly when considering cord clamping for premature babies (Rabe et al., 2019). Animal experiments on newborn lambs indicate that a delay longer than 60 seconds may assist in cardiopulmonary stabilisation without necessarily increasing blood volumes (Bhatt et al., 2013).

The existing literature has not defined an optimal time for cord clamping. The data from the TOCC study was divided into five categories of time and presented as a frequency distribution. Of the 55 term vaginal births, 7% of newborns had cords clamped at less than one minute, 29% at 1-3 minutes, 35%

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at 3-5 minutes, 16% at 5-10 minutes and 13% at over ten minutes (see table 3 and figure 1). These results emphasise that the most common cord clamping time category was 3-5 minutes which is in line with a range of research that identifies improved neonatal outcomes when the cord is clamped in this time frame.

Mode of birth

Of the term vaginal births measured for the TOCC study, 46/55 (84%) were spontaneous (of which one was a waterbirth) and 9/55 (16%) were instrumental (either ventouse or forceps) (refer to table 4). This is a good representation of total births in the TOCC study hospital, in which 81% of all vaginal births were spontaneous and 19% instrumental (CDHB, 2018). Similarly, in a study of cord clamping timing at term vaginal births in a tertiary hospital in Canada 75/89 (84%) were spontaneous and 14/89 (16%) were instrumental (Hutton et al., 2013).

Instrumental birth is indicated to expedite birth in cases of suspected or anticipated fetal compromise and/or for delay in the second stage of labour (RANZCOG, 2019). In these cases, earlier clamping of the umbilical cord is often performed to provide essential care which may be more effective after separation of the mother-baby dyad. In the TOCC study, the median cord clamping time for a spontaneous birth (3.71 minutes) was longer than for an instrumental birth (2.08 minutes). The maximum time that the cord was left intact at a spontaneous birth was 34 minutes, compared to 4.15 minutes for an instrumental birth. In the Canadian study, which informed the TOCC study, the median cord clamping time was also longer if the birth was spontaneous (19 seconds) than if it was assisted by ventouse of forceps (7 seconds) (Hutton et al., 2014).

The neonatal team were present at 100% of TOCC instrumental births and only 25% of the TOCC spontaneous births (refer to table 13). Neonatal resuscitation is more likely to be necessary after an instrumental birth, particularly when fetal compromise has already been diagnosed (ANZCOR, 2017). In addition, fetal complications such as shoulder dystocia, subgaleal haemorrhage and
intracranial haemorrhage are more common with instrumental births and warrant extra staff to be available to care for the neonate (RANZCOG, 2019). The local guideline for the TOCC hospital identifies instrumental births as a reason for calling the neonatal team to attend (CDHB, 2019).

Of the four occasions where the cord was clamped under one minute, three were at instrumental births and only one was at a spontaneous birth (refer to table 13). This would indicate that instrumental births are more likely to result in an early interruption of placental transfusion to allow for neonatal resuscitation (CDHB, 2014). In the future, intact cord resuscitation may be possible at instrumental births at the TOCC study hospital. Other studies have demonstrated this to be safe and acceptable to parents and clinicians (Katheria et al., 2018; Thomas et al., 2014).

The one waterbirth observed in the TOCC study had a cord clamping time of 1.83 minutes with no neonatal team in attendance. No studies have examined differences in cord clamping times for waterbirths compared with non-water births (Cluett, Burns, & Cuthbert, 2018). Knowledge on this topic would be enhanced by future observational studies to determine if cord clamping practice differs when babies are born immersed in water as well as physiological studies to determine if placental blood flow differs when the cord remains underwater.

Other reasons why the cord may be clamped earlier after an instrumental birth, such as maternal position (lithotomy), practitioner (doctor) and third stage management (active) will be discussed below.

Maternal position for birth

In modern Western birthing environments, where a bed is often a dominant feature in the room, women are most likely to adopt a recumbent or lithotomy position for birth (Gupta & Nikodem, 2000; Priddis, Dahlen, & Schmied, 2012b). A RANZCOG statement on routine intrapartum care recommends that practitioners encourage free movement as long as it does not compromise maternal and fetal observations (RANZCOG, 2017b). The birthing women in the TOCC study were most likely to be in a semi-recumbent position (22/55;
When the semi-recumbent group was added to the lithotomy (12/55; 22%) and seated upright (4/55; 7%) groups, this then accounted for well over half (38/55; 69%) of all births. Lithotomy is a position where women are in either recumbent or seated positions with their legs separated, flexed and supported in raised stirrups. Lithotomy was used for 8/9 instrumental births, with one instrumental birth occurring with the woman in the semi-recumbent position. Of the four spontaneous births in lithotomy position, three were facilitated by a doctor. For one of the spontaneous births in lithotomy position the cord was clamped by a doctor at 12.27 minutes, which is a positive indicator that even births that are complicated can include prolonged period of placental transfusion.

Median (IQR) cord clamping times were 3.47 (2.43 - 4.82) minutes for the combined seated / recumbent positions and 2.24 (1.87 - 3.50) minutes for lithotomy (refer to table 7). Both of these groups had shorter cord clamping times than for the kneeling standing group (3.93 (3.27 - 9.17) minutes) and for the side-lying group (6.37 (4.15 - 9.48) minutes). As early cord clamping is linked with births where neonatal compromise is suspected, then it makes sense that births where women who require more intensive monitoring of the fetal heart are more likely to be encouraged into recumbent positions and early clamping is more likely be performed. Conversely, it may be that the position that a woman adopts increases the risk to the fetus. In semi recumbent and lithotomy positions the weight of the pregnant uterus on the inferior vena cava may restrict fetal oxygenation (Gupta & Nikodem, 2000).

Upright positions such as kneeling or standing accounted for 10/55 (18%) of TOCC births. This is a similar rate as another New Zealand tertiary hospital which recorded a 23% rate of upright position for birth (Farry, 2015). In a comparative cord clamping study which observed births in a tertiary hospital in Canada, there were no recorded births in the upright position, all women birthed in a recumbent or seated position (Hutton et al., 2013). This may reflect the high number of births facilitated by doctors (87%) in the Canadian study.

Recumbent positions are favoured by a medical model for birth which may be associated with their involvement in more complicated births (Gupta &
Midwives are more likely to be involved in uncomplicated births where physiological birthing positions are more common. Midwifery-led care is more likely to recognise the physiological advantages of women adopting any position that allows them to cope better with pain and to experience less intervention (Priddis et al., 2012b). In studies comparing different birth settings, New Zealand women were twice as likely to adopt an upright birthing posture when in midwifery-led care (55%) than in a shared care tertiary facility (23%) (Farry, 2015). There were similar differences for Australian women where an ethnographic study recorded 82% of women adopting upright positions in a midwifery-led setting and only 25% in a “delivery ward” setting. (Priddis, Dahlen, & Schmied, 2012a).

In the TOCC study, the position associated with the longest interval between birth and cord clamping (median 6.37; IQR 4.15 - 9.48) was side-lying, adopted by women at 7/55 (13%) births. In the author’s experience, births in the side-lying positions are often followed by an initial period of the newborn lying alongside the woman, on a flat surface and in skin-to-skin contact. This flat surface allows the birth practitioner to position the baby with an effective open airway and thus to encourage newborn spontaneous breathing with an intact cord without having to disturb maternal or infant position. In contrast, with seated/recumbent positions the newborn will lie on the mother’s abdomen which is less likely to be an effective flat surface to assist airway opening and is more likely to be interrupted if the woman has to move.

Early clamping is often performed to move the newborn to a flatter warmed surface for resuscitation if the baby is slow to initiate effective breathing due to obstructed airway. This is evident in the TOCC study as the neonatal team attended all births where the cord was clamped early (i.e. under one minute). In kneeling or standing birthing positions the newborn is usually passed through the woman’s legs to rest either on a surface in front of the woman or to be held by the women against her abdomen. If the woman holds the baby, effective positioning for opening the airway is more challenging than if the baby remains on a flat surface. If the most common reason behind early cord clamping is the need for newborn resuscitation, which is initiated by an effective open airway, this may explain to a certain degree why only 55% of
babies in the seated/recumbent/lithotomy group had a cord clamping time of over 3 minutes compared to 80% in the kneeling/standing group and 86% in the side-lying group.

In summary, when observing maternal position for birth as part of the TOCC study it is not possible to determine how much the maternal position affects timing of cord clamping or how much the position is part of a complicated birth where resuscitation is more likely and therefore linked with early clamping.

Practitioner attendance at the birth (midwifery, obstetric and neonatal)

In New Zealand 94.2% of women who registered with a Lead Maternity Carer (LMC) chose a midwife as their LMC, 5.6% chose an obstetrician and 0.2% chose a General Practitioner (GP) (Ministry of Health (Manatū Hauora), 2019). Where birth is uncomplicated it will generally be the LMC, a back-up LMC if they are unavailable, or a student who catches the baby. If a woman births rapidly before her LMC arrives at the tertiary hospital, a hospital midwife will facilitate the labour and birth. If the birth is complicated, for example if the birth requires assistance with ventouse or forceps, then a hospital doctor from the obstetric team will facilitate the birth. In the TOCC study, midwives facilitated 40/55 (73%) of the births, doctors facilitated 14/55 (25%) and one birth was facilitated by a student under the supervision of a registered healthcare practitioner. The median (IQR) differed considerably between professional groups, with midwives cutting the cord at a mean of 4.06 (2.68 – 6.65) minutes after the birth and doctors at 2.13 (1.48 - 3.28) minutes. In a New Zealand context, this practitioner variation is predominantly driven by the model of care. Most births facilitated by doctors have some degree of complication that may necessitate early separation of the mother-baby dyad to provide resuscitative measures. Midwives have more opportunity to vary their cord clamping practice as they attend both complicated and uncomplicated births.
In an observational study set in a tertiary hospital in Canada, the proportions of practitioners providing care differed considerably from the New Zealand findings: 46 / 100 births were attended by obstetricians, 41 / 100 by family physicians and 13 / 100 by midwives (Hutton et al., 2013). In a New Zealand setting, the majority of women (94.2%) choose a midwife as their lead maternity carer (Ministry of Health (Manatū Hauora), 2019), whereas in the Canadian setting, the majority of women (93%) have an obstetrician or family physician (General Practitioner) as their lead maternity carer (Guliani, 2015). In the Hutton et al. study, wide inter- and intra-professional difference in cord clamping times was noted, similar to those in the TOCC study, as illustrated in Figures 7 and 8. The data presented by Hutton et al. showed that obstetricians clamped the cord the earliest and with less variation than the midwives and the family physicians. In this study, set over a decade ago, all cord clamping times were considerably shorter than in the TOCC study with the median (5th, 95th percentiles) for obstetricians found to be 12 (3, 107) seconds, for family physicians 19 (6, 325) seconds and for midwives to be 81 (6, undefined) seconds.

The practitioner who clamps the cord is usually of the same professional group as the practitioner who facilitates the birth. This was the case in 87% of the TOCC study births. In a tertiary hospital, the practitioner who clamps the umbilical cord is often part of an interprofessional decision-making team. Interprofessional working will be discussed later in the chapter as one of the further aspects of birth practice that affects cord clamping times.

Cord clamping practice of both midwives and doctors is guided by the condition of the baby in the first few minutes after birth. The neonatal team attended 20 / 55 (36.4%) of all TOCC births, indicating that there was known fetal compromise or potential newborn compromise. At these births the doctors and midwives were much less likely to be able to facilitate a cord clamping time of over 3 minutes (see tables 10, 12 and 14). As doctors are called to do all instrumental births, which are often related to concern for the baby’s wellbeing, this will have an impact on the number of babies that are requiring early clamping in the doctor group. Births facilitated by a doctor had a neonatal team member present in 11 / 14 (79%) of cases. Births facilitated by a midwife had a neonatal team member present in 9 / 40 (23%) of cases.
Births with the neonatal team present had a median cord clamping time of 2.13 minutes, compared to 4.73 minutes when they were not present. All the births where the cord was clamped and cut under 1 minute had the neonatal team in attendance. In the Hutton et al. study the median cord clamping time was also over twice as long where there was no neonatal intervention (20 seconds) than were the neonatal team were involved (8 seconds). Further discussion on the results is in the neonatal resuscitation section below.

Adherence to Policies and Guidelines

The median cord clamping time of 3.5 minutes from the TOCC data is considerably longer than demonstrated in previous observational studies, where median cord clamping varied between 0.2 minutes (Hutton et al., 2013), 0.9 minutes (Ersdal et al., 2014) and 0.95 minutes (Nelin et al., 2018). One further observational study in the UK did not provide a median time but did report that 85% of cords were clamped under 30 seconds (Airey et al., 2008).

One possible reason for this longer interval in the TOCC study, when compared with the four earlier studies, is that there have been widespread recent changes to guidelines in response to rapidly growing evidence in favour of deferred cord clamping. When the births were observed as part of UK and Canadian studies in 2006 and 2007 the two meta-analyses of cord clamping were yet to be published (Airey et al., 2008; Stoll & Hutton, 2012). The first large meta-analysis was published the year that data collection in the Canadian and UK studies was completed (Hutton & Hassan, 2007) and the first version of the Cochrane meta-analysis (McDonald, Middleton, Dowswell, & Morris, 2008) was published a year later in 2008. Both of these systematic reviews highlighted the significant increases in neonatal haemoglobin and infant iron stores with delayed cord clamping. Prior to the publication of these cord clamping systematic reviews the two observational studies from the UK and Canada indicate that there existed a culture of early cord clamping, which had been normal practice since the 1960’s.
The two other studies observed births in lower income countries (Ersdal et al., 2014; Nelin et al., 2018). The study in Tanzania observed births from 1999 to 2014 (median 1.07 minutes), the study in Nepal observed births in 2013 (median 0.95 minutes). The World Health Organisation (WHO) guideline on basic newborn resuscitation published in 2012 recommended that, for term or preterm babies who do not require positive pressure ventilation, the cord should not be clamped earlier than one minute after birth (WHO, 2012a). The WHO guidelines are widely followed in low-income countries and may have had a major influence on cord clamping timing in Tanzania and Nepal, which both demonstrate an adherence to the “one minute” rule.

In the hospital location used for the TOCC study there were multiple guidelines that may have influenced practice. The local guideline for the District Health Board (DHB) covering the hospital, at the time of the TOCC study, recommended that, for term infants, the umbilical cord remain unclamped for at least three minutes when the baby is well (CDHB, 2014). This guideline was available to the multiprofessional team of midwives, obstetric doctors, neonatal doctors and neonatal nurse practitioners and would explain the median cord clamping time for TOCC births of 3.5 minutes. The development of a local guideline such as this, with clear definitions of timings, management and exclusion criteria may assist in the successful implementation of placental transfusion at births (Anton et al., 2018). This may be due to the fact that a local guideline can bring together recommendations from different professions, as listed over the next paragraphs, and derive a general interdisciplinary consensus.

The individual practitioner groups involved in the TOCC study would have been influenced by their own professional bodies who each produce guidance for practice. The national consensus statement from the New Zealand College of Midwives recommends that the cord is not cut for at least three minutes after the birth for active management of the third stage, or until after pulsations cease for physiological placental birth (NZCOM, 2013). The obstetric doctors would have been guided by their College statement which, at the time of the TOCC births, did not stipulate an ideal minimum time for cord clamping due to absence of “clear evidence” (RANZCOG, 2017a).
Practitioners providing newborn resuscitation have guidance provided by the New Zealand Resuscitation Council. In most cases of resuscitation at the TOCC study hospital, the lead practitioner would either be a member of the neonatal team or a midwife but in some cases an obstetric or anaesthetic doctor may also be involved. The newborn resuscitation guideline that was current at the time of the study suggested that a cord clamping time of over 30 seconds for uncomplicated term births resulted in improved neonatal iron stores but that this needed to be balanced with a greater likelihood of needing phototherapy for jaundice (ANZCOR, 2017). The benefits of leaving the umbilical cord intact beyond 30 seconds may be given more weight in future editions of resuscitation guidelines as evidence increases around the negative impact of immediate clamping on neonatal transitional physiology (MacDonald, 2019).

It is interesting to note that different guidelines give different weight to the possible link between jaundice and longer cord clamping times. This is likely due to the contradictory evidence at the time, with some studies demonstrating a higher rate of jaundice requiring phototherapy with delayed cord clamping (McDonald et al., 2013) and others that did not find a significant link (Andersson et al., 2011; Hutton & Hassan, 2007). The Cochrane review on cord clamping for term infants recommended at the time that, where neonates have access to phototherapy, the benefits of delayed cord clamping outweigh the risks of jaundice (McDonald et al., 2013).

It may be that the differences in interprofessional guidelines are a reason for the differences in median cord clamping times of TOCC births across the practitioner groups. The median cord clamping time for births facilitated by midwives was 4.06 minutes (IQR 2.68 – 6.65) whereas for doctors it was 2.13 minutes (IQR 1.48 - 3.28). Midwives are more likely to make cord clamping timing decisions at uncomplicated births and, in the absence of complications, are more likely to leave the cord intact for longer periods. In New Zealand, doctors are called to attend births where there are concerns about maternal or fetal wellbeing, and in these circumstances, there may be reasons to separate mother and baby early in order to perform resuscitation.
The need for newborn resuscitation

The need for neonatal resuscitation as a reason for early clamping of the cord is highlighted in the TOCC results by the observation of whether or not the neonatal team were in attendance. The neonatal team is called where there is known fetal compromise in labour and when there is real or potential neonatal compromise at the time of birth.

Around 5% of all babies will need some resuscitation beyond drying and stimulation and for low risk term births this figure drops to around 1% (ANZCOR, 2017). The need for newborn resuscitation can often be anticipated and the neonatal team will be in attendance before the birth but, in some cases, they will be called soon after the birth. Measuring the attendance as “present for the birth or within the first 5 minutes” captured data from all neonates who needed extra resuscitation support. The neonatal team were present at 20/55 (36.4%) of TOCC births, an indication of the complexity of births at a tertiary hospital. For births where the neonatal team were in attendance, comments were documented in the TOCC study notebook by health practitioners in 8/20 births including “fetal bradycardia”, “meconium”, “resus required” and “stunned baby”.

Births where the neonatal team were called to attend had much shorter cord clamping times (median: 2.13 (IQR:1.28 - 3.27)) than those births where the neonatal team were not called (median: 4.73 (IQR: 3.32 - 8.26)). In the TOCC study hospital the neonatal resuscitation equipment, known as a Resuscitaire, is attached to a table that folds down from the wall, approximately 2 metres away from the birthing bed. Therefore, at birth, if an infant appears to require resuscitation, the cord has to be clamped and cut for transfer to this Resuscitaire. Where the neonatal team was in attendance, 70% of babies had their cords clamped under 3 minutes compared to only 17% where the neonatal team were not in attendance.

The neonatal team were in attendance for all 4 of the births where babies had their cord clamped under one minute, indicating that neonatal resuscitation
was probably the reason for early clamping. These babies may have benefited from a longer period of placental transfusion to facilitate cardiopulmonary transition (Bhatt et al., 2013; Ersdal et al., 2014; Hooper et al., 2015; Mercer & Skovgaard, 2002; Niermeyer & Velaphi, 2013) and to improve iron stores up to 6 months of age (Andersson et al., 2011; Hutton & Hassan, 2007; McDonald et al., 2013). A randomised controlled trial published after data collection for the TOCC study has provided new and important information on the benefits of placental transfusion for non-breathing term infants (Andersson et al., 2019). In this trial from Nepal, the mean oxygen saturation 10 minutes after the birth for non-breathing babies who had early cord clamping (97/231; median cord clamping time 25 seconds: SpO₂ 85.4%) was 5% (95% CI: 3.5 to 6.5) lower than in the group who had intact cord resuscitation (134/231; median cord clamping time 105 seconds; SpO₂ 90.4%). No negative consequences were identified when resuscitation was provided with an intact cord in the mother's bed compared to when resuscitation was provided at a separate resuscitation table. The authors hypothesize that the improved oxygenation may be due to several mechanisms including ongoing oxygenation by the placenta, increased pulmonary blood flow and improved perfusion of peripheral tissues resulting from the increased blood volume transferred from the placenta.

With the growing evidence of harm for babies whose cords are clamped sooner than one minute after birth, it will be essential to plan into future birthing rooms the ability to resuscitate with intact cord. Mobile resuscitation trolleys have been invented for this purpose and have demonstrated that a full range of resuscitation procedures can be provided with the umbilical cord is still intact (Katheria et al., 2016; Thomas et al., 2014). Midwives report using intact cord resuscitation at home births and, more rarely, at hospital births (Fulton et al., 2016). These midwives described placing the baby on a tray covered with a warmed blanket, near sufficient lighting and using a bag and mask to provide positive pressure ventilation while the cord remained intact. The evidence for intact cord resuscitation is growing but as yet, the guidelines have not been adapted to incorporate this practice into all maternity care settings.

One method of speeding up placental transfusion is to milk the umbilical cord repeatedly, either before or after it has been clamped, over a period of 10-15
seconds, to push blood towards the baby (Al-Wassia & Shah, 2015). Despite reviewing data from 40 studies involving 4,884 babies, a recently-published Cochrane meta-analysis, does not find sufficient evidence to reliably conclude whether outcomes of cord milking are comparable to outcomes of deferred cord clamping for preterm babies (Rabe et al., 2019). There have been concerns that the intervention is yet to be proven as fully safe and the local guideline at the TOCC hospital advises against the use of milking (CDHB, 2014). In a very recent study, a trial comparing cord milking with delayed cord clamping found an increased risk of severe intraventricular haemorrhage in very premature babies in the milking group and these babies were excluded mid-trial from any further randomization (Katheria et al., 2019).

There is a significant culture change required around the practice of neonatal resuscitation in this era of longer cord clamping times. Neonatologists reviewing recent evidence on placental transfusion describe the babies who we are most inclined to transfer to the Resuscitaire are the ones that are most likely to need deferred cord clamping (Niermeyer, 2015; Niermeyer & Velaphi, 2013; O’Donnell, 2017). In the TOCC study, this may be the case for the four babies who had their cords clamped under one minute.

The presence of a nuchal cord requiring pre-birth cord clamping

Practitioners recording data for the TOCC births were asked to document “0 minutes” if the cord was wrapped around the baby’s neck (a nuchal cord) and cut before the birth of the body. In the 55 births included in the TOCC observational study none were recorded as 0 minutes. This is in contrast to a Canadian study where 5/100 (Hutton et al., 2013) and a Nepalese study where 10/138 (Nelin et al., 2018) births recorded the umbilical cord being cut before the delivery of the body. It is not possible to make comparisons with statistical significance on this difference in view of the relatively small numbers of births involved. It is possible that more practitioners in New Zealand are aware of the somersault manoeuvre, which allows a baby with a tight nuchal cord to be born without early cord cutting (Reynolds, 1999). The somersault manoeuvre
involves holding the baby’s head close to the mother’s thigh while the body of
the baby is born in a “somersault” over the baby’s head, unwrapping the cord
after the full birth of the baby. It is also possible that babies with nuchal cords
in the TOCC study showed signs of fetal heart abnormalities which perhaps
resulted in a caesarean section which would have excluded them from data
collection.

Gestational age at time of birth

The gestational age of babies is likely to influence the timing of cord clamping.
The TOCC study elected to observe only births where the babies were over 37
weeks. One birth was excluded from analysis due to gestation being recorded
as 36 weeks. This allowed a direct comparison with an observational study in
Canada which also excluded preterm births (Hutton et al., 2013).

At the time of the TOCC births there was no local guideline to determine
optimal cord clamping timing for preterm births. For preterm births the
neonatal team would determine the timing of cord clamping according to
extent of prematurity and condition of the baby at birth. For term births, the
recommendations from the local guideline would be to leave the cord intact for
three minutes where baby was not requiring resuscitation. More recently, the
local CDHB guideline has been updated to include recommendations for both
term and preterm births (unable to reference as new version not finalised at
the time of completing this thesis). The update came in response to the meta-
analysis of cord clamping outcomes which found that preterm babies who have
their cords left intact for at least 30-60 seconds have a lower mortality than
those who have their cords clamped immediately (Fogarty et al., 2018). When
the guideline is finalised, one minute of delay between birth and cord clamping
will be recommended for all babies born at the TOCC study hospital, regardless
of gestation, unless there is a cord avulsion or a heart rate under 60 beats per
minute. This is in alignment with cord clamping guidance in the UK (NICE,
2015).

Other observational studies investigating timing of cord clamping have
included both term and preterm babies, e.g. a Nepalese study where 12/128
babies were born at less than 37 weeks gestation (Nelin et al., 2018) and a study from Tanzania in which babies were grouped by their birthweight as an indication of prematurity (Ersdal et al., 2014). The inclusion of preterm births may partly explain why the median birth to cord clamping interval was less than one minute in each of these studies (Ersdal et al., 2014; Nelin et al., 2018).

The position of the baby immediately after the birth

Gravity is one of many factors which is thought to alter blood flow between the placenta and the baby. A Cochrane review on alternative positions for the baby at birth before clamping the umbilical cord was not able to find sufficient evidence to show whether positions affected maternal or neonatal outcomes (Palethorpe et al., 2010). Since the publication of this review one large randomised controlled trial demonstrated minimal difference in placental transfusion between term babies held for 2 minutes either at the level of the woman’s vagina or on her abdomen or chest (Vain et al., 2014). The position of the baby immediately after the birth was not recorded as part of the TOCC data. It may be that the maternal position for birth will dictate to a certain extent where the baby is placed, for example in a kneeling or standing birth the baby may be on a surface lower than the placenta until the mother is ready to pick it up and hold it close to her abdomen. In a side-lying birth the baby will be able to lie next to the woman’s skin, at the same level as the placenta, as the woman usually maintains her birthing position. In recumbent/seat/lithotomy positions the baby will usually be held in a skin to skin position on the woman’s abdomen, which is also level with the placenta.

Choice of active or physiological placental birth

Immediate cord clamping became widely adopted as normal practice when it was introduced as a component of active management of the third stage of labour. The way in which placental birth is managed is a key driver as to the timing of cord clamping. In physiological placental birth, otherwise known as expectant management, the cord is left intact either until it stops pulsating or preferably until after the placenta is born (NZCOM, 2013). In active management, recommendations on cord clamping and cutting vary according
to the timing of the administration of uterotonic medication. Active management used to recommend immediate administration of the uterotonic and early cord clamping but more recently, the cord clamping and uterotonic administration are often delayed, otherwise known as mixed management (Begley et al., 2019).

In tertiary hospitals in New Zealand 34.1% of normal births (spontaneous onset of labour after 37 completed weeks of pregnancy with a cephalic presentation of a single live baby) are followed by a physiological placental birth, according to a study of over 33,000 women in 2004-2008 (Dixon et al., 2009). Data on how placental birth was managed was not collected as part of the TOCC study. It is possible that the majority of births where the cord was clamped over 5 minutes were left intact for longer due to physiological placental birth where the placenta was birthed physiologically without the use of a uterotonic or controlled cord traction. However, this is an unknown factor as some practitioners will use delayed cord clamping and uterotonic administration after the cessation of cord pulsation, referred to as “mixed management” in a recent Cochrane review (Begley et al., 2019)

As midwives are more likely to be involved in uncomplicated birth and therefore more likely use physiological placental birth, it may be that they are more comfortable with extended cord clamping times. They may be less inclined to follow the expectation of the medical patriarchal model which disconnects the woman and the baby to view them as separate patients (Meleo-Erwin & Katz-Rothman, 2011). It has been suggested that the technocratic paradigm, where placental birth is considered highly risky and requiring active management, is most likely to be favoured by doctors whereas the natural social paradigm, where the physiological processes of placental birth are valued, is most likely to be favoured by midwives (Stojanovic, 2012). Despite this polarization in practitioners’ views there are midwives whose beliefs align more with the technocratic paradigm and vice versa with doctors.

Birth in hospitals brings with it an institutional fear of maternal and newborn complications which have led to faster cord clamping times (Murphy-Lawless, 1998; Stojanovic, 2012). Although uterotonics reduce the rate of postpartum
haemorrhage for women with risk factors, it may be that their prophylactic use in active management after normal birth may be a situation described in a systematic review of maternal clinical practice guidelines as “too much too soon” (Miller et al., 2016). “Too much too soon” describes the routine over-medicalisation of childbirth, for example where active management does not improve outcomes at normal birth but may instead cause avoidable harm related to immediate cord clamping.

The decision around active or physiological placental birth is dependent on the woman’s wishes, the complications related to the birth, the knowledge and skills of the birth practitioner and adherence to policy and guidelines. Clinical decision-making for placental birth requires tailoring to each individual woman’s needs rather than a “one-size-fits-all” approach. The evidence around benefits of active management of the third stage of labour in regard to reduction in haemorrhage have been reviewed recently and, in view of the number of harms involved, such as the decrease in blood volume in the neonate due to immediate cord clamping and the maternal side effects such as postnatal hypertension, pain and vomiting after administration of a uterotonic, active management is no longer recommended for all women at low risk of excessive bleeding (Begley et al., 2019; Dixon et al., 2013).

For women who do have an increased risk of bleeding, where a decision is made for active management of labour, there is still uncertainty around timing of administration of uterotonic and how this may affect the blood flow to the newborn. Over the years, recommendations on when to administer the uterotonic has been variable: with crowning of the head; with the birth of the anterior shoulder; immediately after the birth of the baby or after the cord has stopped pulsating (McDonald et al., 2013). The administration of a uterotonic while the cord is still intact may interfere with birth physiology by increasing power, duration and length of contractions, driving more blood into baby than would otherwise occur during physiological placental birth (Yao et al., 1968; Yao & Lind, 1974). Experimental studies on sheep demonstrated a reduced umbilical venous blood flow when a uterotonic was given before the cord was clamped and cut (Stenning et al., 2015).
There is a discrepancy in guidance around timing of uterotonic with relation to cord clamping during active management. In the UK, the directive is to give 10 international units of oxytocin by intramuscular injection with the birth of the anterior shoulder and to clamp and cut the cord between one and five minutes (NICE, 2019). In New Zealand, it is advised that the uterotonic is not given until after the cord has been clamped and cut at least three minutes after the birth (NZCOM, 2013). It is possible that delaying the uterotonic in order to prevent harm to the neonate may increase the rate of maternal haemorrhage but a meta-analysis did not show any difference when the uterotonic was given immediately or after the birth of the placenta (Soltani, Hutchon, & Poulose, 2010). This is an area of birth practice that necessitates further research so that best outcomes for women can be balanced with best outcomes for infants (Niermeyer, 2015).

**Interprofessional teamwork**

A tertiary maternity hospital is equipped to provide care for women with high-risk complex pregnancies by specialised multidisciplinary teams (Ministry of Health (Manatū Hauora), 2019). Women who have straightforward pregnancies may also choose to birth at a tertiary hospital with their LMC in attendance or they may opt for care at a midwifery-led primary birthing unit. On the birthing suite at the TOCC study hospital there are midwifery, obstetric, neonatal and anaesthetic teams working 24 hours a day. At each birth, there will often be 2 or more of these teams sharing the decision making around when to clamp and cut the cord, considering the wishes of the women and her whanau. Interprofessional teamwork is evident in Table 8 for the births where it was a different professional facilitating the birth than clamping the cord.

Each of these professional groups practice within their own boundaries. Boundaries are frequently drawn between midwifery and medicine, with normal birth traditionally being the domain of the midwife and abnormal birth the domain of the obstetric doctor (del Rosario Ruiz & Limonero, 2014; Hunter & Segrott, 2014). When a new practice is implemented within a maternity unit, such as to recommend prolonging the time between birth and cord clamping, multiprofessional collaboration is a key strategy for success (Anton et al., 2018).
At the TOCC study hospital, with a median cord clamping time of over three minutes it would appear that a strategy for prolonging placental transfusion has successfully been implemented.

Four babies in the TOCC study had a cord clamping time of under one minute, signifying that they did not receive a full complement of placental blood. It is likely that these babies all needed resuscitation. During the moments immediately following the birth, when the decision is being made as to whether or not to separate the woman and her baby in order to move to the resuscitation table, the midwife and/or obstetric doctor will be well placed to assess the baby’s condition. The neonatal team member who elects to be in close contact with the baby while the cord is still intact, is better placed to contribute to this decision-making. With all members of the team involved, decision-making is enhanced. In reality, interprofessional dynamics, and in particular hierarchy, play a significant role in this decision making. By recognising how this hierarchy affects the culture of the birthing room, practitioners may be able to achieve a culture change and take steps to improve teamwork (Niermeyer & Velaphi, 2013; O'Donnell, 2017). Taking resuscitation into the “maternal space” may be more challenging for the neonatal team than it is for the obstetric and midwifery teams as it is outside of their normal boundaries. In a questionnaire to clinicians providing care with a bedside trolley, the neonatal providers were more likely to respond negatively to the process than the maternal providers (Katheria et al., 2018).

Strengths and Limitations

One major strength of the TOCC study is the utilisation of a midwifery lens to view cord clamping practice. Cord clamping is an intervention that impacts on both the woman and her newborn infant. Midwifery work involves care of both individuals, in contrast to obstetrics which focusses predominantly on the woman and neonatology which focusses predominantly on the baby. This is the first time that cord clamping practice has been objectively measured in a New Zealand setting. From a New Zealand midwifery perspective, the TOCC study looks at how cord clamping can be achieved as part of a midwifery
model that is based around partnership with women (Guilliland & Pairman, 2010).

The choice of a tertiary maternity hospital as a location for the study gives an opportunity to look at cord clamping practice across a range of births, from uncomplicated midwifery-led births to complicated obstetric-led births that require neonatal team in attendance. This is a strength of the study as the multi-professional practice at the TOCC hospital is able to be compared directly with a previous study set in Canada which also observed a combination of obstetric, family physician and midwifery practice (Hutton et al., 2013).

Another strength of the study is the robust methodology where the interval between birth and cord clamping was timed accurately with a stopwatch. Observation and objective measurement is more likely to be accurate than the use of surveys as it does not rely on memory (Rees, 2011). A rigorous process for obtaining consent from the women and the practitioners meant that the study was ethically sound. The robust nature of the data collection (e.g. stopwatch not clock, consent pre-labour, no retrospective consent) did mean that it took longer than expected to record births fulfilling the TOCC criteria.

By avoiding the use of an additional researcher at the births to record data, the birth territory was more likely to remain as it would have been if the birth had not been recorded (Hastie & Fahy, 2009). Common in most mammals is a need for privacy and minimal disturbance during birth (Buckley, 2005; Odent, 2008). With the lack of an extra observer to record research data in the TOCC study, birth was less likely to be disturbed and stress stimuli for women and their newborn was kept to a minimum.

By choosing to utilise the existing healthcare practitioners as researchers in this study, the extent of data collection had to be restricted so that the workforce at the hospital was not adversely impacted. This was a limitation to the study as data collection stopped at 55 births, despite a 3-month extension to encourage larger numbers. Even with the original number of 100 births, the study was not designed to be analysed with inferential statistics or the ability to control for confounding influences.
It is acknowledged that the midwives who chose to approach women for consent may have a special interest in cord clamping and this may have resulted in a longer median cord clamping times. Another potential source of bias was the over-representation of births consented and recorded by one midwife (22/55 TOCC births). However, as a sub-analysis of these 22 births showed a median cord clamping time of 3.55 minutes, very similar to the median of 3.49 minutes for the 34 births that were not recorded by this midwife, it is likely that the bias did not overly influence the study results.

One further limitation to the study was the fact that the healthcare practitioners knew that the births were being recorded and this may have influenced the discussions they had with women taking part in the TOCC study. These discussions will vary considerably according to the knowledge and beliefs of the LMC, as well as according to the interests of the woman and her whanau. In order not to influence the decision-making around cord clamping the information leaflet did not provide any comments on the evidence, rather stating that “cord clamping choices are usually discussed with your LMC as part of your birth plan”.

The median cord clamping time of 3.5 minutes was longer than expected and, taking into consideration these limitations, the findings represent a considerable change in practice compared to previous observational studies.

**Summary**

This discussion chapter has considered the TOCC results in relation to the existing literature on the timing of cord clamping. The median cord clamping time at 55 term births in a tertiary New Zealand hospital was 3.5 minutes which is line with current research showing benefits of extended periods of placental transfusion. On examination of the literature it appears that there is no clarity on the optimal time for cord clamping, but rather that the practice is based on neonatal transitional physiology and is best individualised according to the condition of the woman and her baby in those first few minutes after birth.
The TOCC results found that cord clamping times vary according to mode of birth, maternal position and involvement of different members of the interprofessional team. The results have been discussed in relation to the wider context of policies and guidelines, interprofessional teamwork and specific practice issues such as resuscitation, prematurity and nuchal cords. The following and final chapter will conclude this Master’s thesis by considering the implications of these findings and suggesting opportunities for changes in practice and for future research.
Chapter 6: Conclusion

The final chapter of this thesis will review whether the original objectives of the TOCC study were met and will summarise the major findings, along with recommendations for research and for practice.

The main finding of this study was a median cord clamping time of 3.5 minutes for the 55 term vaginal births observed at a tertiary New Zealand hospital where the majority of births have a midwife as lead practitioner.

The TOCC study aimed to accurately record birth to cord-clamping interval at 100 term vaginal births and to investigate factors which may influence practice such as mode of birth, maternal position for birth and practitioner involvement. In the final analysis, despite a three-month extension in the recruitment period, the total number of births accurately recorded was 55. While a larger study may provide more generalisable results, there would likely still be considerable challenges to recruitment unless significant resourcing was available. The consistency of findings in this small study does provide confidence that there has been a shift to longer cord clamping times.

One objective of the TOCC study was to compare the findings with a similar study in Canada where 89 births were measured in 2006-7 (Hutton et al., 2013). The TOCC study found a median cord clamping time of 3.5 minutes, compared to a median of 12 seconds in the Canadian study. This major difference is likely due to a change in practice over the last decade in light of evolving evidence of harm from immediate clamping and may also be related to the different models of care between the two countries. Both the TOCC and the Hutton et al. study observed longer cord clamping intervals when the births were spontaneous rather than instrumental, facilitated by a midwife rather than a doctor and when the neonatal team were not present rather than when they were present.

When the study findings were examined alongside the existing guidelines (see Appendix one) the median cord clamping time of 3.5 minutes aligned with the local DHB guideline and the NZ College of Midwives guideline. The Royal
College of Obstetrics and Gynaecology and the NZ Resuscitation Council did not stipulate a specific time for cord clamping. This demonstration of effective guideline implementation at the study hospital, and the resulting benefits for women and their newborn infants, is a credit to all the care providers and to the leadership team.

The most important finding of the TOCC study was that deferred cord clamping of one minute or more was used in almost all (93%) births at the study hospital, and deferred cord clamping of three minutes or more was used for 64% of births. The consistency of results for the 55 TOCC births demonstrates a shift in practice away from immediate cord clamping. As immediate clamping has been shown to be detrimental to term infants, resulting in an impaired physiological transition to extra uterine life and a reduction in iron stores for the first 6 months of infancy, this is encouraging news for the majority of the babies at the study hospital.

However, as discussed in chapter five, the optimal time for cord clamping is not known. As the optimal transfusion time may be longer than three minutes for some babies there may still be a significant number of babies impacted by harms of early cord clamping. Babies in the TOCC study were more likely to receive a prolonged period of cord clamping when their birth was spontaneous rather than assisted by forceps or ventouse, if their mother birthed in an upright or side-lying position rather than seated position, where the birth was facilitated by a midwife rather than a doctor and where there was no neonatal team in attendance. Knowledge of the ways in which these factors influence cord clamping times may assist birth practitioners in identifying areas to improve practice.

The shorter median cord clamping time at instrumental (2.08 minutes) when compared to a spontaneous birth (3.71 minutes) is probably due to the fact that babies requiring ventouse or forceps delivery are more likely to receive newborn resuscitation, with associated early cord clamping, as indicated by the fact that the neonatal team were present at all 9 instrumental births.
The influence of maternal position on cord clamping may also be linked to neonatal compromise. Median cord clamping times for women birthing in lithotomy (2.24 minutes) or seated positions (3.47 minutes) were shorter than for upright (3.93 minutes) and side-lying (6.37 minutes) positions. This may be due to the fact that these seated positions (including lithotomy) are encouraged by practitioners when there is known or potential fetal compromise in labour to allow more intensive monitoring of the fetal heart. These babies would then be more likely to be slower to spontaneously breathe and to have their cords clamped early to facilitate newborn resuscitation.

Observations on practitioner involvement in the TOCC births found that the median cord clamping times for births facilitated by midwives (4.06 minutes) was longer than for births by doctors (2.13 minutes). This is partly due to the maternity system in New Zealand where midwives are more likely than doctors to attend spontaneous uncomplicated births which are less likely to warrant immediate separation of mother and baby for preventative or resuscitative measures. It may also be due the differing philosophies of care between the two practitioner groups.

Where the neonatal team was in attendance, 70% of babies had their cords clamped under 3 minutes compared to only 17% where the neonatal team were not in attendance. It is likely that the main reason for clamping the cord early is to separate the mother and baby to facilitate newborn resuscitation, as observed in the TOCC study where all 4 babies who had their cords clamped under one minute had the neonatal team present at the birth. The birthing rooms in the study hospital have resuscitation equipment that is attached to the wall and not conducive to repositioning at the mother’s side at the time of birth. The introduction of guidelines, training and equipment to promote intact cord resuscitation may mean that compromised babies would benefit from a longer period of placental transfusion, known to facilitate cardiopulmonary transition.

Although it was not documented as part of the research study whether the birth of the placenta was active or physiological, it is likely that the extended cord clamping times (16/55 births had median cord clamping times over five minutes) indicate the use of physiological placental birth. The way in which
placental birth is managed is a key driver as to the timing of cord clamping. For women who require active management due to higher risks of postpartum haemorrhage the safest timing of the uterotonic is not known. When active management was introduced in the 1960’s the administration of the uterotonic and the clamping of the cord were done at the time of or immediately after the birth. With the practice of deferred cord clamping, guidance on timing of uterotonic varies from one guideline to another (see Appendix one). Administration of a uterotonic while the cord is still intact may interfere with the physiology of placental transfusion by increasing power, duration and length of contractions and driving more blood into baby. However, if the timing of the uterotonic is overly delayed to allow for placental transfusion this may increase maternal risk of postpartum haemorrhage. As with all perinatal decision making, this judgement requires a fine balance between risks for the woman and risks for her infant(s).

In conclusion, the median cord clamping time of 3.5 minutes for the 55 babies in the TOCC study is a positive finding as evidence suggests that most babies need at least 3 minutes of intact cord time post-birth to benefit from increased iron stores and stable physiological transition. For the 20 babies that did have their cords clamped under three minutes, this may have been for maternal reasons, fetal reasons, parental choice or practitioner preference. As birth practice evolves in response to growing research in favour of longer cord clamping times we would hope that in the future these 20 babies would have had their full potential of placental blood. Ongoing knowledge of maternal and neonatal physiology may increase practitioner’s confidence in a spontaneous birth of the placenta and an intervention-free transition of the newborn infant from in-utero to ex-utero life. This may involve re-framing early cord clamping as an intervention that must only be used when there is clear evidence that it will add benefit and avoid harm.

Recommendations for further research

This study has highlighted some gaps in the research around umbilical cord clamping. The following areas would provide valuable evidence that would add to the findings of the TOCC study:
• A study with a similar methodology to the TOCC study with a larger number of births observed, including significant resourcing for recruitment.

The TOCC study provided consistent results for 55 births at a tertiary hospital but, due to the small numbers, these results may not be generalisable to a wider population. There may be some statistically significant differences between births that could be demonstrated with a larger data set. Larger observational studies have already been carried out in low-resource settings (Ersdal et al., 2014; Nelin et al., 2018) but there are no large studies from high and middle income countries.

• A qualitative research study to describe the personal experiences of the women and the practitioners at the time of birth.

Although the TOCC study answered important questions around the actual timing of cord clamping it was not able to provide us with an in-depth insight on how the individuals involved perceived or interpreted the situation.

• An observational study of midwifery-led births in a primary setting.

It is likely that midwives practice differently when working in primary care where births are more likely to be physiological, cord clamping times are more likely to be longer and it would be valuable to learn how the median cord clamping time differs in a primary setting.

• A survey of women and their partners/family/whanau.

This would provide valuable data from a consumer perspective. At the time of submitting this Master’s thesis there were no published surveys on women’s views.

• A study on how the timing of administration of the uterotonic (as well as drug, dose and route) fits in with the new version of active management.

Active management used to involve immediate administration of uterotonic and immediate cord clamping. Now that deferred cord clamping is a recommended part of active management, further evidence is required on maternal and neonatal outcomes of placental birth when a uterotonic is administered with an intact cord.

• A meta-analysis on the safety of intact cord resuscitation for term infants.

Since the completion of the TOCC study, one important RCT has demonstrated improved outcomes for non-breathing term infants who
receive intact cord resuscitation in the mother’s bed when compared to resuscitation after cord clamping at a separate Resuscitare (Andersson et al., 2019). A review of studies on intact cord resuscitation lists 14 feasibility studies, completed and ongoing randomised controlled trials. Some of these are specifically looking at term births and a meta-analysis would provide important data to help answer the question as to the clinical benefit of leaving the mother and baby attached during resuscitation (Katheria, 2019).

Recommendations for practice

1. Implementation of strategies for increasing placental transfusion for babies who do not breathe spontaneously, including:
   - Taking stethoscope to the birth space when cord is still intact as newborn heart rate is best indicator of when resuscitation is required.
   - Arrangement of the birthing environment to allow existing equipment to be used for intact cord resuscitation. For example, using a flat warmed surface, out of the birth fluids, with access to ventilation equipment to allow maintenance of newborn temperature, opening of the airway and establishment of respiratory support while the newborn is still attached to the placenta.
   - Investment in “bedside” resuscitation tables to allow complex resuscitation with intact cord

2. When active management of the third stage is indicated, ensure that the cord is clamped before the uterotonic takes effect. The timing of cord clamping will depend on the drug, dose and route of uterotonic. There is insufficient evidence on the impact of uterotonic administration on placental transfusion and, until the evidence is clear, it is safer not to interfere with birth physiology.

Ongoing work to ensure effective and safe placental transfusion for all babies will involve multiple enablers including interprofessional education and practical training for the birthing team, the availability of up-to-date evidence-based guidelines and further research into this fascinating topic of umbilical cord clamping.
# Appendix 1: Summary of Guidelines

A summary of guidance for cord clamping from English-language guidelines from high-resource countries

<table>
<thead>
<tr>
<th>Organisation and Year of guideline</th>
<th>For term births where baby is breathing</th>
<th>Timing of uterotonic in relation to cord clamping for active third stage</th>
<th>For term births where babies do not breathe spontaneously</th>
</tr>
</thead>
<tbody>
<tr>
<td>NZ College of Midwives (NZCOM, 2013)</td>
<td>At least 3 minutes</td>
<td>After cord clamping</td>
<td>May be beneficial to leave cord intact for resuscitation efforts</td>
</tr>
<tr>
<td>Royal Australian and NZ College of O&amp;G (RANZCOG, 2017b, 2017a)</td>
<td>No urgency...appropriate time frame.</td>
<td>Not specified</td>
<td>Not stated</td>
</tr>
<tr>
<td>World Health Organisation (WHO, 2012a, 2012b, 2014)</td>
<td>Not earlier than 1 minute. 1-3 minutes with simultaneous early newborn care</td>
<td>Not specified</td>
<td>Stimulation by rubbing baby’s back 2-3 times before cutting and clamping to initiate IPPV</td>
</tr>
<tr>
<td>National Institute for Health &amp; Care Excellence (NICE, 2015)</td>
<td>Not earlier than 1 minute. Before 5 minutes but women supported if wish to delay further.</td>
<td>Immediate, prior to cord clamping</td>
<td>Before one minute if concern about cord integrity or baby’s heartbeat</td>
</tr>
<tr>
<td>Royal College of O&amp;G 2015 (RCOG, 2015)</td>
<td>Supportive of deferred clamping, timing not specified. Record time in notes</td>
<td>If given before cord clamping, unlikely to have a substantive effect on placental transfusion</td>
<td>Not stated but refer to statements from WHO and NICE</td>
</tr>
<tr>
<td>Organization</td>
<td>Recommendations</td>
<td>Evidence</td>
<td>Timing</td>
</tr>
<tr>
<td>--------------</td>
<td>-----------------</td>
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<td>--------</td>
</tr>
<tr>
<td>American College of O&amp;G (ACOG, 2017; ACOG, 2017)</td>
<td>At least 30-60 seconds for vigorous infants</td>
<td>Delaying until after cord clamping has not been shown to increase PPH</td>
<td>Immediate if resuscitation is needed. Insufficient evidence to support or refute cord milking if immediate clamping required.</td>
</tr>
<tr>
<td>American College of Nurse-Midwives (ACNM, 2014)</td>
<td>5 mins if skin to skin 2 mins if below introitus</td>
<td>Not stated</td>
<td>Early or immediate clamping if resuscitation is required, cord milking may be of benefit</td>
</tr>
<tr>
<td>Society of O&amp;G of Canada 2012 (Garofalo &amp; Abenhaim, 2012)</td>
<td>The possible risk of neonatal jaundice must be weighed against the benefit of greater haemoglobin and iron stores</td>
<td>Not stated</td>
<td>Insufficient evidence to support a delay for non-vigorous infants</td>
</tr>
<tr>
<td>Canterbury District Health Board (CDHB, 2014)</td>
<td>At least 3 minutes.</td>
<td>After the clamping of the cord</td>
<td>If baby needing resus, clamp and cut at 1 minute</td>
</tr>
<tr>
<td>Australian and NZ Committee on Resuscitation (ANZCOR, 2017)</td>
<td>Not specified (review of evidence but no statement)</td>
<td>Not stated</td>
<td>Insufficient evidence to recommend the optimal timing of cord clamping in the compromised newborn</td>
</tr>
<tr>
<td>European Committee on Resuscitation (Wyllie et al., 2015)</td>
<td>At least 1 minute</td>
<td>Not stated</td>
<td>Clamp cord so that resuscitation can commence promptly</td>
</tr>
<tr>
<td>American Heart Association 2015 (Perlman et al., 2015)</td>
<td>Not specified (only for preterm)</td>
<td>Not stated</td>
<td>Not specified (only for term births)</td>
</tr>
</tbody>
</table>
Appendix 2: Information and consent form for Pregnant Women

Locality: *** (deleted for inclusion in thesis)
Lead Investigator: Tina Hewitt
Contact phone Number: *** (deleted for inclusion in thesis)

As you are pregnant and due to have your baby at Christchurch Women’s Hospital between July 2017 and March 2018 you are invited to take part in a study on the timing of cord clamping. Whether or not you take part is your choice. If you don’t want to take part, you don’t have to give a reason and it won’t affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

This information sheet will help you decide if you’d like to take part. It sets out how and why we are doing the study.

Your Lead Maternity Carer (LMC) will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be offered a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is 4 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

**WHAT IS THE PURPOSE OF THE STUDY?**

During pregnancy babies are attached to their placenta by an umbilical cord. At some stage after birth the cord is usually clamped and cut to separate the baby and the placenta. The timing of cord clamping varies. Some babies have their cord clamped a few seconds after the birth. Some babies have their cords left intact until after the placenta is birthed. Cord clamping choices are usually discussed with your LMC as part of your birth plan.

The aim of the Timing of Cord Clamping (TOCC) study is to measure the time that the cord is cut at 100 births and to find out what is usual practice in a New Zealand maternity hospital.

A study in Canada in 2013 found that over half of the babies observed had their cord clamped within 15 seconds of birth. There is no published data on average times between birth and cord clamping in New Zealand. By observing babies born in Christchurch Women’s Hospital this study will be able to describe practice in a New Zealand maternity facility and compare influences on the
practice between the two different maternity systems. We hope to use the information gained from the T.O.C.C study to see what factors influence cord-clamping practice in this country.

**WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?**

If you are booked to birth at Christchurch Women’s Hospital in July-December 2017 you may be asked in late pregnancy if you wish to consent to the study. Your LMC will also be asked to consent.

At most births in New Zealand a hospital midwife is called into the room to assist your LMC. At the time of the birth of your baby, if you and your LMC have consented to take part in the TOCC study, this hospital midwife will time the interval between the birth of your baby and cord clamping using a stopwatch. This time will be recorded in a study notebook along with the following information about your birth:

Type of birth  
Your position for the birth  
Who caught your baby and who clamped the cord  
Whether a neonatal doctor or nurse was present at the birth

*Your participation in this study is voluntary (your choice) and you may refuse to participate or withdraw from the study at any time without any risk to your future healthcare.*

**HOW WILL MY PRIVACY BE PROTECTED?**

No information that can identify you or your family will be recorded or published as part of the study and your privacy will be protected.

**WHO CAN I CONTACT FOR FURTHER INFORMATION?**

If you have any questions or if you would like to discuss the study further please contact Tina Hewitt by phone on *** or by email on tchewitt@icloud.com

If you require advice or support from Hauora Māori please contact Kathy Simmons, Kaiawhina Whaea me Nga Peepi on 03 364 4503

You can also contact the health and disability ethics committee (HDEC) that approved this study on 0800 4 ETHICS or hdecs@moh.govt.nz

Timing of Cord Clamping Study

Consent Form for Pregnant Women

Lead Investigator: Tina Hewitt
Contact phone number: *** (deleted for inclusion in thesis)

Please tick to indicate you consent to the following:

I have read (or have had read to me in a familiar language) and I understand the Participant Information Sheet.  
Yes ☐  No ☐

I have been given sufficient time to consider whether or not to participate in this study.  
Yes ☐  No ☐

I have had the opportunity to use whānau / family support or a friend to help me ask questions and understand the study.  
Yes ☐  No ☐

I have been offered a copy of this consent form and information sheet.  
Yes ☐

I understand that taking part in this study is voluntary (my choice) and that I can stop participating at any time without this affecting my future healthcare.  
Yes ☐  No ☐

I consent to the research staff collecting and processing information about my birth.  
Yes ☐  No ☐

I understand that no material that could identify me will be used in any reports or publications on this study.  
Yes ☐  No ☐

I understand that if I decide to withdraw from the study after March 2018 the information collected about me may continue to be processed.  
Yes ☐  No ☐

I know to contact Tina Hewitt on **** if I have any questions about the study.  
Yes ☐  No ☐
I understand that if I require a summary of the results I can contact Tina Hewitt on *** or tchewitt@icloud.com after September 2018. Yes □ No □

**Declaration by participant:**
I hereby consent to take part in this study.

Participant’s name:  
Signature:  Date:

**Declaration by Lead Maternity Carer (LMC) or member of research team:**

I have given a verbal explanation of the research project to the participant and have answered the participant’s questions about it.

I have offered the participant a copy of this consent form and a copy of the participant information leaflet.

I believe that the participant understands the study and has given informed consent to participate.

LMC/Researcher’s name:  
Signature:  Date:
Appendix 3: Information Sheet and consent form for Birth Practitioners

Locality: *** (deleted for inclusion in thesis)
Lead Investigator: Tina Hewitt
Contact phone Number: *** (deleted for inclusion in thesis)

You are invited to take part in an observational study on the timing of cord clamping conducted as part of a Masters of Midwifery research project at Otago Polytechnic.

Your participation in this study is voluntary and you may refuse to participate or withdraw from the study at any time.

WHAT IS THE PURPOSE OF THE STUDY?

The aim of the TOCC study is to measure the time that the cord is clamped at 100 term vaginal births between July 2017 and March 2018 at Christchurch Women’s Hospital (CWH) and to investigate any factors that may influence our practice.

A study in Canada in 2013 found that over half of the infants observed had their cord clamped within 15 seconds of birth but there is no published data about cord clamping timing in New Zealand. By observing babies born in Christchurch Women’s Hospital, this study will be able to compare influences on practice from the two different maternity systems.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

Birth practitioners who make decisions on the timing of cord clamping at CWH will be approached to be part of this observational study. This leaflet gives information about the study and includes a consent form for practitioners. If any further information is required prior to consent please refer to the contact list on the next page.

In addition, Lead Maternity Carers (LMC’s) will be asked to discuss the study with women at third trimester antenatal appointments. An Information leaflet will be provided for women to read and discuss. If appropriate, the LMC will ask women to sign a study consent form. The forms will be stored in the woman’s clinical notes. If women require any further information prior to consent please ask them to contact Tina Hewitt, study co-ordinator.

If a woman is not consented at time of admission to CWH for labour care and the LMC considers it appropriate for her to consent at that time (i.e. not unduly distressed and not in a circumstance where the discussion will impact on coping with labour), participation in the study may be offered at this time. For example women may be admitted at term with pre-labour rupture of...
membranes or booked for induction of labour. Women are vulnerable at any stage of labour and practitioners must be mindful of the fact that if any concern exists around a woman’s ability to consent, it is essential that she be excluded from the study.

If a practitioner who is conducting the birth is not consented at the time of the women’s admission to hospital, for example if the woman is under the care of another midwife in the group practice, then practitioner consent may be sought at that time. **The lead practitioner who will be making the decision as to timing of cord clamping will be the one who will need to consent to being observed.** If a student or birth support person clamps the cord, this will be at the prompting of the lead practitioner.

Midwives working on birthing suite at CWH will be asked if they agree to be **TOCC Research Assistants** and will be trained to collect data for the study.

Midwife Research Assistants will identify women who fit these **study criteria:**
- Both the woman and her LMC have consented to take part in the TOCC study
- The woman is 37 weeks pregnant or beyond with a singleton cephalic fetus
- The woman is in labour and likely to birth during their shift
- The woman is not identified as planning to birth by caesarean or where a caesarean is highly likely due to complications

When a midwife research assistant attends a birth where all criteria are met, she will time the interval between birth of the baby and the cord clamping using a stopwatch. This time will be recorded in a study notebook along with the following **birth information:**
- Type of birth
- Maternal position for birth
- Who facilitated birth and who clamped the cord i.e. midwife, doctor, student, support person, etc. (professional group only, not individual names)
- Whether a neonatal team member was present at the birth

If the stopwatch is not used, for any reason (e.g. emergencies) then that birth will be excluded from the study.

Study notebooks and stopwatches will be stored in the midwife researcher’s pocket during her shift and then be stored in the TOCC study box in the birthing suite office, a secure location where all other clinical notes are kept. **No data that can identify the woman or any birth practitioners will be stored in the study notebooks.**

**WHERE DO I FIND FURTHER INFORMATION ON THE STUDY?**

If you have any questions or if you would like to discuss the study further please contact Tina Hewitt by phone on *** or by email on tchewitt@icloud.com

If you require advice or support from Hauora Māori please contact Kathy Simmons, Kaiawhina Whaea me Nga Peepi on 03 364 4503 or Kathy.simmons@cdhb.health.nz
You can also contact the health and disability ethics committee (HDEC) that approved this study on 0800 4 ETHICS or hdecs@moh.govt.nz


### Timing of Cord Clamping (TOCC) Study

**Consent Form for Birth Practitioners**

Lead Investigator: **Tina Hewitt**  
Contact phone Number: ***

**Please tick to indicate you consent to the following:**

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>I have <strong>read</strong> and I <strong>understand</strong> the Birth Practitioner Information Sheet.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I have been given <strong>sufficient time</strong> to consider whether or not to participate in this study.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I have had the opportunity to <strong>ask questions</strong> and understand the study.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I have been offered a copy of this consent form and information sheet.</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>I understand that taking part in this study is voluntary and that I can <strong>stop participating at any time</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I consent to a midwife research assistant collecting and processing information about cord clamping practice at births.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I understand that <strong>no material that could identify me</strong> will be used in any reports or publications on this study.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I <strong>know to contact</strong> Tina Hewitt on *** if I have any questions about the study.</td>
<td>Yes</td>
<td></td>
</tr>
</tbody>
</table>
I understand that if I require a summary of the results I can contact Tina Hewitt on *** or tchewitt@icloud.com after September 2018.

Yes ☐  No ☐

**DECLARATION BY BIRTH PRACTITIONER**

I hereby consent to take part in this study.

Practitioner’s name:

<table>
<thead>
<tr>
<th>Signature:</th>
<th>Date:</th>
</tr>
</thead>
</table>

*Please store all signed consent forms in the green T.O.C.C study box on Birthing Suite*
Appendix 4: Template from TOCC study notebooks

<table>
<thead>
<tr>
<th>Date of birth</th>
<th>Time of birth (of entire baby)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Women consented</strong></td>
<td><strong>Time from birth to first cord clamp</strong></td>
</tr>
<tr>
<td>Yes / No</td>
<td>(recorded on stopwatch in minutes: seconds)</td>
</tr>
<tr>
<td>* Ensure that consent forms are stored in TOCC box on B/S</td>
<td>(If &gt;10mins, write &gt;10mins)</td>
</tr>
<tr>
<td></td>
<td>(OR if clamped before full birth of baby, write 0 mins)</td>
</tr>
<tr>
<td><strong>Lead practitioner consented</strong></td>
<td><strong>Who facilitated the birth/”delivered” the baby?</strong></td>
</tr>
<tr>
<td>Yes / No</td>
<td>Midwife / Doctor / Student / Woman</td>
</tr>
<tr>
<td></td>
<td>/ Partner / Support person /</td>
</tr>
<tr>
<td></td>
<td>Other…………………………</td>
</tr>
<tr>
<td>* Ensure that consent forms are stored in TOCC box on B/S</td>
<td></td>
</tr>
<tr>
<td><strong>Mode of Birth</strong></td>
<td><strong>Who clamped the cord?</strong></td>
</tr>
<tr>
<td>Spontaneous water birth / Spontaneous not in water / Instrumental</td>
<td>Midwife / Doctor / Student / Woman</td>
</tr>
<tr>
<td></td>
<td>/ Partner / Support person /</td>
</tr>
<tr>
<td></td>
<td>Other…………………………</td>
</tr>
<tr>
<td><strong>Position of woman at time of birth</strong></td>
<td><strong>Was the neonatal team present at birth?</strong></td>
</tr>
<tr>
<td>Semi-recumbent / Seated upright / Lying on side / Lithotomy / Kneeling / Standing / Squatting / Other………………</td>
<td>(or within the first 5 mins?)</td>
</tr>
<tr>
<td></td>
<td>Yes / No</td>
</tr>
<tr>
<td></td>
<td>Comment:</td>
</tr>
</tbody>
</table>
Appendix 5: Reply from Te Komiti Whakarite

28th March 2017
Tina Hewitt
Maternity
Christchurch Women’s Hospital

Re: Timing of cord clamping T.O.C.C): an observational study of cord clamping practice in a New Zealand maternity hospital

Tena koe Tina,

Thank you for submitting your research for assessment by Te Komiti Whakarite. We have made several general comments for consideration.

We note that you will not be collecting ethnicity data, to ensure privacy. Ethnicity is defined as the ethnic group or groups that people identify with or feel they belong to. Ethnicity is a measure of cultural affiliation, as opposed to race, ancestry, nationality or citizenship. Ethnicity is self-perceived and people can belong to more than one ethnic group. Establishing any ethnicity identified with may highlight within different ethnic populations, understanding, experience and views and help ensure Māori tikanga will be upheld.

Inclusion of accurate contact details for Māori health support in the study’s Participant Information Sheet would be an important addition for those Māori participants which might be enrolled in your study. Kathy Simmons, Kaiawhina Whaea me Nga Peepi, Hauora Māori worker at Christchurch Women’s would be a valuable contact during the course of the study.

Allowing a support person or whānau member to accompany the participant during research interviews/visits/sessions is a positive inclusion that is in keeping with the values of manaaki / caring and tautoko / support and provides an increased security for Māori participants.

Researchers need to be aware of the importance of explaining to Māori participants and/or their whānau how the study/research data will be stored, any security measures, the length of time and the process that takes place up to the destruction of the data. Researchers must take care to ensure that Māori participants understand and agree on which information is to be published in what formats and forums.

It is a requirement of the ethics approval process that a final report be submitted when the research is complete. A copy of the report should be provided to me at that time. We are committed to building on-going relationships with researchers in the hope of improving Māori health.

I hope this letter will suffice in terms of the application. Please contact me should you need any other information that may not have been included in the letter relevant to your research.

Heoi ano

Eru Waiti
Chairperson, Te Komiti Whakarite

Te Komiti Whakarite
245 Antigua Street, Christchurch. Private Bag 4710, Christchurch, New Zealand
Telephone: (64) (3) 364 0640 Ext: 88474 Facsimile: (64) (3) 378 6018
Appendix 6: Reply from Health and Disability Ethics Committee

09 May 2017

Mrs Tina Hewitt
129a Nayland Street
Sumner 8081

Dear Mrs Hewitt

Re: Ethics ref: 17/NTB/82

This application was reviewed by the Northern B Health and Disability Ethics Committee and provisionally approved pending receipt of further information. This decision was made through the HDEC-Expedited Review pathway.

Further information requested

The further information requested in order for the Northern B Health and Disability Ethics Committee to make a final decision is as follows.

- Have you considered the possibility that by informing, consenting and observing cord cutting, you may change the behaviour you are measuring. This could happen if a mum, having signed up, does her research (as pregnant women do) and has a kōrero with her LMC about timing of cord cutting which influences the LMC’s usual practice. Your active PIS encouragement to discuss cord cutting with LMC may amplify this risk.
- Who will consent a stand-in LMC in the labour ward?
- How will you address the possibility that a weary observer-midwife might forget to leave the notebook in the unit and valuable data could be lost eg through the washing machine?
- Consider collecting mum’s ethnicity. This could turn out to be linked to the way in which the third stage of labour is handled.

PISC- Practitioner:

- This needs a clear statement that involvement in the research is entirely voluntary and opting out will not have any consequences.

Consent Form:

- Remove tick boxes from non-optional clauses - offer everyone a summary with a yes/no tick box - add a panel for signing by the researcher who is explaining the PIS and taking the consent.

PISC- Mum To Be:

- Create a heading for “Contacts” and list contacts beneath it.
- Create a heading “Confidentiality” or similar under which you include the information about data being collected and published in a de-identified fashion.
• Offer everyone a summary. You have their details on the consent form so can mail out to those who tick a YES box on it.

Timeline for providing further information, and for giving a final opinion

You have 90 days to provide this further information. Your application will be considered to have been withdrawn if this information is not received on or before 07 August 2017. A new application would be required in this case.

The 15-day clock within which a final decision must be made on this study is suspended as of the date of this letter. This clock, on which 9 days remain, will restart on the date on which all of the further information requested above is received by the Northern B Health and Disability Ethics Committee.

Please remember to track changes made to new versions of documentation.

Please don’t hesitate to contact the HDEC secretariat if you have any queries. We look forward to receiving your response.

Yours sincerely,

Mrs Kate O’Connor
Chairperson
Northern B Health and Disability Ethics Committee
Appendix 7: Response to Health and Disability Ethics Committee (HDEC)

Further information in response to HDEC request in letter dated 9 May 2017 (see Appendix 6) was submitted as follows:

1. With regard to the concern that the TOCC study information and consent process for women may change behaviour, changes were made to the information leaflet/consent form to replace “Please take time to discuss this with your LMC” with “Cord clamping choices are usually discussed with your LMC as part of your birth plan”, in order to not display favourable bias towards discussion of cord clamping in the study material (see Appendix two). With regard to the korero/discussion on cord clamping that takes place between most women and their LMC during late pregnancy, it was anticipated that these discussions would vary considerably according to the knowledge and beliefs of the LMC, as well as according to the interests of the woman and her whānau. In order not to influence these discussions, and therefore to avoid influencing the study, information on the risks and benefits of deferred cord clamping were purposefully excluded from study material. With regard to the observer effect at the time of data collection, this was deliberated at considerable length and will be acknowledged in the discussion section of this thesis.

2. In response to the HDEC query about who will obtain consent from a stand-in LMC, a change was made to the information leaflet/consent form for birth practitioners (see Appendix three) to clarify that if a practitioner conducting the birth is not consented at the time of the woman’s admission to hospital, the investigator would contact the stand-in birth practitioner for consent.

3. It is acknowledged that there was a danger of TOCC study notebooks being accidentally removed from the hospital by the observer midwives. The notebook was chosen to be a of significant size with a hard cover so as to be
clearly felt in practitioner’s pocket. The notebook was well labelled and all the study resources stressed the importance of returning the notebook to the TOCC resource box after use.

4. The collection of ethnicity data was suggested by HDEC as this could turn out to be linked to the way in which the third stage of labour is handled. This had been considered at length in response to Te Komiti Whakarite (CDHB Research Consultation with Māori) and this response was cited to HDEC (see above section “cultural considerations”).

5. A statement was added to the information leaflet/consent form for Healthcare Practitioners to inform them that their involvement in the research was entirely voluntary and opting out would not have any consequences (see Appendix three)

6. The tick box for “no” was removed from both consent forms to indicate that all participants have been offered a copy of the information leaflet and consent form (See Appendices two and three)

7. A panel was added to the consent form for Pregnant Women for a healthcare practitioner to sign to record who was responsible for explaining the study and gaining consent (see Appendix two).

8. A heading for “Contacts” was added to the information leaflet/consent form for pregnant women (see Appendix two).

9. A heading for “Confidentiality” was added to the information leaflet/consent form for pregnant women to include any information about data being collected and published in a de-identified fashion (see Appendix two).

10. In response to the suggestion that every participant be offered an individual summary of the TOCC study I explained that their contact addresses would need to be included on the consent form and this would be an added risk of a breach of privacy. Only a woman’s name and signature would be on her consent form. The data collection notebook recorded that a woman’s
consent has been obtained. The two documents were not matched in any other way. Attention was drawn to the fact that each participant would be left with a copy of the information leaflet which had the contact details of the investigator in the event of that participant wanting a summary of the results.
Appendix 8: HDEC Approval Letter

19 May 2017

Mrs Tina Hewitt
129a Nayland Street
Sumner 8081

Dear Mrs Hewitt

Re: Ethics ref: 17/NTB/82

I am pleased to advise that this application has been approved by the Northern B Health and Disability Ethics Committee. This decision was made through the HDEC-Expedited Review pathway.

Conditions of HDEC approval

HDEC approval for this study is subject to the following conditions being met prior to the commencement of the study in New Zealand. It is your responsibility, and that of the study’s sponsor, to ensure that these conditions are met. No further review by the Northern B Health and Disability Ethics Committee is required.

Standard conditions:

1. Before the study commences at any locality in New Zealand, all relevant regulatory approvals must be obtained.

2. Before the study commences at a given locality in New Zealand, it must be authorised by that locality in Online Forms. Locality authorisation confirms that the locality is suitable for the safe and effective conduct of the study, and that local research governance issues have been addressed.

Non-standard conditions:

— Please provide an email as an alternative contact on the consent forms, for participants who wish to obtain a copy of the results after Sept 2018.

Non-standard conditions must be completed before commencing your study. Non-standard conditions do not need to be submitted to or reviewed by HDEC before commencing your study.

If you would like an acknowledgement of completion of your non-standard conditions letter you may submit a post approval form amendment. Please clearly identify in the amendment that the changes relate to non-standard conditions and ensure that supporting documents (if requested) are tracked/highlighted with changes.

For information on non-standard conditions please see section 128 and 129 of the Standard Operating Procedures at http://ethics.health.govt.nz/home.

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After HDEC review

Please refer to the *Standard Operating Procedures for Health and Disability Ethics Committees* (available on www.ethics.health.govt.nz) for HDEC requirements relating to amendments and other post-approval processes.

**Your next progress report is due by 19 May 2018.**

**Participant access to ACC**

The Northern B Health and Disability Ethics Committee is satisfied that your study is not a clinical trial that is to be conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialled. Participants injured as a result of treatment received as part of your study may therefore be eligible for publicly-funded compensation through the Accident Compensation Corporation (ACC).

Please don’t hesitate to contact the HDEC secretariat for further information. We wish you all the best for your study.

Yours sincerely,

Mrs Kate O’Connor  
Chairperson  
Northern B Health and Disability Ethics Committee

Encl:  
appendix A: documents submitted  
appendix B: statement of compliance and list of members
Appendix 9: Data collection table pre- and post- Locality Authorisation

<table>
<thead>
<tr>
<th>Data fields proposed at initial submission of TOCC study (Options in brackets)</th>
<th>Edited list of data as a result of concerns from Locality Authorisation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Mode of birth <em>(Spontaneous or Instrumental)</em></td>
<td>1. Mode of birth <em>(spontaneous water birth/spontaneous not in water/instrumental)</em></td>
</tr>
<tr>
<td>2. Position of woman at time of birth <em>(Semi-recumbent/Seated upright/Lying on side/Lithotomy/Kneeling/Standing/Squatting/Other)</em></td>
<td>2. Position of woman at time of birth <em>(no change from initial options)</em></td>
</tr>
<tr>
<td>3. Location of woman at time of birth <em>(bed/floor/pool/couch)</em></td>
<td>3. Who facilitated the birth? <em>(no change from initial options)</em></td>
</tr>
<tr>
<td>4. Position of baby between birth and cord clamping <em>(On women’s abdomen or chest/Held by birth practitioner below level of introitus/Other)</em></td>
<td>4. Who clamped the cord? <em>(no change from initial options)</em></td>
</tr>
<tr>
<td>5. Who facilitated the birth? <em>(Midwife/Doctor/Student/Woman/Partner/Support person/Other)</em></td>
<td>5. Was the neonatal team present at the birth or within first five minutes? <em>(Yes/No)</em></td>
</tr>
<tr>
<td>6. Who clamped the cord? <em>(As above)</em></td>
<td></td>
</tr>
<tr>
<td>7. What was the intention of third stage management? <em>(Active/Physiological)</em></td>
<td></td>
</tr>
<tr>
<td>8. Was a uterotonic given? <em>(Yes/No)</em></td>
<td></td>
</tr>
</tbody>
</table>
or after cord clamping? (Before/After)

9. Were there any complications at the time of the birth? (Abnormal fetal heart/ tight nuchal cord/ meconium liquor/ concern around maternal condition/Other/None)

10. Was the neonatal team present at the birth or within first five minutes? (Yes/No)

11. Did the baby require resuscitation, and if so, where? (Ventilation with Ambubag/ Neopuff and/or suction/ At resuscitaire or with woman)

12. Was a cord blood sample required? (Yes/No)
References


after vaginal delivery as part of the management of the third stage of labour. *Cochrane Database of Systematic Reviews*, (9).
https://doi.org/10.1002/14651858.cd004665.pub3


