Factors Influencing Women’s Decisions about Having the Pertussis-Containing Vaccine during Pregnancy

Linda Hill

A thesis submitted for the degree of Master of Health Sciences (Nursing) at the University of Otago, Christchurch, New Zealand

February 2015
ABSTRACT

BACKGROUND: New Zealand (NZ) experienced a major epidemic of pertussis (whooping cough) from September 2011 to January 2014. With numbers of pertussis notifications reported totalling 5793 in 2012, compared with 1392 notifications in 2011; infants less than one year of age represented 7% of cases reported in 2012. The Canterbury region had high numbers of notifications reported therefore, the Canterbury District Health Board (CDHB) were first to fund the pertussis-containing (tetanus, diphtheria, and acellular pertussis (Tdap)) vaccine for pregnant women 30-36 weeks’ gestation and two weeks postpartum living in the CDHB area; after considering international and national recommendations. The research study’s main focus was to explore the factors influencing pregnant women relating to their decisions about having the pertussis-containing vaccine.

AIM: This involves two separate research projects: Study One’s primary aim was to explore the factors influencing women’s decisions regarding having the pertussis vaccine during pregnancy. Study Two’s primary aim was to explore whether the acceptance of immunisation during pregnancy is associated with infant immunisation status and timeliness.

METHODS: The thesis comprises two separate studies using quantitative, retrospective, observational cohort research designs; conducted within the CDHB area. Study One explored the influencing factors of women considering Tdap vaccine during pregnancy, and utilised a self-reported survey approach, and data collection with 596 postpartum women occurred from June to October 2013. Study Two investigated whether the acceptance of immunisation during pregnancy will influence infants’ vaccination status and timeliness at six weeks, three months, and five months of age with 363 infants of women who had received the Tdap vaccine in pregnancy. Study Two collected retrospective data retrieved from NZ National Immunisation Register (NIR).

RESULTS: The findings indicate the main influencing factors of women who accepted the Tdap vaccine during pregnancy were: the desire to protect their baby, the recommendation from a health professional, the threat of pertussis in the community, and that the vaccine was funded. In contrast, women who did not receive the Tdap vaccine reported the main influencing factors to be; that they did not know the vaccine
was available, fear of side effects, and doubt regarding vaccine effectiveness. A health professional’s recommendation was found to be a significant influencing factor, however it would appear that there are a number of health professionals not communicating any or sufficient information to their patients. In fact a proportion provided discouraging information to women which led to them deciding not to get vaccinated. Infants of women who had received Tdap vaccination during pregnancy were more likely to receive their primary immunisation series on-time.

CONCLUSION: No previous NZ study has investigated the factors that influence women’s choice to be immunised during pregnancy. A clear health professional recommendation for maternal Tdap immunisation was a significant factor influencing pregnant women in making such a choice. Improving the amount of positive messages women receive about Tdap vaccination during pregnancy would most likely improve the uptake of the vaccine and increase protection of infants from pertussis. Receipt of Tdap vaccine during pregnancy appears to have a positive effect for on-time infant immunisations.
ACKNOWLEDGEMENTS

It is with much gratitude and thanks that I acknowledge the following people who have contributed and supported the completion of this thesis in many ways.

I would like to greatly thank my supervisors Dr Beverley Burrell and Dr Tony Walls, for their guidance, knowledge and encouragement throughout this project, and for their invaluable input and assistance. Your care, patience and thoughtful deliberation to ensure my thesis reached completion are sincerely appreciated. I would also like to acknowledge Dr Jonathan Williman, Biostatistician, for your expert advice, guidance and assistance.

Dr Helen Petousis-Harris, thank you for the conversations, advice and support from the beginning to the end of this project. Many thanks also to Dr Lance Jennings, Dr Peter Mitchell, and Associate Professor Nikki Turner for your ongoing guidance and support at different stages of the research.

I also extend my appreciation to the National Immunisation Register Team (Canterbury District Health Board) for your time and support.

To my colleagues and friends thank you for your support and assistance, especially Bernadette Heaphy, Bridget Lester, Catherine Flanagan, Deb Batchelor, Janette Philp, Jill Geary, Kathryn Jones, Margaret Kyle, Rachel Hall, Rebecca Milburn, and Tracey Poole.

Finally to my incredibly patient family, thank you for your endless love, support, and encouragement, this has enabled me to achieve this goal. To my husband Noel, and children Matthew and Letitia, my sincere appreciation for your willingness to travel this journey with me.
TABLE OF CONTENTS

ABSTRACT ........................................................................................................................................ii
ACKNOWLEDGEMENTS .................................................................................................................iv
TABLE OF CONTENTS ..................................................................................................................v
LIST OF TABLES ..........................................................................................................................x
LIST OF FIGURES ........................................................................................................................xi
1 CHAPTER ONE: Introduction ......................................................................................................1
  1.1 Background ..........................................................................................................................2
  1.2 Aims of the Study .................................................................................................................2
  1.3 Structure of Thesis ...............................................................................................................3
2 CHAPTER TWO: Literature Review ............................................................................................5
  2.1 Introduction to Pertussis .......................................................................................................5
  2.2 Microbiology .......................................................................................................................6
    2.2.1 Diagnostic Tests ..............................................................................................................7
  2.3 Clinical Presentations ..........................................................................................................7
    2.3.1 Infants and Young Children .........................................................................................7
    2.3.2 Adolescents and Adults ...............................................................................................8
  2.4 Immunology - General principles ......................................................................................8
    2.4.1 Immune Correlates of Protection for Pertussis ...........................................................10
    2.4.2 Duration of Pertussis Immunity ..................................................................................11
  2.5 Epidemiology .......................................................................................................................11
    2.5.1 Global Epidemiology ....................................................................................................12
    2.5.2 New Zealand Epidemiology .......................................................................................13
  2.6 Pertussis Vaccine Options ....................................................................................................14
    2.6.1 Whole-cell Pertussis Vaccine .....................................................................................14
    2.6.2 Acellular Pertussis Vaccines ......................................................................................15
    2.6.3 Efficacy of the Vaccines .............................................................................................16
    2.6.4 Different Vaccine Schedules used Globally ...............................................................18
  2.7 Strategies to Reduce the Burden of Pertussis in New Zealand ...........................................19
    2.7.1 Timeliness of Vaccination .........................................................................................20
    2.7.2 Protecting Health Care Workers ..............................................................................21
    2.7.3 Cocooning ..................................................................................................................21
    2.7.4 Maternal Vaccination .................................................................................................24
2.8 The Safety of Vaccination during Pregnancy - General Principles ........26
2.8.1 Tetanus and Diphtheria Vaccine ...........................................26
2.8.2 Influenza Vaccine ................................................................27
2.8.3 Safety of Tetanus, Diphtheria, Acellular Pertussis (Tdap) Vaccine during Pregnancy ..........................................................27

2.9 The introduction of Tdap Vaccine during Pregnancy in New Zealand ....28
2.9.1 Factors Considered, Epidemiology, and the USA Recommendations ....28
2.9.2 Factors Considered, Epidemiology, and the United Kingdom Recommendations ...........................................................................29
2.9.3 Timeline of Introduction In Relation to the New Zealand Epidemic ....30

2.10 Influencing Factors Relating to Vaccination in Pregnancy ..................30
2.10.1 Seasonal Influenza Vaccine .......................................................31
2.10.2 Tetanus, Diphtheria, Acellular Pertussis Vaccines (Tdap) ..............32

2.11 Conclusion ................................................................................34

3 CHAPTER THREE: Research Methodology Overview ..........................35
3.1 Research Aims: .........................................................................35
3.2 Methodology Approach ...............................................................35
3.3 Descriptive Correlation Design ....................................................35
3.3.1 Descriptive Research .................................................................36
3.3.2 Correlation Research .................................................................36
3.3.3 Cohort studies .........................................................................36
3.4 Research Methodology .................................................................37
3.5 Sampling Method .......................................................................38
3.6 Setting of the Study .....................................................................38
3.7 Summary ....................................................................................38

4 CHAPTER FOUR: Research Methodology and Methods: Study One .......39
4.1 Research Aims ..........................................................................39
4.1.1 Hypotheses ...........................................................................39
4.2 Research Methodology ...............................................................39
4.3 Methods: Approach and Instrument ............................................39
4.3.1 Questionnaire Development ....................................................41
4.3.2 Pilot Study of the Survey ..........................................................41
4.4 Sample Method ..........................................................................41
4.4.1 Inclusion Criteria ....................................................................42
4.4.2 Sample Size ........................................................................................................... 42
4.5 Data Collection Procedures ..................................................................................... 42
4.6 Ethical Considerations ............................................................................................. 43
  4.6.1 The Right to Self-Determination ....................................................................... 43
  4.6.2 Maintaining Confidentiality .............................................................................. 44
4.7 Treaty of Waitangi .................................................................................................. 44
4.8 Data Analysis ......................................................................................................... 44
4.9 Summary .................................................................................................................. 45

5 CHAPTER FIVE: Results and Analysis - Study One .................................................. 46
  5.1 Survey Response Rate ........................................................................................... 46
5.2 Participant Age Characteristics ............................................................................... 47
5.3 Participant Ethnicity, Highest Qualification and Vaccine Status Characteristics ....... 47
  5.3.1 Ethnicity Characteristics ................................................................................... 47
  5.3.2 Education Characteristics ................................................................................. 48
5.4 Lead Maternity Carer (LMC) .................................................................................. 50
5.5 Most Helpful Source for Information ..................................................................... 51
5.6 Encouraging or Discouraging Information Received: Relating to the Tdap Vaccine during Pregnancy ............................................................... 52
5.7 Factors Associated with Receiving the Tdap Vaccine ............................................. 54
  5.7.1 Women Who Received Tdap during Pregnancy; Influencing Factors ....... 55
  5.7.2 Women Who Did Not Receive Tdap during Pregnancy: Influencing Factors .......................................................... 58
  5.7.3 Knowledge of the Vaccine Availability of those who did not receive the vaccine ........................................................................................................ 61
  5.7.4 Knowledge about the Pertussis Disease and Vaccination in General ......... 63
5.8 Knowledge of the Pertussis Outbreak/Disease Impact on Decisions .............. 66
5.9 Infants Enrolled with General Practitioner ......................................................... 68
5.10 Chapter Summary ................................................................................................. 69

6 CHAPTER SIX: Study One – Discussion, Limitations and Recommendations .... 70
  6.1 Discussion ............................................................................................................. 70
  6.1.1 Health Professionals Recommendations ....................................................... 70
  6.1.2 Main Considerations for Receiving the Vaccine ........................................... 71
  6.1.3 Main Considerations for Not Receiving the Vaccine ..................................... 72
6.1.4 Convenience/access of Tdap vaccine ........................................... 73
6.2 Limitations ......................................................................................... 73
6.3 Summary ............................................................................................ 74
6.4 Recommendations ............................................................................ 75
6.4.1 Recommendations for Improved Communication ..................... 75
6.4.2 Recommendation for Health Professional Education ................ 76
6.4.3 Recommendations for Future Research ..................................... 77
7 CHAPTER SEVEN: Research Methods Study Two .......................... 78
7.1 Research aim ...................................................................................... 78
7.1.1 Hypothesis ...................................................................................... 78
7.2 Research Method .............................................................................. 78
7.3 Sample Method ................................................................................. 79
7.3.1 Inclusion Criteria ........................................................................... 79
7.3.2 Sample Size ................................................................................... 79
7.4 Data Collection Procedures ............................................................. 79
7.5 Ethical Considerations ...................................................................... 80
7.5.1 The Right to Self-Determination ................................................ 80
7.5.2 Maintaining Confidentiality ......................................................... 80
7.6 Data Analysis ..................................................................................... 80
7.7 Summary ........................................................................................... 81
8 CHAPTER EIGHT: Results and Analysis - Study Two ..................... 82
8.1 Sample included ............................................................................... 82
8.2 Prevalence of On-time Immunisation Coverage by Inclusion in the SMART VIP Study Cohort ................................................................. 82
8.3 Summary ........................................................................................... 83
9 CHAPTER NINE: Study Two– Discussion, Limitations and Recommendations .. 84
9.1 Discussion ........................................................................................ 84
9.1.1 Vaccination Timeliness ................................................................. 84
9.1.2 Early Vaccinations ....................................................................... 84
9.2 Limitations ....................................................................................... 86
9.3 Summary .......................................................................................... 86
9.4 Recommendations ........................................................................... 87
9.4.1 Extension of the Tdap Vaccine on the National Immunisation Schedule 87
9.4.2 Future Research .......................................................................... 87
Table 5.1  Participant Characteristics: Age, Ethnicity, Qualification and Vaccine status
__________________________49
Table 5.2: Discouraging Information Source of GPs vs Receipt of Tdap Vaccine ___53
Table 5.3: Knowledge about the pertussis disease and vaccination in general ______65
Table 8.1: Prevalence of on time immunisation coverage by inclusion in the SMART VIP study cohort __________________________________83
Table 8.2: Infant Immunisation given early (>5 days early) ________________________83
LIST OF FIGURES

Figure 5-1 Characteristics of participants compared by age _____________________________47
Figure 5-2 Characteristics of participants compared by ethnicity ______________________48
Figure 5-3 Lead Maternity Care Provider ______________________________________________50
Figure 5-4 When deciding whether or not to receive the Tdap vaccine, participants were asked to indication the information sources that were “most helpful”__________________________51
Figure 5-5 Participants indicated the sources of “encouraging information” received._____________________________52
Figure 5-6 Participants indicated the sources of “discouraging information” received. ________________________________53
Figure 5-7 Overview of the returned survey result and the path participants followed, depending on whether they had received the Tdap vaccine or not. ____54
Figure 5-8 Statements put to women who received the Tdap vaccine relating to protection/prevention __________________________________________________________55
Figure 5-9 Statements put to women who received the Tdap vaccine relating to recommendations or awareness ______________________________________________________56
Figure 5-10 Statements put to women who received the Tdap vaccine relating to vaccine access/threat of pertussis circulating ________________________________57
Figure 5-11 Statements put to women who had not received the Tdap vaccine relating to vaccine access/convenience ________________________________________________58
Figure 5-12 Statements put to women who had not received the Tdap vaccine relating to perceptions about the vaccine _________________________________________________59
Figure 5-13 Statements put to women who had not received the Tdap vaccine relating to vaccine confidence ______________________________________________________60
Figure 5-14 Women who did not receive Tdap vaccine were asked if they were aware that the Tdap vaccine was available to them_______________________________61
Figure 5-15 Women who did not know the vaccine was available were asked “would you have considered having tdap vaccine during pregnancy if it had been offered?” __________________________62
Figure 5-16 Participants were asked “how concerned are you that a vaccine would not prevent the pertussis disease?” ____________________________________________66
Figure 5-17 Participants indicated their main concern when deciding about Tdap vaccine during pregnancy ________________________________________________67
Figure 5-18 Participants were asked “have you ever known someone affected by pertussis?” ___________________________________________________________68
Figure 5-19 Infants enrolled with a General Practitioner ________________________________69
CHAPTER ONE: Introduction

New Zealand (NZ) experienced a major epidemic of pertussis (whooping cough) from September 2011 to January 2014 (Institute for Environmental Science and Research (ESR), 2014). Young infants were particularly affected during the epidemic, even with high vaccination coverage the incidence of disease remains inadequately controlled (World Health Organisation (WHO), 2010).

In the absence of maternal immunisation, pregnant women have only small amounts of protective antibodies possible to be transferred across the placenta to the unborn infant prior to birth. The main reason for the limited protection from maternal antibodies is due to waning immunity and low antibody titres in pregnant women (Edwards & Decker, 2013). This leaves young infants unprotected from pertussis as they only receive small amounts of protective antibodies to be transferred across the placenta, and they are too young to be immunised (Crowcroft, Duclos, & Birmingham, 2003; Quinn, Habig, Snelling, Chiu, Spokes, & McIntyre, 2013).

On-time immunisation of infants is the focus of reducing the risk of pertussis in infants (Petousis-Harris, Grant, Goodyear-Smith, Turner, York, Jones, & Stewart, 2011; Somerville, Grant, Scragg, & Thomas, 2007) during an epidemic, a key public health intervention and a current NZ Health Target. Delayed immunisation, especially of pertussis, has been associated with increased rates of pertussis in infants and hospitalisation (Grant, Roberts, Scragg, Stewart, Lennon, Kivell, Ford, & Menzies, 2003).

A more recent preventive strategy has been the recommendations for the pertussis-containing (tetanus, diphtheria, and acellular pertussis (Tdap)) vaccination late in the third trimester of pregnancy (Gall, 2012). Maternal Tdap vaccination has been estimated to have a vaccine effectiveness of 91 percent protection against infants developing pertussis in the first two months of life (Amirthalingam, Andrews, Campbell, Ribeiro, Kara, Donegan, Fry, Miller, & Ramsay, 2014). In NZ currently, the Tdap vaccine is available fully funded to pregnant women as part of the national immunisation schedule.
1.1 Background

The NZ national immunisation schedule includes a three dose infant schedule of acellular pertussis-containing vaccine at six weeks, three months and five months of age, and two booster doses at four years and 11 years of age (Ministry of Health (MoH), 2014a). All vaccines on the national immunisation schedule are provided through private general practices (family medicine specialist, doctors known as General Practitioners (GP) and nurses known as Practice Nurses (PN)); the vaccines administered are recorded on the National Immunisation Register.

A Lead Maternity Care (LMC) is the healthcare professional responsible for the antenatal care of the women through until the infant is six weeks of age, at which time the mother and infant care is transferred to the GP. Antenatal care is provided at no charge to families as part of routine mother and infant healthcare during this time period, and predominantly provided in NZ by midwives. Most midwives do not have the resource to provide administration of vaccines routinely. Therefore, women are required to visit their GP to receive the funded vaccines during pregnancy, the visit is additional to and not part of routine antenatal healthcare, but funded for the purpose of the receiving the maternal vaccination of Tdap or influenza vaccines. Of which both vaccines are funded as they are included on the national immunisation schedule.

There is limited literature relating to the factors that influence women’s decisions about having the pertussis-containing vaccine during pregnancy, with the majority relating to the vaccines administered to postpartum women. Therefore, this thesis research design has the primary focus to explore the factors influencing women’s decisions about having the Tdap vaccine during pregnancy.

1.2 Aims of the Study

This thesis involves two separate research projects. Study One titled: “factors influencing women’s decisions about having the pertussis-containing vaccine during pregnancy”, and Study Two: “Acceptance and timeliness of infant vaccination of mothers who received the Tdap vaccine during pregnancy”.

Study One had the primary aim to survey what factors for pregnant women had the greatest influence on the decisions to accept or decline immunisation during pregnancy. Secondly, whether knowledge had influenced the decisions, and finally whether a
recommendation from a significant source had an influence on the participants’ decisions.

Study Two had the primary aim to compare infant vaccination status and timeliness of infants born of women who had received immunisation during pregnancy, with the overall CDHB area birth cohort.

The findings from this research will inform the body of knowledge relating to immunisation, and what impacts the decisions of women about vaccination in pregnancy and whether this strategy has any impact on infants’ vaccination timeliness. Findings from this research may have implications for policy development, and provide valuable information to both pregnant women and the health sector in the context of immunisation in NZ.

1.3 Structure of Thesis

The thesis design comprises two separate studies with two populations. Study One used a survey methodology, while Study Two retrieved data from the NZ National Immunisation Register (NIR) retrospectively. This section provides an overview of the following chapters including an outline of the background, informs the methods used and discusses the findings of the two studies separately.

Chapter two presents the relevant international and national literature on *Bordetella pertussis* (whooping cough), including the microbiology of *B. pertussis*, pertussis epidemiology, clinical presentation of the disease, the burden and implications of the disease and the global and national epidemiology. Strategies of reducing the burden of this disease are discussed, including vaccination during pregnancy, safety of vaccination, and the influencing factors relating to vaccination during pregnancy.

Chapter three provides an overview of the research methodology approach and justification of the methods utilised for the collection and analysis of data for the two studies.

Chapter four outlines the research methodology and methods used for the collection and analysis of data for Study One. Including an explanation of the research methods utilised and includes the description of the instrument, process of data collection,
sample used, and the ethical and cultural considerations identified throughout the research process.

Chapter five presents the results of the self-administered survey. This will include the response rates, participant characteristics and the overall findings from the survey.

Chapter six discusses the key findings identified in chapter five. The limitations of Study One, recommendations for improved communication, health professional education, and future research will be offered at the end of the chapter.

Chapter seven provides the research methods for Study Two. This will include the study sample, data collection process, and ethical considerations identified throughout the research process.

Chapter eight describes the results of Study Two, including the sample size, and key findings.

Chapter nine discusses the key findings identified of Study Two. The limitations of Study Two will be outlined, and recommendations relating to infant vaccination timeliness and future research are offered.

Chapter ten offers a conclusion of the two studies of the thesis research.
2 CHAPTER TWO: Literature Review

This chapter provides an overview of pertussis, including the microbiology of *B. pertussis*, epidemiology, clinical presentation of the pertussis disease, its burden and implications of the disease for adults, adolescents and infants in particular. Strategies of reducing the burden of this disease are discussed, including vaccination during pregnancy, safety of vaccination, and the influencing factors relating to vaccination during pregnancy. The chapter often refers to the textbook “Vaccines” (Plotkin, Orenstein, and Offitt, 2013) an authoritative source for vaccinology; other authoritative research studies are also included.

2.1 Introduction to Pertussis

Pertussis is a highly contagious bacterial respiratory infection which remains a common, serious and potentially fatal disease for infants. Pertussis resulted in more infant deaths than measles, diphtheria, poliomyelitis and scarlet fever combined, in the United States of America (USA) during the 1940s (Gordon & Hood, 1951). A whole-cell pertussis vaccine was introduced during the 1940s with significant reduction in the incidence of pertussis disease in infants (Higgs, Higgins, Ross, & Mills, 2012; Wiley, Zuo, Macartney, & McIntyre, 2013b). While the whole-cell vaccine was very effective, it was also a more reactogenic vaccine, and replaced during the 1990s in most developed countries with the acellular pertussis vaccine which has an improved reacotogenicity profile than the whole-cell pertussis vaccines (Higgs, et al., 2012; Wiley et al., 2013b).

Despite the significant reduction of pertussis incidence from the introduction of pertussis vaccines and high vaccine coverage, epidemics continue to occur every four to five years in NZ (MoH, 2014a). An infant in NZ has a risk of being hospitalised from pertussis disease that is three times greater than an infant in Australia or England (Grant & Reid, 2010). During the recent epidemic, September 2011 until January 2014, there were more than 600 hospitalisations and three infant deaths in NZ (Institute for Environmental Science and Research (ESR), 2013).

Incomplete immunisation is a major factor for NZ’s high pertussis burden of disease (Grant & Reid, 2010). Delay in receipt of any of the infant doses of pertussis vaccine is associated with a five-fold increase risk of hospitalisation admission, one in three NZ
infants are at increased risk of hospitalisation due to their delayed immunisations (Grant et al., 2003). Historically NZ has had low rates of coverage for the infant immunisations measured at two years of age, with 60 percent in 1992, 77 percent in 2005 (Grant & Reid, 2010), and 92 percent in 2014 (MoH, 2014b). Lower rates of coverage are also evident at the four year immunisation event, of 80 percent in 2014 (MoH, 2014b), therefore, older children may have less protection from circulating pertussis. The national NZ immunisation coverage rates measured at 6 months were 84 percent, and 94 percent for both 8 months and two years of age, for the year ending December 2014 (MoH, 2014b).

2.2 Microbiology

Pertussis is a severe bacterial respiratory tract infection caused by the *B. pertussis* organism, a small gram-negative bacillus, and a highly contagious disease, spread from person to person by respiratory droplets (Edwards & Decker, 2013). Outbreaks of pertussis were described in the 16th century, and the organism was first grown in culture medium in 1906 by Bordet and Gengou. A further Bordetella organism is *B. parapertussis*, responsible for a similar pertussis like illness. Although closely related, only *B. pertussis* produces pertussis toxin (PT), and therefore parapertussis is a less severe illness clinically (Edwards & Decker, 2013).

Pertussis has a marked attraction to ciliated epithelial cells of the respiratory tract and attaches to them. The organism multiplies in the epithelial cells but does not penetrate submucosal cells or the blood stream. However, the bacterium produces a range of toxins, adhesins, and fimbriae which are associated with adhesion and colonisation; these include filamentous hemagglutinin (FHA), pertactin, and some PT (Edwards & Decker, 2013; Lee & Bishop, 2010). Components of the PT including adenylate cyclase, tracheal cytotoxin, and endotoxin, are able to enter the blood stream, and combined, are responsible for the pathogenesis of clinical features of pertussis disease. The *B. pertussis* components are responsible for an immune response to one or more of the components which produces immunity following infection or immunisation (Atkinson, Wolfe, Hamborsky, & McIntyre, 2009a; Edwards & Decker, 2013; Lee & Bishop, 2010).
2.2.1 Diagnostic Tests

Pertussis cases are confirmed by culture of the organism from a swab of the nasopharynx of symptomatic patients, by detection of pertussis DNA using polymerase chain reaction (PCR) assays. Isolation rates of pertussis are highest early in the illness; samples obtained after 21 days of the cough are significantly less likely to yield the organism (Edwards & Decker, 2013).

2.3 Clinical Presentations

The incubation period of pertussis averages nine to ten days. Pertussis disease manifestations may be different in infant presentation to that of adolescents and adults, as described below. Furthermore, there is recognition of milder and less typical presentation, in those whose immunity may have waned over time after infection or vaccination, particularly in adolescents and adults (Cherry, 2012; Fortner, Kuller, Rhee & Edwards, 2012). The clinical course of the disease is described in three stages; catarrhal, paroxysmal, and convalescent (Edwards & Decker, 2013).

2.3.1 Infants and Young Children

The catarrhal stage is the insidious onset of coryza, and sneezing, with fever minimal throughout the infection, and a mild or occasional cough, similar to a common cold; symptoms are indistinguishable from an acute upper respiratory infection (Paisley, Blaylock, & Hartzell, 2012). Crowcroft & Pebody (2006) and Edwards & Decker (2013) describe the typical characteristics of the disease as follows; the paroxysmal stage refers to the cough, which progresses within one to two weeks to become paroxysmal. The paroxysms increase in frequency and severity, then gradually decreases, lasting no longer than two to six weeks (Crowcroft & Pebody, 2006; Edwards & Decker, 2013). The characteristic “whoop” occurs as the cough is most severe, caused by forced inspiration through a narrowed glottis immediately after a paroxysm of rapid, short coughs without inspiration; the “whoop” may be seen less often in infants and may be replaced by apnoic episodes (Edwards & Decker, 2013). Furthermore, cyanosis and post-tussive vomiting may occur during a paroxysm; clinical assessment of such paroxysm is required as apnoea or respiratory arrest may occur.

---

1 The three clinical stages; catarrhal, paroxysmal, and convalescent are discussed under headings “Infants and Young children” and “Adolescents and Adults” (Edwards & Decker, 2013).
After a paroxysm episode, the child is exhausted; unfortunately many paroxysms may occur in succession within minutes and may be triggered by eating, laughing, crying or other stimuli, and usually the cough worsens at night (Edwards & Decker, 2013). During the convalescent stage, paroxysms become less frequent and milder, and the “whoop” disappears.

Complications of pertussis in childhood, described by Crowcroft & Pebody (2006), include pneumonia, failure to thrive from post-tussive vomiting, seizures, encephalopathy, cerebral hypoxia leading to brain damage, secondary bacterial infection, pulmonary hypertension, sub-conjunctival haemorrhage, and rectal prolapse. Those less than six months of age are at greatest risk of death (Top, Halperin, Baxendale, MacKinnon-Cameron, & Halperin, 2010).

2.3.2 Adolescents and Adults

Pertussis can also present as the typical disease described above in adolescents, adults and the elderly, although the catarrhal phase may be mild or absent, or present as a prolonged cough; these variations may be due to partial immunity from prior infection or immunisation (Edwards & Decker, 2013). Evidence shows that adolescents and adults are often the reservoir for pertussis infection and a source of pertussis spread to young infants (Edwards & Decker, 2013; Healy & Baker, 2012; Paisley et al., 2012).

Adolescents and adults may experience profuse sweating and post-tussive vomiting, and the inspiratory “whoop” is often absent or occasional (Edwards & Decker, 2013). Adults have been reported with higher rates of complications than adolescents, with pneumonia, urinary incontinence, fractured ribs, severe weight loss, and seizures; death in these age groups from pertussis is rare (Atkinson et al., 2009a; Cherry, Tan, Wirsing von Konig, Forsyth, Thisyakorn, Greenberg, Johnson, Marchant, & Plotkin, 2012; Edwards & Decker, 2013; Paisley et al., 2012).

2.4 Immunology - General principles

The immune system has the ability to provide protection from disease, through the recognition of a specific pathogen (viruses and bacteria), and production of antigen-specific antibodies (humoral immunity) and T-cell responses (cell-mediated immunity) (Siegrist, 2013). Disease control or elimination involves protective immunity in a sufficient proportion of a population (Siegrist, 2013).
Most disease is prevented by physical barriers of the body such as skin, cilia, and mucosa. When a pathogen breaches these barriers, the innate (non-specific) immune system, which includes dendritic cells, monocytes and neutrophils, will recognise and kill the pathogen, and alert the adaptive (specific) arm of the immune system (Siegrist, 2013). On exposure to an antigen, the antigen-presenting cells (APCs) adapt to display specific surface receptors and migrate to the lymph nodes, where they activate the T and B cell immune responses (Siegrist, 2013; Theeten, Van Damme, Hoppenbrouwers, Vandermeulen, Leback, Sokal, Wolter, & Schuerman, 2005). The process induces highly efficient B cells through specific structures called germinal centres, in which antigen-specific B cells multiply and change into antibody-secreting plasma cells or memory cells; these changes induce antigen-specific T and B cells, which also result in T and B memory cells (Siegrist, 2013).

Long term protection from an antigen requires persistence of antibodies and the generation of immune memory cells capable of rapid and effective reaction to subsequent antigen exposure. Such disease protection describes active immunity from the disease or immunisation, which provides duration of protection for years or life depending on the specific disease or vaccine (Siegrist, 2013).

Passive immunity may provide short duration of protection from maternal protective antibodies passed by mothers to their infant via placenta transfer (Atkinson et al., 2009a; Edwards & Dekker, 2013; Siegrist, 2013). Another example of passive immunity is by immunoglobulin or donor blood transfer, essentially the donor antibodies will protect the recipient immediately. Both examples of passive immunity rely on the protective antibodies being present and will only provide protective duration for weeks or months, depending on the specific disease (Atkinson et al., 2009a).

Pertussis vaccination during in the last months of pregnancy results in high levels of passive antibody protection transferred to the infant via placenta from the vaccinated mother to her infant (Amirthalingam et al., 2014), and should protect against pertussis from birth (Gall, 2012; Gall, Myers, & Pichichero, 2011). Premature babies will have

---

2 Passive immunity is the antibody protection transferred from either the mother to the unborn infant via the placenta, or by administration of an antibody product (known as immunoglobulin) from one human to another to offer protection if the recipient is thought to have no immunity or has an impaired antibody production (Atkinson et al., 2009). These antibodies will protect the recipient from certain diseases, although the protection wanes with time usually weeks to months (Atkinson et al., 2009).
lower concentration of antibodies, therefore a shorter duration of protection; babies born prior to 28 weeks gestation will have few or no protective antibodies transferred (Siegrist, 2013). The half-life of the transplacental acquired pertussis antibodies for the newborn is approximately six weeks, and by four months of age most infants have no detectable maternal antibodies (Edwards & Dekker, 2013; Van Savage, Decker, Edwards, Sell & Kazron, 1990).

Young infants, particularly those less than two months of age, are at greatest risk of pertussis and highest risk of severe complications, hospitalisation and death from pertussis infection (Health Protection Agency, UK (HPA), 2012). Such young infants are too young to be immunised (HPA, 2012).

There is a theoretical concern relating to the pre-existing maternal pertussis antibody levels in the young infants suppressing or blunting their immune response to the infant vaccines (Healy, Rench, & Baker, 2013; Van Savage et al., 1990). These concerns are important as NZ recommends the first pertussis-containing vaccine at six weeks of age. This is expected to be less of a concern with acellular vaccine than whole-cell (Healy et al., 2013; Van Savage et al., 1990), but is unknown and further research is needed.

2.4.1 Immune Correlates of Protection for Pertussis

Correlates of protection can be defined as an immune response that is statistically correlated with protection against infection, disease or vaccination; which is quantified and associated with a threshold value that can be measured (Van Damme, Ward, Shouval, Wiersma, & Zanetti, 2013). An example of a correlate of protection is the Hepatitis B (HB) virus; the vaccine induced protection against HB virus infection is having an anti-HB level of 10 milli-International Units/mL or higher, measured one to three months after receipt of a complete vaccination course (Van Damme et al., 2013).

Immune correlates of protection are established in randomised, placebo efficacy trials to find the specific post-vaccination level of immunity that correlates with preventing the disease (Edwards and Decker, 2013). There is no established serologic correlation of protection for pertussis immunity (Edwards and Decker, 2013; Healy et al., 2013) and therefore considerable difficulty in measuring pertussis vaccine immunogenicity, efficacy and effectiveness. The substantial variability of individual vaccines make the
results of efficacy trials difficult to interpret and cannot provide correlates that are generalisable to all pertussis vaccines (Edwards & Decker, 2013; McCormick, 2012).

2.4.2 Duration of Pertussis Immunity

The duration of protection for pertussis is unknown (Siegrist, 2013). Duration of protection from vaccination is thought to be shorter than after the natural infection, however immunity from both the vaccine and natural disease is incomplete and will wane over time (Theeten et al., 2005).

Protective immunity after natural pertussis infection is estimated to wane after seven to 12 years (Edwards & Decker, 2013). It is estimated that the whole-cell vaccine duration of immunity ranges between four to 12 years, and protection acquired by acellular vaccine is approximately six years (Edwards & Decker, 2013; Lyseng-Williamson & Dhillon, 2012; McCormick, 2012).

Vaccine induced immunity may be less vigorous, but more protective against the disease than the infection (Theeten et al., 2005; Warfel, Zimmerman, & Merkel, 2012). Cell-mediated immunity, as well as humoral immunity, of pertussis is important for protection against pertussis (Higgs et al., 2012). The cell mediation of the T-helper cells varies between the whole-cell vaccine and acellular vaccine which provides such protective immunity for pertussis (Higgs et al., 2012; Warfel et al., 2013).

Current recommendations state an acellular pertussis vaccine booster to be offered every ten years. Especially, healthcare professionals working in paediatric, gynaecologic, obstetric health areas (Edwards & Decker, 2013; MoH, 2014a), and also anyone employed to care for preschool children.

2.5 Epidemiology

Pertussis remains a public health problem worldwide, particularly in young infants and children (WHO, 2010). Even in countries with high vaccination coverage, the incidence of disease remains inadequately controlled (WHO, 2010). However, much of the morbidity and almost all of the mortality have occurred among the infants too young to immunised (Versteegh & Edwards, 2012). The focus of pertussis vaccination worldwide is to reduce the risk of severe pertussis in infants, with an aim to achieve greater than 90 to 95 percent coverage with a primary course of three doses of high quality pertussis vaccine in infants (Grant, 2013; WHO, 2010).
2.5.1 Global Epidemiology

In the early 1940s, prior to the introduction of the whole-cell pertussis vaccine, pertussis was a major cause of infant death worldwide, with over 200,000 cases and nearly 7,000 deaths per year occurring in the USA (Paisley et al., 2012). Vaccination reduced the incidence of pertussis by 92 percent and the mortality by 99 percent (Paisley et al., 2012). The WHO (2010) estimated that in 2008 about 16 million cases of pertussis occurred worldwide, which affected both developed and developing countries; about 195,000 children died from the disease.

The epidemic intervals do not appear to have altered over the years, since 1996 when pertussis became a notifiable disease in NZ (Grant & Reid, 2010), with epidemic peaks occurring approximately every three to four years and lasting approximately 18 months, regardless of widespread pertussis vaccination of children (Crowcroft & Pebody, 2006; de Greeff, Dekkers, Teunis, Rahamat-Langendoen, Mooi, & De Melker, 2009; Kmitowicz, 2012; ESR, 2013). It seems that childhood immunisation has had no significant impact on circulating pertussis disease in communities (Edwards & Decker, 2013). However, the introduction of highly sensitive PCR assays has shown an increase in pertussis in adolescents and adults, and in individuals with no clinical evidence of pertussis (Cherry, 2013; de Gref et al., 2009; Edwards & Decker, 2013).

Increases of pertussis disease have been observed internationally in the last decade, among adults, adolescents and primary school aged children, who represent important sources of transmission to infants too young to be immunised (de Gref, Hester, de Melker, Westerhof, Schellekens, Mooi, & van Boven, 2012; Edwards & Decker, 2013; van Hoek, Campbell, Amirthalingam, Andrews, & Miller, 2013). The USA 2010 pertussis outbreak reported more persons effected that year than in any single year during the previous six decades, with adults and adolescents accounting for over 50 percent of cases, and accounted for the deaths of ten infants less than three months old (Healy & Baker, 2012; Paisley et al., 2012). Furthermore, England and Wales reported that pertussis affected nearly ten times the number of adults and older children in 2012 than in 2008, when the disease last peaked (Kmietowicz, 2012).

The Netherlands, despite having high infant immunisation coverage, have reported increased notifications since 1996 (de Gref, de Melker, van Gageldonk, Schellekens, van der Klis, Molema, Mooi, & Berbers, 2010). A serological surveillance study,
between 2006 and 2007, identified approximately nine percent of the population over nine years of age had a pertussis infection in the previous year (de Greeff et al., 2010). Such increased rates of pertussis in older age groups contribute to high transmission of pertussis to susceptible young infants from household contacts, and reported to range from 76 percent to 90 percent (de Greeff et al., 2009; de Greeff et al., 2010; Versteegh & Edwards, 2012); transmission rates in a school setting range from 50 percent to 80 percent (Edwards & Decker, 2013; WHO, 2011).

In the Asia-Pacific region, in the majority of countries, children less than five years old bear the greatest burden of disease (Forsyth, Thisyakorn, Wirsing von Konig, Tan, & Plotkin, 2012). However, in Australia the disease burden is broader, and includes adolescents, children and infants; the difference in detectable rates in Australia to other Asia-Pacific countries may be due to greater use of laboratory diagnostics and a heightened awareness of the disease by the public and the medical professionals (Forsyth et al., 2012).

The literature indicates that the factors for the recent increased statistics on pertussis disease incidence and the changing distribution of age include: increased awareness of health professionals, the introduction and access of more specific and sensitive diagnostic tests, and the effectiveness of the acellular vaccines compared to whole-cell vaccines on the causative strains circulating (Cherry, 2012; de Greeff et al., 2009; de Greeff et al., 2010; Mooi, 2010; Paisley et al., 2012; van Hoek et al., 2012). Waning immunity from either the vaccine or infection affects the increase in recent disease due to the continuation of circulating bacteria in the community (Guiso, 2009; Mooi, 2010). Finally, it has been suggested that changes in genetic pertussis strains have led to increased vaccine failure (Mooi, 2010); at present however, there is no evidence to support this idea (Cherry, 2012; Guiso, 2009).

### 2.5.2 New Zealand Epidemiology

NZ experienced significant increase in pertussis notifications from September 2011 to January 2014. The highest weekly notification count occurred during week 51 of 2012 (Institute for Environmental Science and Research (ESR), 2013). The most vulnerable are those under one year of age, with cumulative notification rates in 2012 of 663.8 per 100,000 population, the highest of all age groups (ESR, 2013). The notification data
for 2012 indicates there were 414 cases of pertussis in those less than one year of age, representing 182 hospitalisations and two infant deaths (ESR, 2013).

Of cases in 2012, the ethnic cumulative rates were highest for the European/pakeha population (162.4 per 100,000), followed by Māori (139.0 per 100,000) and Pacific peoples (90.6 per 100,000). However, the ethnic distribution of pertussis cases aged less than one year old, were highest for Māori (926.5 per 100,000), followed by Pacific peoples (800.6 per 100 000). While higher notification rates across all other age groups occurred in Europeans, there were higher hospital admissions for Pacific (23.6%) and Māori (14.5%) children (ESR, 2013).

Geographically in NZ, the rate of notifications is highest in the Nelson-Marlborough District Health Board (DHB) area (478.2 per 100,000) followed by the West Coast DHB (458.1 per 100,000). Vaccination status was known for 1654 cases of 2554 confirmed cases of pertussis with known age, nationally. Of the 1654 cases, 589 were not vaccinated, which included 24 cases aged less than six weeks and therefore not eligible for vaccination. Six hundred and thirty-five cases reported between one and four doses and 119 cases reported having completed pertussis vaccination. A further 311 cases reported being vaccinated but no dose information was available (ESR, 2014). Possible reasons for pertussis cases in the vaccinated group are: waning immunity five to eight years after children receive their final pertussis-containing vaccine, rendering adolescents and adults susceptible to pertussis (Castagnini, Healy, Rench, Wootton, Munoz, & Baker, 2012), and the possible changes in circulating pertussis strains, yet to be verified (Cherry, 2012).

2.6 Pertussis Vaccine Options
Most developed countries currently use a multicomponent acellular vaccine, whereas most resource-limited countries continue to use the older whole-cell vaccines consisting of inactivated whole B. pertussis bacteria. There are no monovalent pertussis vaccines available internationally; all come combined with at least diphtheria and tetanus toxins (Heininger, 2012).

2.6.1 Whole-cell Pertussis Vaccine
Whole-cell vaccines were introduced in the late 1940s (Plotkin & Plotkin, 2013) and remain the most widely used vaccines globally, as they have been shown to be
efficacious and are inexpensive to produce, with many produced locally in numerous regions of the world. Whole-cell pertussis vaccines are suspensions of killed *B. pertussis* cells, which generally use a formalin-inactivation process (Atkinson, et al., 2009a; Edwards & Decker, 2013).

Some countries suspended the routine use of whole-cell vaccines in the 1970s-1980s, despite the clear benefits in reducing the substantial mortality and morbidity of pertussis, due to concerns about potential adverse effects. The whole-cell pertussis vaccines have been one of the most reactogenic vaccines. The whole-cell vaccine commonly caused reactions that were minor such as: redness, swelling, pain at the side of injection, fever, and a high pitched cry. Uncommon reactions that occurred included: febrile seizures, or a shock-like state known as hypertonic-hypo-responsive episode (HHE) which were transient but frightening and occasionally seen with the acellular vaccines (Edwards & Decker, 2013).

Whole-cell vaccines were thought to be causally related to such outcomes as encephalopathy or sudden infant death syndrome, but epidemiologic studies have dispelled these concerns (Edwards & Decker, 2013). The epidemiologic studies referred to were examined by the Institute of Medicine (IOM), in 1991 and 1993, who convened the Committee to Study the Adverse Consequences of Pertussis and Rubella Vaccines; the Committee examined data from: reported serious adverse events over a 20 month period, case studies and individual case reports, both published and unpublished, epidemiologic studies, studies in animals, and other laboratory studies. Their findings dispelled the concerns related to such outcomes as encephalopathy or sudden infant death syndrome (Howson, Howe, & Fineburg, 1991; Stratton, Johnson Howe, & Johnston, 1994; Howson & Fineburg, 1992).

2.6.2 Acellular Pertussis Vaccines

Due to the common occurrence of the minor but troublesome local reactions, and the less common but more severe systemic reaction which were causing public concern associated with the whole-cell vaccine; a newer and less reactogenic pertussis vaccine was developed (Edwards & Decker, 2013). The first acellular vaccine was developed and licenced for use in Japan in 1981, with the expectation that it would be as effective, but less reactogenic, than the whole-cell vaccine (Bechini, Tiscione, Boccalini, Levi, & Bonanni, 2012; Plotkin & Plotkin, 2013).
The acellular pertussis vaccine required a greater understanding and isolation of individual components of the *B. pertussis* organism, and the specific role in disease pathogenesis and immunity (Edwards & Decker, 2013). The first, acellular pertussis vaccine used in Japan, was based on two of the main protective antigens of *B. pertussis*, inactivated pertussis toxin and filamentous hemagglutinin. Further multicomponent acellular vaccines have been developed since then, some with additional protective antigens (Plotkin & Plotkin, 2013), often with two or five *B. pertussis* antigen components (Heininger, 2012).

Acellular pertussis vaccines contain purified, inactivated components of a *B. pertussis* cell, which use either formaldehyde, glutaraldehyde, or genetic inactivation processes depending on the manufacturing process (Atkinson et al., 2009a). All acellular pertussis vaccines are associated with significantly lower rates and severity of every adverse reaction, except vomiting compared with the whole cell vaccine (Edwards & Decker, 2013).

### 2.6.3 Efficacy of the Vaccines

Efficacy varies between different whole-cell and acellular pertussis vaccines (Heininger, 2012). Immunogenicity data from different vaccines, in terms of their vaccine effectiveness, is difficult to interpret due to the lack of clear serological correlation of protection, and the range of case definitions used in studies limits comparability (Cherry, 2012).

Not all whole-cell pertussis vaccines have the same efficacy; there is substantial variation between individual vaccines (Greco, Salmaso, Biol, Mastrantonio, Giuliani, Tozzi, Anemona, Ciofi, Giammanco, Panei, Blackwelder, Klein, & Wassilak, 1996; Zhang, Prietsch, Axelsson, & Halperin, 2011). Whole-cell pertussis vaccines have efficacy estimates against typical pertussis ranging from 38 percent to 92 percent, although substantial lot-to-lot variation has been demonstrated (Heninger, 2012).

Acellular vaccines that contain three or more *B. pertussis* antigens are reported to have a greater efficacy for mild and typical pertussis presentation than one or two component

---

3 The bacterium produces a range of toxins, adhesins, and fimbriae which are associated with adhesion and colonisation; these include filamentous hemagglutinin (FHA), pertactin, and some pertussis toxin (PT) (Edwards & Decker, 2013; Lee & Bishop, 2010).
vaccines (Mattoo & Cherry, 2005). The efficacy of multicomponent acellular vaccines vary from 84 percent to 85 percent in preventing typical pertussis, and from 71 percent to 78 percent in preventing mild pertussis disease (Zhang et al., 2011). Furthermore, the five antigen component vaccines may have better efficacy than three component vaccines (Mattoo & Cherry, 2005), but there is insufficient data to determine whether there is a clinical difference (Zhang et al., 2011). There is conflict in the literature, Cherry (2013) argues that estimates of vaccine efficacy have been inflated due to the variations of case definitions. Cherry (2013) as a WHO committee member, disagrees with the primary case definition which required laboratory confirmation and > 21 days of paroxysmal cough; as such would eliminate mild to moderate clinical presentation being identified and reported. Therefore, when less severe cough illness is included the efficacies of two multicomponent vaccines are estimated to decrease to 71 percent from 78 percent (Cherry 2013).

Identifying the optimal preparation for an acellular vaccine has been difficult, as no simple method exists to determine the protective capability of a pertussis vaccine (Plotkin & Plotkin, 2013). A major limitation of all pertussis vaccines is the short duration of immunity, and means that infant and childhood vaccination programmes fail to control pertussis circulating. Such limitations enable pertussis disease to reoccur in older age groups as immunity wanes (Castagnini et al., 2012; Poolman, Hallander & Halperin, 2011).

There is debate in the literature regarding the replacement of the whole-cell pertussis vaccines with the acellular pertussis vaccines attributing to possible evolution of pertussis strain changes, enabling a wider number of strains to circulate and led to increased incidence of pertussis statistics (Mooi, 2010); there is no evidence epidemiologically as the disease differs across countries and it is unclear whether any changes in the incidence of disease is from vaccine pressure or genetic drift (Cherry, 2010; Guiso, 2009). Such patterning has not occurred in countries where acellular vaccines have been used for over 15 years (Cherry, 2012; Mooi, 2010). Many agree that the contribution of strain variability may be less of a concern than the accumulation of susceptible individuals due to waning immunity (Cherry, 2010; Guiso, 2009; Mooi, 2010).
2.6.4 Different Vaccine Schedules used Globally

The WHO (2011) recommends a three dose primary course, however most countries first dose of the primary course starts at two or three months of age and not six weeks as recommended; with the exception of the Czech Republic who start at nine weeks of age (Edwards & Decker, 2013) and NZ at six weeks of age (MoH, 2014a). Subsequent doses are recommended at age ten to 14 weeks and 14 to 18 weeks, the last of the three dose primary course to be completed by six months of age (WHO, 2011). Versteegh & Edwards (2012) concur, to reduce the burden of pertussis administration of infant formulation of diphtheria, tetanus and acellular pertussis (DTaP) vaccine should be administered at six weeks, as opposed to waiting until eight weeks, as unimmunised children put immunised children at risk of pertussis.

A booster dose of a pertussis vaccine is recommended for children aged between one to six years, preferably in the second year of life (WHO, 2011). In 1996 NZ introduced a booster dose of the pertussis vaccine in the second year of life, in 2006 the national immunisation schedule was reviewed and the booster dose, at 15 months, was removed (Grant & Reid, 2010). Overall, the majority of countries offer a paediatric booster dose in the second year of life, with the exception of NZ, Australia, Sweden, Peru, and Indonesia all of whom currently do not (Edward & Decker, 2013). Only acellular pertussis vaccines are recommended for those six years and older (WHO, 2011). WHO (2011) acknowledge that vaccination is able to prevent pertussis in adults and adolescents, but had insufficient evidence to support additional booster doses in these age groups in order to reduce severe pertussis in infants, which would be the primary goal for the recommendation. Internationally, very few countries include an adolescent or adult booster dose in their recommended immunisation schedule (Edwards & Decker, 2013). Vaccination reduces the risk of pertussis by 92 percent (Ward et al., 2005) therefore, adult and adolescent booster vaccination should be considered (Lavine, Bjornstad, de Blasio, & Storsaeter, 2012; Versteegh & Edwards, 2012; Zepp, Heinginger, Mertsola, Bernatowska, Guiso, Roord, Tozzi, & Van Damme, 2011). Cherry (2012) concurs that with circulating pertussis in all age groups, there is a need for universally vaccination for all age groups at frequent intervals.

The NZ immunisation schedule recommends a pertussis-containing vaccine at six weeks, three months, and five months of age, with a booster dose added at four years of...
age, which was introduced in 2002 to protect children during early primary school years and reduce transmission of pertussis to younger infants/siblings. In 2006, a further change occurred to extend a booster dose to protect into adolescence, given at 11 years of age; reflecting the current NZ immunisation schedule (MoH, 2014a). However, vaccination at 11 years of age is unlikely to have an effect on pregnant women, as their immunity will have waned therefore, they will have insufficient pertussis-specific antibodies passed onto their infants to protect against pertussis infection (Healy et al., 2013).

2.7 Strategies to Reduce the Burden of Pertussis in New Zealand

The Global Pertussis Initiative (GPI), an expert scientific forum was formed in 2001 to respond to rising rates of pertussis internationally; part of their focus is developing effective immunisation strategies for pertussis control (Forsyth et al., 2012; Grant & Reid, 2010). The 2001 GPI recommendations focused on strategies to reduce transmission to infants, to develop broad immunity within a population and reduce morbidity and mortality in all age groups; NZ was represented in the 22 delegates from 12 countries (Forsyth et al., 2012). The recommendations from this initiative include:

- Reinforcement and/or improvement in current infant and toddler immunisation strategies
- Selective immunisation of child care workers
- Selective immunisation of healthcare workers
- Cocoon immunisation
- Universal pre-school booster doses (at four and six years of age)
- Universal adolescent immunisation
- Universal adult immunisation

The GPI proposed that not all strategies should be weighted equally in all geographic settings; the emphasis to be on the adherence for the primary vaccinations series of infants and toddlers (Forsyth et al., 2012). Delay in receipt of the first vaccine dose in the primary series is one of the strongest and most consistent predictors of subsequent incomplete immunisation (Petousis-Harris et al., 2011)
2.7.1 Timeliness of Vaccination

Delayed immunisation leaves the infant unprotected from pertussis therefore a specific risk factor for hospitalisation of infants with pertussis than any other acute respiratory illness. The 1996 pertussis epidemic associated a five-fold increase risk of hospitalisation with pertussis (Somerville et al., 2007; Petousis-Harris et al., 2011). Delayed vaccination leaves the infant vulnerable, and mortality is highest in those who develop disease in the first six months of life (Crowcroft et al., 2003).

To control pertussis well, 95 percent vaccine coverage (Fine & Mulholland, 2013) for all three doses of the primary course by six months of age is needed. Immunisation in NZ became a Health Target in 2010, with the focus on infants fully immunised by two years of age (Grant & Reid, 2010). However, despite the intensive coverage, timeliness is still an issue (Grant & Reid, 2010), hence the change of national Health Target in 2012 to focus on those fully immunised by the eight months, better reflecting the timeliness of the infants’ primary course of the scheduled vaccines on the NZ national immunisation schedule. National coverage for the 12 months ending September 2014 for infants six months of age was 78 percent, and 91 percent by eight months of age (MoH, 2014b); which still reflects a delay of immunisations for some infants.

Antenatal primary care is provided predominantly by midwives in NZ, and it is therefore necessary for parents/caregivers of a new-born child to then identify a family medical practice for Well Child/Tamariki Ora care (Petousis-Harris et al., 2011). Prompt transition between these two health providers of the primary health care system is evidently necessary to achieve a good start to the immunisation aspects of Well Child care (Petousis-Harris et al., 2011). Delay of enrolment at general practice may lead to delay in the uptake of the first vaccination as it is identified that contact with confident, engaged health providers will support and improve immunisation coverage (Petousis-Harris et al., 2011).

As on-time coverage increases, additional strategies become just as important. These include: vaccination of healthcare workers and childcare workers, cocoon immunisation around newborns, which are all aimed to protect children who are too young to be

---

4 Well Child / Tamariki Ora is a series of health assessments and support services for children and their families from birth to five years of age; which includes health promotion, access primary specialist health care, education and social services (MoH, 2014).
vaccinated and at risk from being exposed to circulating pertussis (Forsyth, Campins-Marti, Caro, Cherry, Greenberg, Guiso, Heininger, Schellekens, Tan, von König, & Plotkin, 2004). At least eight present of adults, who seek medical care for a cough illness of at least five days duration, will have pertussis (Grant & Reid, 2010).

2.7.2 Protecting Health Care Workers

Healthcare workers (HCW) are at increased risk of pertussis, and outbreaks have occurred in hospital settings. Calugar, Ortega-Sanchez, Tiwari, Oakes, Jahre, & Murphy (2006) reported 17 symptomatic cases of pertussis among HCWs, in America, which resulted from a one day exposure to an infant with pertussis. Contact tracing identified 307 exposed close contacts of the symptomatic HCWs. The single nosocomial pertussis outbreak resulted in substantial disruption and cost to the hospital, HCWs, their families and their patients. The benefit of immunising HCWs to the hospital is estimated to be 2.38 times the dollar amount spent (Calugar et al., 2006).

2.7.3 Cocooning

Household members have been reported to be responsible for 76 percent to 83 percent of transmission of pertussis to young infants (Versteegh & Edwards, 2012). Gall (2012) states that a person with pertussis disease is highly infectious and will infect 80 - 90 percent of non-immune household contacts. With household transmission identified as the primary source of pertussis in infants, pregnancy would be a key opportunity to review immunisation records of household members and ensure all those living in the household are fully immunised (Grant & Reid, 2010). In NZ, this would rely on early communication from antenatal primary care providers, predominantly midwives, to the pregnant women’s general practitioner to review patient and family records.

There is conflict in the literature whether the cocoon strategy is effective or not. Grant & Reid (2010) argue that the theoretical case for cocoon vaccination around newborns is strong, though its efficacy lacks supporting evidence. Quinn, Habig, Snelling, Chiu, Spokes, & McIntyre (2013) found that maternal pertussis immunisation before pregnancy reduced the risk of pertussis by approximately 50 percent for the infants less than four months of age; especially for families with significant risk factors for infant

---

5 Cocoon immunisation or cocooning, focuses on protecting newborn infants by selective vaccination of close contacts of the newborn (Grant & Reid, 2010; Versteegh & Edwards, 2012).
pertussis which include large households and less favourable socio-economic circumstances. Healy and Baker (2012) report cocooning could lead to a 70 percent reduction in pertussis cases in infants less than three months of age. A Netherlands prospective study between 2006 and 2009 collected data on transmission of pertussis within households nationwide with clinically confirmed infection; which included 140 households in total consisting of 140 infants, 140 mothers, 133 fathers, and 188 other family members, (de Greeff et al., 2012). The study showed high transmission rates within the households, with mothers being the most infectious to their infants than other household members, and fathers least. The high estimated infectiousness of mothers compared with fathers and other household members may be due to their more intensive contact with the infant as a result of “pregnancy leave”, as law in the Netherlands at the time of the study was only provided for mothers (de Greeff et al., 2012).

An Australian cross-sectional survey, from 2009 to 2012, surveyed parental attitudes, awareness and uptake of a cocooning strategy found that parents had reasonable knowledge of pertussis and a willingness to be vaccinated to protect their child; 70 percent of mothers and 53 percent of fathers (Donnan, Fielding, Rowe, Franklin, & Vally, 2013). Factors identified to increase vaccine uptake for the cocoon strategy would include stronger, specifically targeted communication messages, particularly relating to the susceptibility of adults to pertussis and the potential severe effects for infants; with a focus for fathers to increase the vaccine uptake in this important group.

A Canadian study modelled effectiveness of the cocoon strategy using surveillance and epidemiology data from 2000 to 2009, which included at least one cyclical peak (Skowronski, Janjua, Ouakki, Hoang, & DeSerres, 2012). The number needed to vaccinate (NNV), for parental immunisation cocoon strategy, was at least one million to prevent one infant death, approximately 100,000 to reduce one intensive care unit admission, and greater than 10,000 to reduce one hospitalisation. The authors conclude that where disease incidence is low, cocooning to prevent infant pertussis morbidity and mortality is ineffective and resource intensive (Skowronski et al., 2012).

Gall (2012) challenges the cocooning strategy and identified several problems; firstly, the strategy was never field tested before being recommended in the USA by the Centre for Disease Control (CDC) in 2006; secondly, there had been research reporting that
over 50 percent of disease in neonates is from a non-identifiable source; thirdly, the logistical challenge of the funding and administration of the vaccine for family units if they can be located; finally, the importance of ensuring that the vaccination is implemented at least two weeks prior to coming into contact with the infant to be able to offer protection, relating to the immune response required within that time period.

Furthermore, Bechini et al. (2012) and Castagnini et al. (2012) state the importance of a cocooning strategy to incorporate immunisation of all household and key contacts of the newborn with a pertussis containing vaccine, not only mothers. Targeting only mothers creates an incomplete cocoon of protection for the infant who is vulnerable from other unimmunised and susceptible contacts (Bechini et al., 2012). Castagnini et al. (2012) report a strategy only immunising postpartum women did not reduce pertussis illness in infants less than six months of age. Healy, Rench, Wootton, & Castagnini (2015) concur, after conducting an evaluation of a cocoon strategy programme that was implemented in an American Hospital. The study included 196 infants, less than six months of age, diagnosed with pertussis pre-intervention, 140 infants during the intervention for Tdap vaccination of postpartum women only, and 64 infants of mothers vaccinated with the Tdap vaccine postpartum combined with vaccination of all contacts of the infant. Healy et al. (2015) found that postpartum immunisation and cocooning were not effective on their own to reduce pertussis in infants; however state that efforts should be made combined both cocooning and vaccination during pregnancy.

In summary, vaccinating siblings maybe less effective in preventing household transmission, but could be effective overall as siblings often introduce infection into the household (Gall, 2012). Vaccination of fathers is expected to be the least effective strategy (Gall, 2012); unless they are the primary caregiver. In the context of low pertussis incidence cocooning maybe inefficient, resources intensive, and difficult to implement (Versteegh & Edwards, 2012) for the focus of preventing serious infant disease complications (Skowronski et al., 2012).

However, where pertussis rates are a significant threat to infants, high risk population, cocooning may provide 50 percent to 70 percent reduction of cases in young infants (Healy & Baker, 2012; Quinn et al., 2013). Vaccinating parents is two-fold; firstly to protect infants too young themselves to receive the pertussis vaccine and most at risk.
Secondly, the most common and consistent source of pertussis infection acquired by young infants are parents, especially mothers; through the immunity of adults, it should also reduce transmission to infants (Healy et al., 2013; Quinn et al., 2013). Furthermore, timely maternal vaccination is associated with a lower risk of pertussis in unimmunised infants (Quinn et al., 2013); and combined with cocooning may further reduce pertussis in infants (Healy et al., 2015).

2.7.4 Maternal Vaccination

Many authors agree that vaccination of pregnant women may be a more effective strategy than cocooning (Bechini et al., 2012; de Greeff et al., 2012; Gall, 2012). The strategy was investigated, in small studies, during the 1930s using a whole-cell pertussis vaccine administered late in pregnancy which resulted in high levels of pertussis-specific antibodies in infants (Bechini et al., 2012; Healy et al., 2013; Lichty, Slavin & Bradford, 1938). In principle, vaccination of mothers during pregnancy would help to protect mothers from infection and offer protect to infants from birth and until immunity is induced by active vaccination (Bechini et al., 2012; de Greeff et al., 2012; Gall, 2012).

In a small (n=33) American phase 1-2 randomised controlled clinical trial from 2008 to 2012, Munzo, Bond, Maccato, Pinell, Hammill, Swamy, Walter, Jackson, Englund, Edwards, Healy, Petrie, Ferreira, Goll, & Baker (2014), found that the concentrations of the Tdap vaccine induced pertussis-specific antibodies of infants born to mothers immunised with Tdap during pregnancy were significantly higher at birth and at two months of age, than in infants whose mothers were immunised postpartum. Furthermore, no increased risk of adverse events was found among women who had received the Tdap vaccine during pregnancy, 30-32 weeks’ gestation, or their infants (Munzo et al., 2014).

An observational study (England) estimates vaccine effectiveness of acellular-pertussis vaccine administered late in the third trimester can provide 91 percent protection against the infant developing pertussis disease in the first two months of life (Amirthalingam et al., 2014). Furthermore, Dabrera, Amirthalingam, Andrews, Campbell, Ribeiro, Kara, Fry, & Ramsay (2015) found the estimated vaccine effectiveness of women vaccinated during pregnancy to be 93 percent in preventing pertussis infection in infants less than eight weeks of age. This was demonstrated in a
case-control study, in England and Wales, which involved infants less than eight weeks of age at onset of a pertussis infection (n=58), and 55 healthy infants identified as controls for the study, with the mother’s pertussis vaccination status was verified as to whether she had received the Tdap vaccine during pregnancy, and the gestational ages as at vaccination and at delivery (Dabrera et al., 2015).

Mitchell, Green, Mulrine, & Dong (2014), reviewed the notifications from five South Island District Health Boards in NZ, 2009 to 2013, and analysed data from 1997 to 2013 to evaluate the extent of epidemics in the South Island historically. Their findings included a significant overall reduction (41.7 percent) in the percentage of notifications of infants less than three months of age in the 12 months following the commencement of the maternal Tdap programme for the South Island (Mitchell et al., 2014).

The transportation of immunoglobulin G (IgG) across the placenta is an active, selective, and intracellular process beginning at about 17 weeks and increases as gestation progresses (Englund, 2007; Esposito, Bosi, Morlacchi, Bassi, Sabatini, & Principi, 2012). By 33 weeks gestation maternal and foetal IgG levels are equal, and by 40 weeks gestation, the foetal IgG concentration is higher than that of the mother (Englund, 2007; Esposito et al., 2012). The efficacy of the process is dependent on multiple factors including the absence of placental abnormalities, total IgG concentration in maternal blood, the type of vaccine, the time of vaccination of the mother and delivery, and the gestational age of the foetus at birth (Englund, 2007; Esposito et al., 2012).

In 2011, the American Advisory Committee on Immunisation Practices (ACIP) recommended pregnant women receive Tdap in the third or late second trimester of pregnancy in preference to postpartum, as had previously been recommended. Healy et al., (2013) studied pertussis-specific immunoglobulin G (IgG) concentrations in delivery plasma from mothers who received Tdap vaccine within the prior two years. The authors conclude that infants of mothers immunised in preconception or early pregnancy have insufficient pertussis-specific antibodies to protect against infection (Healy et al., 2013; Quinn et al., 2013). However, even third trimester immunisation with Tdap vaccine would benefit only the offspring from that pregnancy, protection of future offspring would require repeated immunisation with each subsequent pregnancy (Healy et al., 2013).
Gall (2012) and Libster & Edwards (2011) highlight a theoretical concern that maternally derived antibodies may interfere with the infant’s immune response to the primary course of pertussis acellular vaccine offered on recommended immunisation schedules. Although vaccination during pregnancy could potentially protect both mother and infant, more data is needed relating to the extent of the antibody transfer (Healy et al., 2013; Zepp et al., 2011), the safety of such an approach, and whether there would be implications for the infant’s subsequent primary immunisation schedule (Gall, 2012; Libster & Edwards, 2011; Zepp et al., 2011).

2.8 The Safety of Vaccination during Pregnancy - General Principles

Administration of a vaccine is not usually recommended in pregnancy due to the fear of severe adverse effects for the foetus, however contraindications to vaccination during pregnancy applies only to vaccines based on live attenuated viruses; for the theoretical possibility that they might infect the foetus (Esposito et al., 2012). The potential risk has been studied in women who were inadvertently vaccinated during pregnancy with live attenuated rubella, influenza and yellow fever with no reported adverse outcomes (Lindsey, Kampmann, & Jones, 2013).

The administration of inactivated vaccines can be useful in pregnancy; for example tetanus and influenza (Esposito et al., 2012). Maternal vaccination during pregnancy focuses on protecting against vaccine preventable diseases for the mother and infant, or in the case of neonatal tetanus offers the infant protection in the first months of life (Lindsey et al., 2013).

2.8.1 Tetanus and Diphtheria Vaccine

Tetanus and diphtheria toxoid (Td) vaccines have been used extensively worldwide to prevent neonatal tetanus, and have not shown any teratogenic outcomes when administered during pregnancy (ACIP, 2011; Bechini et al., 2012). In developing countries, maternal tetanus immunisation is the most important means of preventing neonatal tetanus (Esposito et al., 2012). Tetanus vaccine, often combined with diphtheria, has been safely administered to several millions of pregnant women without documented serious outcomes (Lindsey et al., 2013).
2.8.2 *Influenza Vaccine*

Inactivated Influenza vaccination has been recommended internationally for pregnant women since 1994, and expanded in 2004 to include administration in the first trimester (Schlaudecker & Steinhoff, 2010). Munoz (2012) concludes that all available data to date support the safety of vaccination of pregnant women with inactivated influenza vaccine; a strategy focused to protect the mother and her infant. An American retrospective cohort study, over five years examined delivery and neonatal outcomes of 10,225 women after antenatal administration of the seasonal trivalent inactive influenza vaccine; outcomes by trimester of those vaccinated were compared with women who did not receive the vaccine (Shefeild, Greer, Rogers, Roberts, Lytle, McIntire, & Wendel, 2012). The authors found that influenza vaccination in the first trimester was not associated with an increase in major malformation rates and was associated with a decrease in the overall stillbirth rate (Sheffield et al., 2012).

Vaccination against influenza can protect women from a disease that can lead to hospitalisation and death in a significantly higher number of cases than in the general population, and can induce protective specific antibody levels as well as being effective in infants in the first months of life (Esposito et al., 2012). Pregnant women are at greater risk from complications associated with influenza illness (MoH, 2014a). Inactivated seasonal influenza vaccine is strongly recommended and often funded for pregnant women during the influenza season, regardless of gestation (Fortner et al., 2012; MoH, 2014a). Maternal vaccination with inactivated influenza virus vaccine is the most effective tool in reducing febrile respiratory infections among pregnant women (Fortner et al., 2012).

2.8.3 *Safety of Tetanus, Diphtheria, Acellular Pertussis (Tdap) Vaccine during Pregnancy*

Pertussis-containing vaccine (Tdap) was not licenced for use in pregnancy, and safety of administration during pregnancy was not studied in the pre-licensure evaluations. Therefore, due to the lack of information the manufacturers established a register to collect such information and pregnancy outcomes from pregnant women vaccinated with Tdap (ACIP, 2011). The ACIP (2011) included in their review of Tdap published and unpublished data, including the data from the pregnancy registers of the
manufacturers, and concluded that there was no suggestion of elevated frequency or patterning of adverse events in pregnant women who had received the Tdap vaccine.

From a safety perspective, the ACIP in 2011 concluded that administration of Tdap from 20 weeks’ gestation is preferable to minimise the low frequency risk of adverse effects and the possibility of any unrelated association that might appear causative. The Joint Committee for Vaccination and Immunisation (JCVI, 2012) in the United Kingdom independently recommended the Tdap vaccine during pregnancy. Only specifically planned studies can provide evidence as to whether vaccinating pregnant women with pertussis vaccine is safe and effective in preventing pertussis in infants, and without interfering with the infant’s immune response to subsequent vaccination (Esposito et al., 2012). The WHO (2011), concluded there was insufficient evidence for their recommendation for vaccinating pregnant women against pertussis, but when future research results are available they would review these studies on maternal vaccination using acellular pertussis vaccines.

In summary, administering the pertussis vaccine to mothers during their last months of pregnancy, results in high levels of antibodies against pertussis being transferred to the baby, offering protection against the illness from birth. This offers protection for infants too young themselves to receive the pertussis vaccine, and who are at greatest risk of the severe disease. Furthermore, a comprehensive review, encompassing more than five years of reports, to the Vaccine Adverse Event Reporting System (VAERS) in the USA, of pregnant women found no safety concerns for maternal Tdap vaccination (Zheteyeva, Moro, Tepper, Rasmussen, Barash, Revzina, Kissin, Lewis, Yue, Haber, Tokars, Vellozzi, & Broder, 2012). Timely maternal vaccination provides greater protection of pertussis in infants too young to be immunised (Quinn et al., 2013).

2.9 The introduction of Tdap Vaccine during Pregnancy in New Zealand

2.9.1 Factors Considered, Epidemiology, and the USA Recommendations

In 2011, ACIP reviewed their strategy and recommendations for pertussis control after considering factors of their existing strategy and the option of maternal vaccination, in light of their burden of disease at that time (ACIP, 2011). The majority of pertussis cases, hospitalisations, and deaths occurred in infants less than two months of age and
were too young to vaccinated (ACIP, 2011). A mean of 3,055 infant pertussis cases with more than 19 deaths were reported each year since 2004 (ACIP, 2011).

Therefore, in 2005 the ACIP had recommended Tdap vaccines to unvaccinated postpartum mothers and other family members of newborn infants, aiming to provide protection to the infant from pertussis (ACIP, 2011). Cocooning programmes over the five years achieved moderate vaccination coverage at best, due to the difficulties to implement the strategies to all potential infant contacts (ACIP, 2011).

Due to the substantially higher rates of pertussis in infants, compared to older children and adults the ACIP (2011) made new recommendations for the use of Tdap vaccine in unvaccinated pregnant women in June 2011. The ACIP (2011) recommendations considered the safety of Tdap in pregnant women, the evidence available for transplacental maternal antibodies, the possibility of maternal antibodies interference with infant immune response to primary infant vaccination, the cocooning strategy, and cost effectiveness analysis of maternal Tdap vaccination compared with immediately postpartum.

2.9.2 Factors Considered, Epidemiology, and the United Kingdom Recommendations

In 2012, the United Kingdom (UK) reviewed their current epidemiology and prevention strategy in relation to pertussis, finding that epidemiological data from England and Wales reported 1700 laboratory confirmed cases of pertussis in quarter two of 2012 (JCVI, 2012). Most of the reported cases were infants less than six weeks of age, and a high incidence in infants under three months of age (JCVI, 2012). Nine confirmed infant deaths reported up until week 39 in 2012, compared with between one and eight infants deaths annually over the period of 2001 and 2011 respectively (JCVI, 2012). The JCVI (2012) noted the recent USA recommendations for maternal vaccination with the Tdap vaccine brand, which was similar to a routine childhood vaccine available in the UK with the exception of the additional inactivated polio content. After consideration of the available data and the USA recommendations, a temporary programme was introduced to offer pregnant women immunisation against pertussis in response to the outbreak (JCVI, 2012).
2.9.3 Timeline of Introduction In Relation to the New Zealand Epidemic

In 2012, after reviewed all the recommendations and evidence, the Canterbury District Health Board (CDHB) decided to fund the Tdap vaccine and the administration of the vaccine, for pregnant women between 30-36 weeks gestation and women in the first two weeks postpartum, during the pertussis outbreak for women living in the CDHB area (CDHB, 2012). Later that year, the NZ Immunisation Sub-committee of the Pharmacology and Therapeutics Advisory also considered the ACIP and JCIV recommendations, and international evidence on the safety and effectiveness of the Tdap vaccine and in 2012 recommended the use of the Tdap vaccine during pregnancy in NZ (MoH, 2012a).

In January 2013, the NZ Pharmaceutical Management Agency (PHARMAC) began funding the use of Tdap during pregnancy, for women 28 to 38 week’s gestation, in NZ nationally as a temporary response to the current pertussis outbreak. The MoH (2014) recommends the influenza vaccine and is fully funded by PHARMAC for all pregnant women in NZ as well.

2.10 Influencing Factors Relating to Vaccination in Pregnancy

Concerns that immunisation during pregnancy poses a risk to the developing foetus are mainly theoretical (Healy, 2012; Riley & Beigi, 2013). As already discussed postponing the pertussis immunisation until the second trimester or later avoids concerns relating to pregnancy loss and foetal development (Healy, 2012; Riley & Beigi, 2013), and enhances maternal antibody levels for transfer to the infant (Lindsey et al., 2013). Vaccination of pregnant women with inactivated virus, bacterial vaccine, or toxoid vaccines have been recommended and no evidence have been associated with an increased risk of adverse foetal effects (Healy, 2012; Munoz, 2012; The American College of Obstetrics & Gynaecologists, 2012).

Provider support for recommendations following from this evidence regarding vaccination during pregnancy is strongly associated with vaccine uptake among pregnant women and can overcome their concerns about safety (Hayles, Cooper, Wood, 2014).

---

6 PHARMAC; The Pharmaceutical Management Agency (PHARMAC) is the New Zealand Crown agency that decides, on behalf of District Health Boards, which medicines and related products are subsidised for use in community and public hospitals.
Sinn, & Skinner, 2015; Eppes, Wu, You, Cameron, Garcia, & Grobman, 2013; Fortner et al., 2012; Tong, Biringer, Ofner-Agostini, Upshur, & McCreer, 2008; Wiley, Massey, Cooper, Wood, Ho, Quinn, & Leask, 2013a. Healthcare provider education is a key aspect in increasing providers’ awareness and support for recommendations leading to successful outcomes of such an important health intervention (Hayles, et al., 2015; Esposito et al., 2012; Wiley et al., 2013a).

2.10.1 Seasonal Influenza Vaccine

In the USA seasonal influenza vaccine coverage rates administered during pregnancy in 2010 were 51 percent, however a lot of work remains to achieve the CDC’s Healthy People 2020 goal of 80 percent influenza coverage recommended for all women pregnant during the influenza season (Lessin & Edwards, 2012). Interestingly, women who had a recommendation from a health professional for vaccination were three to ten-fold more likely to receive a vaccine than women whose health care provider did not encourage vaccination (Lessin & Edwards, 2012; Tong et al., 2008). Kuehn (2010) concurs that patients whose physician recommended the vaccination were more likely to be vaccinated than those who did not have a recommendation or have the vaccine mentioned to them, 70 percent versus 18 percent respectively.

The most important factor found in a cross-sectional study of maternity care providers’ and postpartum women’s knowledge, attitudes and behaviours towards the influenza vaccine during pregnancy, was that women accepting a vaccine during pregnancy was having a recommendation from a maternity care provider, and yet the most common barrier for providers included uncertainty about discussing, recommending, and administering the vaccine (Tong et al., 2008). One third of maternity providers were not aware of the national expert recommendations on maternal vaccinations (Tong et al., 2008). In an American study, vaccination safety was sighted as the most common reason for refusing the influenza vaccine; cited by 66 percent of the 307 women surveyed who declined (Kuehn, 2012). Lindsay et al. (2013), a study from England, reported women frequently reported refusing a maternal vaccine due to safety concerns.

An Australian study that surveyed the uptake of influenza vaccine by 88 pregnant women, reported healthcare provider recommendation, safety and efficacy perceptions and access to vaccines are major factors in vaccine uptake (Wiley et al., 2013a). Women’s concerns for their unborn child can be overcome by healthcare provider
recommendation, 68 percent agreed that they would have the vaccine if their doctor or midwife recommended it (Wiley et al., 2013a). Meharry, Colson, Grizas, Stiller, & Vazquez (2013) concur, adding that maternal influenza vaccination is underutilised due to missed opportunities by providers to recommend the vaccine to their patient, and prevent pertussis to the two most vulnerable populations, being the mother and foetus. Furthermore, those unvaccinated in the community are potentially the source of infection to others and each other (Carrico & O’Keefe, 2013).

In their (Australia) study McCarthy, Pollock, Nolan, Hay, & McDonald (2012), interviewed 439 new mothers during 2010 and 2011, and found that more women would have accepted maternal vaccination in the absence of three obstacles: poor availability during antenatal care, absent or inconsistent advice and practice from maternity providers compared to other health providers, and lack of discussion about the vaccination during the antenatal stage. McCarthy et al. (2012) concluded that the vaccination rate could have been as high as 78 percent in the absence of these obstacles. In 2011, the Royal Australian and NZ College of Obstetricians’ published a statement providing clear guidance for women and maternity providers, with a focus to increase the chance of influenza vaccination and its benefits being discussed with and delivered to pregnant women in Australasia.

2.10.2 Tetanus, Diphtheria, Acellular Pertussis Vaccines (Tdap)

There is limited literature directly relating to factors influencing women’s decisions about having the Tdap vaccine during pregnancy. The majority of the literature relates to Tdap vaccine administration for postpartum women, unless a correlation can be taken from studies relating to the influenza vaccine in pregnancy.

A Taiwanese study surveyed 1207 postnatal women to determine factors that influenced their decisions to accept or decline Tdap postpartum vaccination found that women that declined thought their infants were at low risk of exposure to pertussis, were concerned about the safety of the vaccine, or did not trust the information they had received (Cheng, Huang, Shaw, Kao, Chueh, Chang, Hsu, Kung, & Hsieh, 2010). In contrast, women who accepted Tdap believed they would be the most likely source of pertussis infection for their baby, thought they had received adequate information, and trusted the information source (Cheng et al., 2010).
An American prospective convenience study surveyed 900 postpartum women who had received postpartum Tdap and maternal influenza vaccination; acceptance of maternal vaccination was compared with their infant’s immunisation record (Calarco, Myers, Jackson, & Williams, 2012). Mothers who accepted pertussis containing vaccine postpartum and influenza during pregnancy were 82 percent and 63 percent higher, respectively, to have a fully vaccinated infant than women who had not accepted the vaccine or had received the vaccine in previous years (Calarco et al., 2012).

Furthermore, an Australian study surveyed 1080 postpartum women prospectively to evaluate the role of message-framing versus standard health information when promoting pertussis vaccination (Hayles et al., 2015). The study involved a ‘loss, ‘gain’, and ‘control’ framing of information; results suggested overall pertussis vaccine coverage had increased from the baseline of 23 percent to 77 percent of all mothers screened. There was no significant difference between the intervention groups.

Results from a French study suggested that an implemented strategy, which involved parents receiving information about pertussis vaccination and a prescription for the vaccine, increased vaccination coverage in mothers and fathers over time (Leboucher, Sentilhes, Abbou, Grimpel, & Descamps, 2012). This was a prospective, single centre study over two time periods; three months at the beginning of 2008 and 2009. Furthermore, the study identified physicians to be an essential link in this strategy for the postpartum vaccination delivery of information and vaccination.

An American prospective, controlled evaluation of hospital-based procedures for postpartum Tdap vaccine administration from 2009 to 2010, to determine the impact of specific interventions on the postpartum use of Tdap compared with a non-intervention hospital (Yeh, Mink, Kim, Naylor, Zangwill, & Allred, 2014). Yeh et al. (2014) found that the inclusion of pertussis vaccination as part of a hospital-based procedure resulted in significant improvement of mothers postpartum.

An Australian quantitative self-administered study surveyed 815 women receiving antenatal care to determine awareness and intentions toward recommendations for the pertussis vaccine postpartum, and their willingness to accept the vaccine during pregnancy if recommended (Wiley, Massey, Cooper, Wood, Quinn, & Leask, 2013c). Eighty percent of women reported willingness to receive the vaccine during pregnancy if recommended. Women who intended to have the vaccine postpartum represented 34
percent, while 45 percent had never heard of the vaccine, thought about it, or were undecided about having it. Women who had received a recommendation were 7 times more likely to report an intention to have the vaccine than women who had not received a recommendation (Wiley et al., 2013c).

2.11 Conclusion

Due to pertussis proving to be such a serious threat to vulnerable infants too young to receive vaccination, new strategies are needed. Vaccinating parents, especially mothers during pregnancy, provides protection for those most at risk of this vaccine preventable disease, but this is not enough.

The evidence shows the complexity of the pertussis disease as the profile and performance of the available vaccines and despite the significant reduction of pertussis incidence due to high coverage, epidemics continue to occur. Therefore, it is essential that such strategies as cocooning and especially maternal vaccination are understood and recommended, and provided by health professionals to the pregnant women in their care.

However, if infants are not vaccinated on time they are left most vulnerable to pertussis. Therefore, the strategies discussed in this chapter need to be integrated in order to provide the best protection. Young infants are most vulnerable, and optimal protection relies on each infant receiving their vaccination on-time to build their own immunity.
3  CHAPTER THREE: Research Methodology Overview

This chapter provides the justification of the research methods used for the two studies of this thesis design, and includes the limitations and consideration of the approach for the studies. This includes an overview of the study methods, sampling, and the geographical setting of the studies. The two studies will be discussed in more detail separately in later chapters.

3.1 Research Aims:
The design is a two-part study with two populations.

Study One had the primary aim to survey what factors for pregnant women had the greatest influence on the decisions to accept or decline immunisation during pregnancy. Secondary aims included whether knowledge about pertussis had influenced the decisions, and finally whether a recommendation from a significant source had an influence on the participants’ decisions.

Study Two had the primary aim to compare infant vaccination status and timeliness of infants born of women who had received immunisation during pregnancy, with the overall CDHB area birth cohort.

3.2 Methodology Approach
The studies utilised the methods approach of quantitative research, which is a broad term for research that uses systematic and objective methods that collects evidence able to be transformed into numerical data (Topping, 2010) to obtain information in order to answer research questions and/or hypotheses (Parahoo, 2006). Descriptive, correlation statistics analyse the data to examine the relationship of one variable to another (Parahoo, 2006); such as factors that influenced the decisions of those who received the funded Tdap vaccine during pregnancy and those who did not. Descriptive data may enable the researcher to identify any outlying variables gathered, and to analyse and illustrate the findings without distorting the overall results collected (Unsworth, 1999).

3.3 Descriptive Correlation Design
Descriptive correlation research aims include; describing populations, studying associations between variables, and establishing relationships between variables (Grove, Burns, & Gray, 2013; McKenna, Hasson, & Kenney, 2010). Although this
information is valuable, it cannot provide enough evidence about the cause and effect of the relationships identified (Grove et al., 2013; Heard & Harris, 1999; McKenna et al., 2010). Both descriptive and correlative approaches to research are non-experimental and therefore, there is no attempt to manipulate or control the variables but to identify and measure variables as they exist (Grove et al., 2013; McKenna et al., 2010), therefore observational.

3.3.1 Descriptive Research

Descriptive research is to provide an accurate account of the population being studied, measure and describe variables and frequency of which they occur (McKenna et al., 2010). The descriptive research design suited this thesis as it aims to evaluate the factors that may influence the acceptance of Tdap vaccine during pregnancy, which included exploring knowledge, perceptions and beliefs of the postpartum women.

Descriptive research describes phenomena of which little is known, through collection of data, patterns or trends that may emerge. It is possible links between the variables gathered (Grove, et al., 2013), but the emphasis is on the description (Parahoo, 2006).

3.3.2 Correlation Research

Correlational studies focus to explore relationships between the variables (Parahoo, 2006). Therefore, to examine relationships between two or more variables and may be able to determine the positive or negative effect and strength of the relationships (McKenna et al., 2006).

3.3.3 Cohort studies

Cohort studies research a group of people over time to measure their exposure to certain conditions, or who receive a particular treatment and are compared with another group who are not affected by the condition or treatment under investigation; a type of observational study (McKenna et al., 2006). The strengths of a cohort study include the ability to research multiple effects of one cause, and direct measure of incidence (Jolley, 1999). Cohort studies are vulnerable to follow-up bias, which may occur when the exposed group is more closely monitored for the treatment outcome than the unexposed group (Jolley, 1999). Therefore, the increased monitoring may lead to an apparent increased incidence rate within the exposed group compared to the unexposed group (Jolley, 1999).
3.4 Research Methodology

Survey research methods are an accessible and valuable research tool for studying human concepts such as attitudes, knowledge, beliefs and behaviours of individuals or groups, and can be applied retrospectively (Lacey, 2010; Parahoo, 2006). Survey tools can be used to gather self-reported data and measure such human concepts, having the advantage of minimal contact with the study population (Brown, 2012; Lacey, 2010; Parahoo, 2006).

Advantages of survey research include; the generalisability of the findings of the sample population, and lead to the ability to determine the characteristics and concepts found of the population (Polit & Beck, 2008). Surveys are considered to be relatively economical, flexible and not geographically limiting (Polit & Beck, 2008; Parahoo, 2006), allowing researchers to gather information on a population across a large region.

Limitations of such research tools include; that self-reported surveys can only provide information on questions asked, and rely on participants providing accurate and honest answers (Lacey, 2010; Polit & Beck, 2008). Therefore, the researcher’s skill to construct the survey that can best capture the concepts being explored is relied upon (Parahoo, 2006).

A further problem with self-reported surveys concerns the possibility of low response rates, which may result in the respondents not being representative of the target population (Brown, 2012). Response rates to mail-out questionnaires greater than 65 percent are considered good but lower response rates are the norm (Jones & Rattray, 2010; Polit & Beck, 2008); a response rate of approximately 35 percent is considered reasonable (de Vaus, 1999). However, the more anonymous, internet or postal surveys, methods may achieve a better response rate for sensitive topics where the individuals anonymity is important (de Vaus, 2002). Consultation was sought from the Health Sciences Statistician with the Master’s Supervisors to advise on the number of surveys needed to send out and the numbers of completed responses required during the data collection period to minimise bias for the study, and advise on strategies to maximise response rates. Options for surveys include, telephone surveys, self-administered questionnaires, and face-to-face interviews (Grove et al., 2013).
In Study Two, the SMART VIP infants’ vaccination statuses were confirmed using the NIR and the timeliness of their receipt of vaccines was compared to that of the overall CDHB area births for the same period of time. The data set in Studies One and Two are not directly linked to, but separate from each other. It is feasible that some individuals may be in both studies, there is no way to assess whether this has occurred.

3.5 Sampling Method

Sampling is the process of selecting a portion of a population to represent that population (Polit & Beck, 2008). The sampling method utilised is one of convenience. The problem with convenience sampling is that those who respond, or agree to enrol in a study, may be atypical of the overall population being represented (Polit & Beck, 2008).

3.6 Setting of the Study

The thesis research was carried out in the Canterbury District Health Board (CDHB) area; which is based in Christchurch. The CDHB geographically covers an area from Kekerengu in the north, down to Ashburton in the south, and inland to the Southern Alps, with approximately 6000 live births annually.

3.7 Summary

As discussed, both of the thesis studies use quantitative, retrospective, observational research methods. The next chapter will provide further detail on the research methods used for Study One, and include the collection and analysis of the data.
4 CHAPTER FOUR: Research Methodology and Methods: Study One

This chapter outlines the research methodology and methods in Study One titled “Factors influencing women’s decisions about having the pertussis-containing vaccine during pregnancy”. An explanation of the research methods utilised will include the description of the instrument, process of data collection, sample used, and the ethical and cultural considerations identified throughout the research process.

4.1 Research Aims

The focus was to survey what factors for pregnant women had the greatest influence on the decisions to accept or decline immunisation during pregnancy. Secondly, whether knowledge had influenced the decisions, and finally whether a recommendation from a significant source had an influence on the participants’ decisions.

4.1.1 Hypotheses

1. The attitudes to, and knowledge of pertussis disease will positively influence the acceptance of Tdap vaccine during pregnancy.

2. A clear recommendation from a health professional regarding Tdap immunisation during pregnancy will positively influence the decisions made by women in their care.

4.2 Research Methodology

Study One is descriptive correlation research study. Such research may be achieved by a range of data collection methods, such as surveys, case studies or observation (Parahoo, 2010). The chosen research method was a self-reported structured survey.

For this study a formal structured, self-administered questionnaire tool was used to collect quantitative data from participants. The questionnaire was used to access the individuals’ attitudes and opinions about vaccination during pregnancy, and their knowledge on immunisation and the pertussis disease and outbreak in general.

4.3 Methods: Approach and Instrument

This included women who received the Tdap vaccine and those who did not, and both groups of women were approached for this study retrospectively. Careful consideration was given to approaching the women for this study, and it was decided that women would be approached immediately after the birth of their baby, in order not to influence
decisions of those who had not received the vaccine during their pregnancy. The thesis study obtained ethics approval (see appendix one) as an extension to the Safety and Monitoring of Adverse Reactions of Tdap Vaccine In Pregnancy (SMART VIP study) Observational Study 7 conducted by Dr Tony Walls, Christchurch Paediatrics Department.

Review of the available literature and research on the topic, found two valid survey tools. The survey was adapted from the two published questionnaires. Permission was obtained from by Calarco et al. (2012) to use their survey tool relating to acceptance of maternal postpartum Tdap vaccine. Petousis-Harris et al. (2011) used a caregiver and parent telephone survey tool to assess knowledge and attitudes relating to immunisation; and also gave permission for their survey questions to be used and adapted for this research study.

The questionnaire (see appendix two) consisted of three sections, and used closed-ended questions with fixed alternative answers that gave a uniform frame of reference for participants to answer the questions. This offered quick responses for participants, reducing the time needed to complete the survey, and increased the likelihood of participants to take part and complete the survey (Polit & Beck, 2008).

Section one of the survey ascertained the respondent’s vaccination status, administration of a vaccine given during pregnancy, their lead maternity health provider, information received about immunisation during pregnancy and from what sources, concerns about the disease and the Tdap vaccine, and their reasons for accepting or not accepting the Tdap vaccine during pregnancy.

Section two reviewed the respondents’ knowledge about pertussis, general vaccination, and general health beliefs of which the responses were offered using a five point Likert scale. Likert scales can be used to measure attitudes and to indicate the degree to which the respondents agree or disagree with the opinion expressed by the statement given (Polit & Beck, 2008). Section three ascertained the participants’ socio-demographic and professional/educational background and utilised fixed alternative answers.

7 Observational study: Safety and Monitoring or Adverse Reaction of Tdap Vaccine In Pregnancy (SMART VIP study).
4.3.1 Questionnaire Development

The development of the questionnaire tool occurred in stages. The content and questions were initially adapted and modified by the researcher from the two published questionnaires (Calarco et al., 2012; Petousis-Harris et al., 2011). During the planning stages of the study, consultation was sought with Dr Helen Petousis-Harris with a focus on development of the questionnaire and collection data processes. The questionnaire was examined by both Masters’ Supervisors and a midwife for research appropriateness, accuracy, clarity and design. Recommendations made were reflected in revisions and adjustments of the tool prior to distribution to the pilot group.

4.3.2 Pilot Study of the Survey

A pilot group was undertaken to test the instrument and evaluate the success of the data collection technique (de Vaus, 2002). This involved a final draft of the questionnaire to be given to people who represented the planned sample as closely as possible (Polit & Beck, 2008). The pilot group comprised of ten women similar to actual participants planned for the main study (Lacey, 2010; Polit & Beck, 2008). The pilot group were asked to review the survey tool in relation to its readability, flow, clear instructions, clarity of the questions, ease of administration, and time required to complete the survey. The group did not report any problems with the wording, length or usability of the survey tool. The researcher determined that the length of the survey would take 15 minutes to complete, based on the pilot group’s feedback.

4.4 Sample Method

Study One utilised a retrospective observational cohort sampling between June until October 2013; the period of time was limited to enable completion of the research qualification. The retrospective approach enabled the researcher to approach all postpartum women, from birth notifications which included hospital and home births, in the CDHB area via mail with the survey. The surveys were mailed within one to two days of an infant birth. However, this relied on the women to complete the survey and send it back. This method meant that the researcher had minimal contact with the potential participants.

---

8 Director of Immunisation Research and Vaccinology, Immunisation Advisory Centre, Auckland University, Auckland.
4.4.1 Inclusion Criteria

The study included all women who delivered a live birth from June to October 2013, whether or not they had received the Tdap vaccine during pregnancy from birth notifications. Participants were postpartum women in the CDHB area.

4.4.2 Sample Size

The number of women recruited was determined by the number of potentially eligible women available within the study recruitment period; four months was allowed for participant recruitment. A total of 1883 surveys were sent, identified by birth notifications during the four month period. Every effort was made to achieve the highest response rate possible, while mindful that response rates to postal surveys could be very low, with 300 participant responses was the minimum number anticipated to recruit; an expected response rate of at least 15 percent. The low expected response rate is due to the awareness that community mailed surveys commonly achieves a low response rate, and the coverage rate of pregnant women accepting Tdap was unknown. A sample size of 300 would provide an estimate of the true Tdap rate to be within at least plus or minus 5.7 percent.

Study One included a total of 1883 surveys mailed to postpartum women within the CDHB area from June to October 2013. A total of 596 surveys returned, a response rate of 31.6 percent.

4.5 Data Collection Procedures

All postpartum women in the CDHB area were approached for this study after the birth of their baby, in order not to influence decisions of those who did not receive the vaccine during pregnancy. Information flyers (see appendix three) were inserted into all new-born information packs given by the Lead Maternity Carers (LMCs) to every parent after the birth; introducing the research study and advised women being discharged during the time of the study that they would be contacted by mail to offer participation in the study.

The CDHB administration staff mailed an information sheet (see appendix four), including log in details for the online survey option, and a hard copy of the survey to all birth notifications in the CDHB area. The physical appearance and layout of the questionnaire can influence its appeal and response rate (Jones & Rattray, 2010),
therefore the quality and colour of the paper was considered (Polit & Beck, 2008); the
information sheet was printed on coloured paper for appeal and to stand out.

A pre-paid envelope was included for the return of the surveys, as failure to do so can
have an adverse effect on response rates (Polit & Beck, 2008; de Vaus, 2002). Two
weeks after the survey was distributed a follow up phone call or text message was made
by the researcher to offer participation in the study, and as a reminder to complete the
survey.

The Access Database package was set up to mirror the questionnaire and coded
numerically prior to any data being entered. As the completed surveys were returned,
the information was entered directly into the Access Database package for data storage.
The data was double entered into the database, by the researcher, to ensure accuracy
and check for potential errors or omissions during data entering (Grove et al., 2013;
Freeman & Walters, 2010) any errors were checked and corrected. The data was then
uploaded into the Statistical Package for the Social Sciences (SPSS), where the data
was further checked and data cleaning occurred by running initial statistical analyses
to check for outliers and wild codes (Polit & Beck, 2008).

4.6 Ethical Considerations

Prior to conducting the survey research, ethics approval application was made to the
Upper South A Regional Ethics Committee as an extension to the SMART VIP safety
study conducted by Dr Tony Walls, Christchurch Paediatrics Department; mentioned
earlier.

Verbal approval from the Director of Midwifery and consultation letter (see appendixive) to the CDHB LMCs prior to any contact being made with the potential
participants, which included information about the study, as well as an opportunity for
the LMCs to specifically exclude a women being contacted for any reason. The
Locality Authorisation (see appendix six) for the CDHB was sought and approved prior
to the commencement of the study.

4.6.1 The Right to Self-Determination

Self-determination is the principle that individuals have the right to voluntarily decide
whether or not to participate in the study, without any penalty or prejudicial treatment
(Polit & Beck, 2008). Furthermore the individual has the right to ask questions of the
study, refuse to give information, or to withdraw from the study at any time (Johnson & Long, 2010; Polit & Beck, 2008).

Participants were fully informed of the study and an emphasis that participation was their choice and voluntary, and that they could withdraw their participation at any time. The study participants were advised that their consent was implied by completion and return of the survey questionnaire via mail or on-line.

4.6.2 Maintaining Confidentiality

The author used the National Health Index (NHI) number during data collection to mask participants identification, a random study number was allocated to manage and further anonymise the data collected. The study number was not included with any identifying details of the study participants.

The data collected has been stored on a password protected database. The research data will be kept for ten years at the Centre for Postgraduate Nursing Studies, University of Otago, Christchurch; and then destroyed in accordance with the University of Otago guidelines.

4.7 Treaty of Waitangi

The research proposed sought consultation from the Māori Research Advisor at the University of Otago, Canterbury, to ensure the study questionnaire design was culturally acceptable for Māori. The response from the Māori Research Advisor (see appendix seven) was supportive of the research and determined that there were no ethical implications for Māori, or any procedures or questions that could affect Māori cultural protocol. Furthermore, a request for a report of the study on its completion, as the findings may contribute to the development of future research projects.

4.8 Data Analysis

The Statistical Package for the Social Sciences (SPSS) database was used for descriptive statistical analysis of the data collected for Study One. All percentages were based on the number of respondents for the given question, not the total sample size of the study; 95 percent confidence intervals were calculated for proportions using “bootstrapping” with 1000 simulations within the SPSS database.
Consultation with the University of Otago, Christchurch Campus Biostatistician occurred in relation to the collection and recording of the data. All stages of analysis were supported and verified with the Biostatistician for accuracy.

4.9 Summary

This chapter has described the methods and collection processes of the data considered to best meet the aims of the first study, and included the ethical and cultural considerations. Justifications were made for the self-reporting survey tool, including the research, development and content of the process. Results and analysis of Study One will be discussed in the following chapter.
5  CHAPTER FIVE: Results and Analysis - Study One

This chapter presents the results of the self-administered survey which explored the factors influencing women’s decisions regarding having the pertussis-containing (Tdap) vaccine during pregnancy, within the CDHB area. It will outline the response rates, participant characteristics and the overall findings from the survey.

5.1  Survey Response Rate

A total of 1883 surveys were mailed to postpartum women, from all birth notification within the CDHB area which included hospital and home births, from June to October 2013. A total of 596 surveys were returned, giving a response rate of 31.6 percent. The majority of those who responded to the survey had received the Tdap vaccine during pregnancy, representing 74.1 percent (441/596), compared to 25.9 percent who had not received the Tdap vaccine (154/596); one person could not remember (appendix 2, question 1).
5.2 Participant Age Characteristics

Of the 596 postpartum women who responded to the survey, the majority indicated their age; two women did not answer the question. The age ranged in groupings from under 18 years to those between 46 to 50 years. Due to small numbers in those under 25 years and over 38 years, it was advised by the biostatistician to combine the outer laying age groups as reflected in figure 5.1 (and table 5.1, includes vaccination status). Population characteristics compared the participants’ age, with the total surveys that were sent; being all birth notification during the time period. The mean age of women who responded were in the 30-33 year age group. Participants were under represented in age group less than 29 years of age (figure 5.1).

![Figure 5-1 Characteristics of participants compared by age](image)

5.3 Participant Ethnicity, Highest Qualification and Vaccine Status

Characteristics

5.3.1 Ethnicity Characteristics

Ethnicity was collected based on the Statistics New Zealand standard classification for ethnicity; level two which had 15 categories (appendix 2, question 35). The ethnicities have been prioritised and reported based on level one of the standard classification of
ethnicity, of five categories; European, Māori, Pacific, Asian, and Middle Eastern/Latin American/African (MELAA). Eighty three percent of the respondents recorded ethnicity as European, Māori represented 4.4 percent of respondents, and several other ethnic groups were also represented (see figure 5.2); fewer Māori, Pacific and Asian women responded to the survey compared with the overall CDHB area population. See Table 5.1 for vaccination status by ethnicity of study participants.

![Figure 5-2 Characteristics of participants compared by ethnicity](image)

5.3.2 Education Characteristics

The majority of the participants reported having completed a tertiary qualification, either undergraduate or postgraduate degree (n=358). A small number had no secondary school education (n=6), some secondary schooling with no exams (n=27), or other secondary school exam qualification, such as NCEA; 19 respondents did not state their highest educational qualification (appendix 2, question 36).

---

9 NCEA: National Certificates of Educational Achievement (NCEA) are national qualifications for New Zealand senior secondary school students. NCEA was introduced as the main secondary schools qualification between 2002 and 2004. This replaced School Certificate, University Entrance, Sixth Form Certificate and University Bursary qualifications (New Zealand National Qualifications, 2014).
### Table 5.1 Participant Characteristics: Age, Ethnicity, Qualification and Vaccine status

<table>
<thead>
<tr>
<th>Age</th>
<th>Surveys Received (n)</th>
<th>Vaccinated (%)</th>
<th>Unvaccinated (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;25</td>
<td>60</td>
<td>6.1</td>
<td>21.7</td>
</tr>
<tr>
<td>26-29</td>
<td>100</td>
<td>17</td>
<td>16.4</td>
</tr>
<tr>
<td>30-33</td>
<td>188</td>
<td>35.4</td>
<td>21</td>
</tr>
<tr>
<td>34-37</td>
<td>158</td>
<td>27</td>
<td>25.7</td>
</tr>
<tr>
<td>≥38</td>
<td>87</td>
<td>14.5</td>
<td>15.2</td>
</tr>
<tr>
<td>Total</td>
<td>593</td>
<td>n=441</td>
<td>n=152</td>
</tr>
<tr>
<td>Missing</td>
<td>3</td>
<td></td>
<td>2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ethnicity</th>
<th>Surveys Received (n)</th>
<th>Vaccinated (%)</th>
<th>Unvaccinated (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>European</td>
<td>496</td>
<td>86</td>
<td>79</td>
</tr>
<tr>
<td>Māori</td>
<td>27</td>
<td>4</td>
<td>6</td>
</tr>
<tr>
<td>Pacific</td>
<td>9</td>
<td>1.1</td>
<td>2.6</td>
</tr>
<tr>
<td>Asian</td>
<td>49</td>
<td>8.2</td>
<td>8.5</td>
</tr>
<tr>
<td>MELAA</td>
<td>11</td>
<td>1.1</td>
<td>3.9</td>
</tr>
<tr>
<td>Total</td>
<td>n=592</td>
<td>n=439</td>
<td>n=152</td>
</tr>
<tr>
<td>Missing</td>
<td>4</td>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Highest Qualification</th>
<th>Surveys Received (n)</th>
<th>Vaccinated (%)</th>
<th>Unvaccinated (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;Secondary School</td>
<td>6</td>
<td>0.7</td>
<td>2</td>
</tr>
<tr>
<td>No Secondary School exams</td>
<td>27</td>
<td>3.5</td>
<td>8.1</td>
</tr>
<tr>
<td>NCEA1</td>
<td>32</td>
<td>5.1</td>
<td>6.8</td>
</tr>
<tr>
<td>NCEA2</td>
<td>38</td>
<td>5.4</td>
<td>10.1</td>
</tr>
<tr>
<td>Higher School Cert</td>
<td>16</td>
<td>2.8</td>
<td>2.7</td>
</tr>
<tr>
<td>Bursary</td>
<td>7</td>
<td>1.4</td>
<td>1.4</td>
</tr>
<tr>
<td>Tertiary</td>
<td>358</td>
<td>65</td>
<td>52.7</td>
</tr>
<tr>
<td>Vocational</td>
<td>93</td>
<td>16.1</td>
<td>16.2</td>
</tr>
<tr>
<td>Total</td>
<td>577</td>
<td>n=429</td>
<td>n=148</td>
</tr>
<tr>
<td>Missing</td>
<td>19</td>
<td>12</td>
<td>7</td>
</tr>
</tbody>
</table>
5.4 Lead Maternity Carer (LMC)

Lead maternity care is most often provided by midwives in NZ, and apparent from results in the survey, with midwives representing 86.5 percent (95% CI, 83.8-89.2; n=511) of the participants, and 10.2 percent (95% CI, 7.8-12.5; n=60) shared care with a midwife and obstetrician. Of the 596 respondents, 591 completed this question; missing data representing five responses (appendix 2, question 9).

Figure 5-3: Lead Maternity Care Provider
5.5 Most Helpful Source for Information

When making the decision about the Tdap vaccine, the two most useful sources of information identified by the majority of the women were their midwife representing 64.1 percent (95% CI, 59.7%-67.8%; n=382), and practice nurse with 48.7 percent (95% CI, 44.3%-52.5%; n=290); further sources of information were indicated. Multiple responses were possible.

Figure 5-4: When deciding whether or not to receive the Tdap vaccine, participants were asked to indication the information sources that were “most helpful”. 
5.6 Encouraging or Discouraging Information Received: Relating to the Tdap Vaccine during Pregnancy

It was important to identify if the information received was encouraging or discouraging; including the source of the information provided (appendix 2, questions 11 and 12). The question was asked of all participants (n=596), and enabled multiple responses of one or more information sources. The proportion of participants’ who responded to have received encouraging information (n=327), 54.9 percent of these reported midwives (95% CI, 50.8%-58.7%), followed by general practitioners (37.9%; 95% CI, 34.2%-41.6%) and then practice nurses (11.7%; 95% CI, 9.4%-14.6%); other sources were identified but at lower proportions.

Figure 5-5: Participants indicated the sources of “encouraging information” received.
All participants were asked to report the source of any discouraging information they received, with multiple responses possible. Interestingly, general practitioners (GPs) were identified as the largest proportion of discouraging information source (40.8%; 95% CI, 36.7%-44.5), otherwise participants were largely not discouraged (37.8%; 95% CI, 33.7%-41.8%). Whanau and friends were also identified in very small numbers (1.7%; 95% CI, 0.7%-2.7%), similar to information via the internet (2.5%; 95% CI, 1.3%-3.9%).

![Figure 5-6](image)

**Figure 5-6:** Participants indicated the sources of “discouraging information” received.

Due to the higher proportion of responses that identified GPs as the source of discouraging information, the data was analysed to explore women who did not receive the vaccine (n=154) and reported that they received discouraging information from their GP (n=93) (table 5.5). Sixty percent of those who did not receive the Tdap vaccine also received discouraging information from a GP source (93/154).

**Table 5.2:** Discouraging Information Source of GPs vs Receipt of Tdap Vaccine

<table>
<thead>
<tr>
<th>No, No Discouraging GP Information</th>
<th>Yes, Discouraging GP Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>No, Vaccine Received (n)</td>
<td>61</td>
</tr>
<tr>
<td>%</td>
<td>40</td>
</tr>
<tr>
<td>Yes, Vaccine Received (n)</td>
<td>93</td>
</tr>
<tr>
<td>%</td>
<td>60</td>
</tr>
</tbody>
</table>
5.7 Factors Associated with Receiving the Tdap Vaccine

The survey directed women to answer specific questions depending on whether they had received the Tdap vaccine or not.

**Surveys returned n=596**

**Did you receive the pertussis vaccine in pregnancy?**

- **Yes (n=441)**
  - Q18, (n=421): I decided to have the vaccine to:
    - Prevent the pertussis disease circulating
    - Protect myself from the disease
    - Protect my baby from the disease
  - Q19, (n=419): I decided to have the vaccine, because it was:
    - Recommended by a health professional
    - Recommended by my spouse/family/friend
    - I knew others who had, had it
  - Q20, (n=419): I decided to have the vaccine because:
    - The vaccine was free and available
    - There is a lot of pertussis in the community
    - Of the convenience and ease to receive it

- **No (n=154)**
  - Q22, (n=86): I decided not to have the vaccine because:
    - Too expensive
    - I was unable to get to the practice
    - I didn’t know about the vaccine
  - Q23, (n=54): I decided not to have the vaccine because:
    - The low risk of pertussis in Canterbury
    - Fear of side effects
    - Fear of needles/injections
  - Q24, (n=46): I decided not to have the vaccine due to being:
    - Doubtful of the vaccine’s effectiveness
    - Anti-vaccines
    - Mistrust of the information

- **Did not remember (n=1)**

Figure 5-7: Overview of the returned survey result and the path participants followed, depending on whether they had received the Tdap vaccine or not.
5.7.1 Women Who Received Tdap during Pregnancy; Influencing Factors

Women who received the Tdap vaccine during pregnancy were asked to identify the statement considered to be the “most important” when deciding to consent to the Tdap vaccine; three statement options were given for each of the three questions (appendix 2, questions 18-20); relating to protection/prevention, recommendation or awareness of the disease, and the convenience to access the vaccine or threat of circulating pertussis. Question 21 of the survey was not included in the analysis, as it would not add any further information due to prior questions of a similar focus. Respondents could only select one option, and considered invalid if more than one response was given.

The first set of statements related to “protection/prevention” and answered by 421 women of the possible 441 participants. The majority of women reported that the main influencing factor to receive the Tdap vaccine was to protect their baby (96.4%, 95% CI, 94.5%-98.1%).

![Figure 5-8: Statements put to women who received the Tdap vaccine relating to protection/prevention (n=421).](image-url)
The second set of statements related to the importance of recommendations for this group (n=419). The women who responded reported a recommendation from a health professional was a significant factor with 84.2 percent, (95% CI, 80.7%-87.8%).

Figure 5-9: Statements put to women who received the Tdap vaccine relating to recommendations or awareness (n=419).
The third set of statements related to the convenience to access the vaccine or the threat of pertussis circulating or that the vaccine was funded (n=419); the majority of those who responded, indicated that the main influencing factors were the threat of pertussis in the community representing 50.8 percent (46.1%-55.8%), and 42.5 percent (95% CI, 37.7%-47%) were aware the vaccine was funded.

Figure 5-10: Statements put to women who received the Tdap vaccine relating to vaccine access/threat of pertussis circulating (n=419).
5.7.2 Women Who Did Not Receive Tdap during Pregnancy: Influencing Factors

Women who did not receive the Tdap vaccine during pregnancy were asked to identify a different set of statements when they considered the “most important” factors relating decisions made about the Tdap vaccine (appendix 2, questions 22–24). Question 25 of the survey was not included in these findings, as it would not add any further information due to prior questions of a similar focus. Three statement options were given for each of the three questions, with one response possible for each set; relating to vaccine access/convenience, perceptions and fears of side effects or needles, and confidence in the vaccines.

Of the 154 women who indicated they had not received the Tdap vaccine, reflected in question one of the survey, many did not respond to these statement questions. The first set of statements was answered by 86 of the 154 women, and related to the vaccine access and convenience. The majority, 73.3 percent (95% CI, 64%-82.6%), responded that they did not know the vaccine was available.

Figure 5-11: Statements put to women who had not received the Tdap vaccine relating to vaccine access/convenience (n=86).
The second set of statements related to perceptions of the risk of pertussis in Canterbury, fears of side effects or a fear of needles/injections. A smaller number of women responded (n=54) to this question. Of those who did participate, the proportion who reported their fear of side effects (68.5%, 95% CI, 55.6%-81.4%), were greater than the proportion who indicated their perception of a low risk from pertussis in Canterbury (22.2%, 95% CI, 11.1%-33.3%), followed by the proportion indicating fear of needles/injections (9.3%, 95% CI, 1.9%-16.7%).

![Bar chart showing fear of side effects, fear of needles/injections, and low risk of pertussis in Canterbury.]

Figure 5-12: Statements put to women who had not received the Tdap vaccine relating to perceptions about the vaccine (n=54).
The third set of statements related to confidence in the vaccine (n=46), and again a much smaller number of participants responded. Those who participated indicated being doubtful of the vaccine effectiveness (56.5%, 95% CI, 41.3%-71.3%) as their main concern, followed by anti-vaccination beliefs (28.2%, 95% CI, 15.2%-41.3%), and lastly mistrust of information (15.2%, 95% CI, 6.5%-26.1%).

Figure 5-13: Statements put to women who had not received the Tdap vaccine relating to vaccine confidence (n=46).
5.7.3 Knowledge of the Vaccine Availability of those who did not receive the vaccine

The survey asked women who had not received the Tdap vaccine to answer two questions specifically relating to the vaccine availability; 1) “were you aware the pertussis-containing vaccine was available to you during pregnancy?” If they answered “no” they were then asked, 2) “would you have considered having the pertussis-containing vaccine during pregnancy if you had been offered it?”

Of the 154 women who did not receive the Tdap vaccine during pregnancy, 151 women responded to question two, “were you aware the pertussis-containing vaccine was available to you during pregnancy?” With 56.3 percent (95% CI, 48.3%-63.6%) indicated they were aware, compared to 43.7 percent (95% CI, 36.4%-51.7%) were not aware that the vaccine was available; three participants missed the question.

![Figure 5-14: Women who did not receive Tdap vaccine were asked if they were aware that the Tdap vaccine was available to them (n=151).](image-url)
Those who responded they were not aware the Tdap vaccine was available, were asked; “would you have considered having the pertussis-containing vaccine during pregnancy if you had been offered it?” Of the 66 participants represented, 55.4 percent (95% CI=43.9%-66.7%) indicated they would have considered the Tdap vaccine if it had been offered to them.

![Bar chart showing the percentage of women who would have considered having the Tdap vaccine if offered.]

**Figure 5-15:** Women who did not know the vaccine was available were asked “would you have considered having Tdap vaccine during pregnancy if it had been offered?” (n=66).
5.7.4  **Knowledge about the Pertussis Disease and Vaccination in General**

All participants (n=596) were asked a series of knowledge statements and to respond using a five point Likert Scale; “Agree, Somewhat Agree, Don’t Know, Somewhat Disagree, or Disagree”. Responses are presented in table 5.6, comparing the response of women who received the Tdap vaccine and those that did not, 10 participants missed these questions; appendix 2, questions 26-32.

The majority of both groups responded that they “agreed” that “pertussis disease is a serious disease for young children and babies”; statement 26. Which would suggest these women were aware of the risk pertussis poses to babies and children.

However, there was more variation in the responses with the statement relating to, “vaccination is more likely to make us sick than keeping us healthy”; statement 27. Women who did not receive the Tdap vaccine responded with 12.6 percent “somewhat agreed”, 16.6 percent “did not know”, and 18.6 percent “somewhat disagreed”, and 46.6 percent “disagreed”; compared to the women who did receive the Tdap vaccine, reported 78 percent “disagreed” with this statement. Question 28 had a similar outcome from responses; which related to the statement: “if you keep yourself, well fed and otherwise healthy, you will not catch pertussis”.

Statements 29 related to “parents have a responsibility to ensure their children are immunised to prevent diseases spreading” which found the majority in both groups indicated they “agreed” with the statement; being 80.7 percent of women who did receive the Tdap vaccine compared, to 64.4 percent of women who did not receive Tdap vaccine. Similar responses were found for statement 30, relating to “I am confident about having myself/child/children immunised”. It seems reasonable to suggest that a large proportion of women from both groups appear to have a reasonable level of confidence and possible intention for immunisation from these statements.

The majority of women who received the Tdap vaccine (84%) “disagreed” with statement 31, “childhood diseases are no longer around much so you don’t have to worry about immunising against them”. Compared to the women who did not received the vaccine, 66.4 percent who “disagreed”, and 19.5 percent “somewhat disagreed”.

63
Indicating the majority of women had a good understanding that such disease are still a threat to communities, and require immunisation to prevent such diseases.

Finally, statement 32 related to “Canterbury is currently having high numbers of pertussis cases”, those who “agreed” with this statement represented 62.5% of women who had received the Tdap vaccine, compared to 42.3 percent of women who did not have the Tdap vaccine. Both groups had higher numbers who indicated that they “did not know” 57 percent compared to 39.6 percent respectively.
Table 5.3: Knowledge about the pertussis disease and vaccination in general

<table>
<thead>
<tr>
<th>Survey Question</th>
<th>Received Tdap vaccine</th>
<th>Total responses</th>
<th>Agree (%)</th>
<th>Somewhat Agree (%)</th>
<th>Don’t Know (%)</th>
<th>Somewhat Disagree (%)</th>
<th>Disagree (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q26: Pertussis disease can be a serious disease for young children and babies</td>
<td>Yes</td>
<td>434</td>
<td>96</td>
<td>3</td>
<td>0.5</td>
<td>0</td>
<td>0.5</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>150</td>
<td>88</td>
<td>8</td>
<td>4</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Q27: Vaccination is more likely to make us sick rather than keeping us healthy</td>
<td>Yes</td>
<td>434</td>
<td>1.6</td>
<td>3</td>
<td>4.4</td>
<td>13</td>
<td>78</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>150</td>
<td>3.3</td>
<td>12.6</td>
<td>16.6</td>
<td>18.6</td>
<td>46.6</td>
</tr>
<tr>
<td>Q28: If you keep yourself, well fed, and otherwise health, you will not catch</td>
<td>Yes</td>
<td>435</td>
<td>0.6</td>
<td>5</td>
<td>9.7</td>
<td>14.3</td>
<td>70.5</td>
</tr>
<tr>
<td>pertussis</td>
<td>No</td>
<td>150</td>
<td>4</td>
<td>14</td>
<td>18</td>
<td>17.3</td>
<td>46.6</td>
</tr>
<tr>
<td>Q29: Parent/caregivers have a responsibility to ensure they and their children</td>
<td>Yes</td>
<td>435</td>
<td>80.7</td>
<td>15.7</td>
<td>1.8</td>
<td>1.4</td>
<td>0.7</td>
</tr>
<tr>
<td>are immunised to prevent diseases spreading</td>
<td>No</td>
<td>150</td>
<td>64.6</td>
<td>20.6</td>
<td>5.3</td>
<td>4.6</td>
<td>4.6</td>
</tr>
<tr>
<td>Q30: I am confident about having myself/child/children immunised</td>
<td>Yes</td>
<td>435</td>
<td>79.8</td>
<td>16.8</td>
<td>2.3</td>
<td>0.7</td>
<td>0.4</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>149</td>
<td>67.3</td>
<td>18</td>
<td>5.3</td>
<td>4</td>
<td>5.3</td>
</tr>
<tr>
<td>Q31: Childhood diseases are no longer around much so you don’t have to worry</td>
<td>Yes</td>
<td>435</td>
<td>0.4</td>
<td>1.6</td>
<td>2</td>
<td>12</td>
<td>84</td>
</tr>
<tr>
<td>about immunising against them</td>
<td>No</td>
<td>149</td>
<td>2.7</td>
<td>2</td>
<td>9.4</td>
<td>19.5</td>
<td>66.4</td>
</tr>
<tr>
<td>Q32: Canterbury is currently having high numbers of pertussis cases (also known</td>
<td>Yes</td>
<td>435</td>
<td>62.5</td>
<td>16.8</td>
<td>57</td>
<td>0.7</td>
<td>0.4</td>
</tr>
<tr>
<td>as an outbreak</td>
<td>No</td>
<td>149</td>
<td>42.3</td>
<td>14.1</td>
<td>39.6</td>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>
5.8 Knowledge of the Pertussis Outbreak/Disease Impact on Decisions

Questions 15 to 17 of the survey related to knowledge statements about the pertussis outbreak, disease or vaccination in general. The statements were asked of all participants (n=596).

Question 15 asked “how concerned are you that a vaccine would not prevent the pertussis disease?” Responses were indicated by five point Likert Scale; “Very Concerned, Somewhat Concerned, Don’t Know, Not too Concerned or Not at all Concerned”. The majority of participants responded “not too concerned”, 40.8 percent (n=223), followed by “somewhat concerned” (19.2%) and “not at all concerned” (18.5%).

![Bar Chart]

**Figure 5-16:** Participants were asked “how concerned are you that a vaccine would not prevent the pertussis disease?” (n=596).
Question 16 asked “what concerned you the most when deciding whether or not to accept the pertussis-containing vaccine?” Of the 562 who responded, 51.5 percent (95% CI, 47.2%-55.7%; n=281), identified “safety/side effects for your baby” was the main concern about the vaccine, followed by “no concerns” (20.5%, 95% CI, 17.3%-23.7%; n=114) and the “threat of whooping cough infection/effects” (12.3%, 95% CI, 9.6%-14.9%; n=67).

![Bar chart showing the main concerns when deciding about Tdap vaccine during pregnancy.](chart.png)

**Figure 5-17:** Participants indicated their main concern when deciding about Tdap vaccine during pregnancy (n=562).
Interestingly, the majority of participants (n=580) reported in question 17 that they had not known anyone affected by pertussis disease, representing 61.6 percent (95% CI, 57.7%-65.6%, n=357) compared to 38.4 percent (95% CI, 34.4%-42.3%, n=223) of whom have known someone with pertussis. When the data was further analysed to explore the representation of women who received the Tdap vaccine, to women who did not receive the Tdap vaccine in relation to having known someone who had been affected by pertussis disease; both groups’ findings were similar to the overall result; indicating that this is not an influencing factor when deciding about having the vaccine during pregnancy.

![Percentage](image)

**Figure 5-18:** Participants were asked “have you ever known someone affected by pertussis?” (n=546).

### 5.9 Infants Enrolled with General Practitioner

Early enrolment\(^{10}\) (or pre-enrolment) with a general practitioner may ensure early engagement with the general practice team and enables early communication regarding vaccinations prior to the first immunisation schedule date and other health checks for the mother and baby.

---

\(^{10}\) Enrolment with a General Practitioner (GP); is an enrolment with a Primary Health Organisation (PHO) the GP is a member. A PHO represents local groups of primary health care providers and responsible for organising and delivering primary health care to meet the needs of those enrolled with them (MOH, 2014).
In October 2012, the NZ MoH implemented a “newborn policy” with the focus to support the new Health Target for immunisation of 95 percent of eight month olds will be fully immunised by December 2014 (MoH, 2014c). Early enrolment is defined as: “enrolment as close to birth as possible and no later than two weeks after birth” (MoH, 2014c). The early enrolment of an infant will be coded with a “B” which provides the MoH to identify this newborn group (MoH, 2012b). The code also enables the Ministry to monitor and report on this new policy (MoH, 2012b).

The majority of participants self-reported that they were enrolled with the general practice provider (74.4%, n=442), 14 participants missed the question, and 37 responded that they did not know. The study participants were sent the survey within days of their recent birth; however, the age of the infant is unknown in relation to the completion of this question.

Figure 5-19  Infants enrolled with a General Practitioner

5.10 Chapter Summary

This chapter has presented the results from Study One of the thesis research. The data obtained provides information relating to the factors influencing women’s decisions about Tdap vaccine during pregnancy. The next chapter will discuss the key findings from this chapter.
6 CHAPTER SIX: Study One – Discussion, Limitations and Recommendations

This chapter will discuss the key findings identified in Study One, which includes the factors that influenced women’s decisions about Tdap vaccination during pregnancy; and the implications of health professionals practice involved in the delivery of maternity services. The study limitations will be outlined, followed by the recommendations based upon the findings of Study One.

6.1 Discussion

6.1.1 Health Professionals Recommendations

Women who received the Tdap vaccine in the current study reported receiving encouraging information from three key health professionals; their midwife (Lead Maternity Care (LMC)) (54.9%), general practitioner (GP) (37.9%) and Practice Nurse (PN) (11.7%), indicating good support and positive recommendations were provided to these women during their pregnancy. Encouraging information is critical for pregnant women when deciding about accepting the vaccine, and in doing so ensures they are aware of the vaccine’s availability. Thus providing further evidence of the strong association of health professional support for recommendations regarding maternal vaccination and the vaccine uptake among pregnant women (Eppes et al., 2013; Fortner et al., 2012; Hayles et al., 2015; Tong et al., 2008; Wiley et al., 2013a); as mentioned earlier see pages 7 and 30.

A high proportion of women who did not receive the Tdap vaccine in the current study highlighted that they had not received any information that the Tdap vaccine was funded, available, or recommended during their pregnancy; representing 43.7 percent. As indicated earlier, this information relied on the LMCs or GPs team to advise women to visit their GP, and also for the GP or PN to confidently recommend and administer the vaccine at the time of contact. Earlier studies (see page 33 & 41) also reported that women who had a recommendation from a health professional for vaccination were three to ten-fold more likely to receive a vaccine than women whose health care provider did not encourage vaccination (Lessin & Edwards, 2012; Tong, et al., 2008; Wiley et al. 2013c).

The current study unexpectedly, identified GPs (40.8%) to be the main source of discouraging information about Tdap vaccine during pregnancy, a question asked of the
total study population (n=596). A total of 242 women received discouraging information about the Tdap vaccine from their GP, and of these women 38 percent did not have the vaccine. Whilst mindful of the limitations (see below), it appears that women who received discouraging information from their GP may have been influenced about whether to have the Tdap vaccine during pregnancy.

It is important to highlight that the discouraging information received from the GP, in the current study, was not specified and therefore it might have been that they were not confident in discussing vaccination during pregnancy, not aware or unsure of the national expert recommendations or the funding available. Tong et al. (2008; see page 41) identified a similar finding from their study, being that one third of health professionals felt unsure about administering vaccines during pregnancy, and unaware or less confident about national expert recommendations that involved administering a medication during pregnancy.

6.1.2 Main Considerations for Receiving the Vaccine

Study One found that women who received the vaccine, reported four factors as the “most important factors” that influenced their decision to accept the Tdap vaccine during pregnancy were; “to protect their baby from pertussis”, “the recommendation from a health professional”, the “threat of pertussis in the community”, and “the vaccine was funded”. Firstly, a significant proportion of women (96.4%) were aware and identified that it was important to receive the Tdap vaccine during their pregnancy, to protect their baby; which is the main rationale for offering Tdap during pregnancy. Secondly, the respondents identified a health professional’s recommendation to be of significant importance, which represented 84.2 percent of women. Finally, the threat of pertussis in the community and the fact the Tdap vaccine was funded were also important factors, representing 50.8 percent and 42.3 percent respectively.

Similarly, the study by Cheng et al. (2010; see page 43) found that a discussion with or advice from a health professional played a critical role in the acceptance of maternal Tdap vaccination, and that women were more likely to receive vaccination than those who had not. In addition, women were more likely to consent to the Tdap vaccine if they considered they could be a likely source of the pertussis infection, and had enough information to make an informed decision; 50.1% versus 15% (Cheng et al., 2010).
6.1.3 Main Considerations for Not Receiving the Vaccine

There were three “most important factors” reported by women who had not received the Tdap vaccine during their recent pregnancy, which included: they were “not aware the vaccine was available”, “fear of side effects”, and “doubtful of the vaccine effectiveness”. A high proportion of the 154 women (43.7%) did not receive the vaccine because they did not know the vaccine was available. Furthermore, 55.4 percent of those women would have considered the Tdap vaccine if it had been offered to them. Secondly, 68.5 percent reported they had a fear of side effects for the vaccine to be administered during pregnancy. Finally, women reported they were doubtful of the vaccine effectiveness (56.5%).

Cheng et al. (2010) and McCarthy et al. (2012), see pages 31-32, also found that a lack of discussion, inconsistent or absent information about vaccination during pregnancy from a healthcare provider during antenatal stages, was a significant barrier to the acceptance of a vaccine by pregnant women. In the absence of these barriers, McCarthy et al. (2012), reported that vaccination rates from their study would have been as high as 78 percent. As previously mentioned (see pages 24, 26, 30, 31 & 32), many authors concur and report an association between a lack of patient information about the safety and the effectiveness of vaccination during pregnancy, with the refusal of vaccination in this population (Cheng et al., 2010; Eppes et al., 2013; Kuehn, 2012; Lindsey et al., 2013; McCarthy et al., 2012; Munoz, 2012; Tong et al., 2008; Wiley et al., 2013a).

In the author’s opinion, even with the limitations of this study (see below), the data indicates that Tdap vaccination has been underutilised due to missed opportunities to discuss, recommend, offer and administer maternal pertussis vaccination to eligible patients. Meharry et al. (2013) as previously mentioned (see page 31) highlighted similar findings with their study which involved maternal influenza vaccination. This is concerning, as the unvaccinated population is a real threat and a source of the pertussis infection to others and each other (Carrico & O’Keefe, 2013; see page 31); and yet women who had not had the vaccine, from this study, reported they would have had the vaccine if it had been offered (36/66).
Convenience or access to receive the vaccine has been questioned by health professionals in the sector when reviewed coverage and strategies to improve maternal vaccination. It has been suggested that access or convenience may be a factor to consider, and that enabling LMCs and obstetricians to administer vaccines to patients in their care could enhance the service delivery of funded vaccines. The logistics of this would be challenging as most LMCs are mobile, often visiting patients in their own homes; therefore, the storage and handling of vaccines would be greatly problematic.

Women in the study, who did not receive the Tdap, were asked if they felt it was “inconvenient to get to the GP”; only 22 percent reported this as a potential influencing factor. However, the main issue for this group was that they were not aware the vaccine was available (73.3%). Based on these findings, in the author’s opinion an improvement to communication and awareness of the vaccine is a high priority.

### 6.2 Limitations

There are several limitations of Study One for consideration and discussion. The first of which is the response rate of 31.6 percent, despite strategies to follow up potential study participants. Response rates to mail-out questionnaires greater than 65 percent are considered good but lower response rates of approximately 25-30 percent are more common (Jones & Rattray, 2010; Polit & Beck, 2008); therefore, the study response rate of 31.6 percent would be acceptable, however a greater response would have been desirable. Response rates for self-reported questionnaires are commonly low and may be related to the study topic (Jones & Rattray, 2010; Polit & Beck, 2008). There may have been limited interest in the topic of pertussis disease and/or vaccination generally, and may not have motivated potential participants to complete the survey; especially immediately after the birth of their baby. If vaccination was perceived as a sensitive issue for some individuals, this too could have contributed to the low return of surveys (de Vaus, 2002). However, all efforts were made to ensure the survey offered a good level of anonymity through postal or internet response options; as better response rates can be achieved if individuals perceive anonymity as an important factor (de Vaus, 2002).

The second limitation was in relation to the sample size, which could be described as two small subgroups and therefore, care should be taken if there is a desire to generalise
the findings from the study. Seventy-four percent of respondents had received Tdap vaccine, while only 26 percent of respondents had not received the vaccine. The data collected is useful but cannot provide an accurate representation of the CDHB area population without further research. A more comprehensive study involving larger numbers in both subgroups, including other regions, and outside of an epidemic period could give differing results.

The third limitation is that the study utilised a self-reported questionnaire, which can only provide information on questions asked, and relied on participants providing accurate and honest answers (Lacey, 2010; Polit & Beck, 2008). It is documented that social desirability may be a limitation of questionnaire data, which is when participants try to influence the impression they provide through the responses they give, however self-reported questionnaires are thought to be less prone to such bias than those administered by researchers or interviewers; known as “self-presentation bias” (Jones & Rattray, 2010).

With the participant’s anonymity ensured, and they were able to complete the questionnaire at a time and place that allowed privacy, this should have offered an environment which encouraged honest responses from the individual. A further aspect of self-reported questionnaires completed in privacy is that it is then uncontrolled and as such participants could check their answers with others, and there is no way to confirm who actually completed the questions; all of these aspects need to be considered.

Finally, the influencing factors of the non-respondents remain unknown as participation was completely voluntary. The women who participated in the study may have been more interested or motivated in the topic. Hence, there is a limitation on how representative this is of the CDHB area population.

6.3 Summary

Study One provides valuable data that describes influencing factors for women relating to Tdap vaccination during pregnancy in the CDHB area. The findings indicate that more needs to be done to improve effective, accurate and consistent communication to patients by health professionals’. It is essential that all healthcare providers, of all disciplines in contact with pregnant women, are aware of the expert international and
national recommendations, and funding resource available for maternal pertussis vaccination.

6.4 Recommendations

6.4.1 Recommendations for Improved Communication

It is concerning that a proportion of health professionals provided discouraging information or no information to pregnant women, and that this was reported to be a significant influencing factor. This has highlighted gaps in the service delivery model being used currently; which is reliant on prompt referral and transition from one health professional to another. Although this study did not question the women about the specifics of the information received, this factor appeared repeatedly in this study and had been previously reported in other studies (Lessin & Edwards, 2012; Tong et al., 2008). It is the author’s opinion that health professionals providing care for pregnant women, at any stage of pregnancy, need to be urged to evaluate their current practices and consider better ways to include information on maternal and infant vaccination (Hayles et al., 2015; Tong et al., 2008; Wiley et al. 2013c).

One option to improve the profile, awareness and potentially the uptake of the vaccine would be a national Health Target for Tdap vaccination in pregnancy; similar to the USA “Healthy People 2020” target of 80 percent coverage for influenza vaccination for pregnant women (American College of Obstetricians and Gynaecologists, 2014). It is evident that when there is a Health Target, recommendations, knowledge and often national communication campaigns provide the high profile needed. A national communication campaign would broadly heighten awareness of the current expert recommendations for Tdap vaccine to all; for example, health professionals, patients, whanau, and communities. An ongoing national communication campaign has the potential to improve maternal pertussis vaccination acceptance nationwide. It is of the utmost importance that maternal immunisation becomes routine in the provision of care; that is, discussed at each and every contact with pregnant women and their whanau throughout the pregnancy, similarly to the monitoring and practice of antenatal bloods, blood pressure or urine analysis.

A further option may be to enable and support approved pharmacist vaccinators to provide funded vaccines to pregnant women; both influenza and pertussis vaccines.
This would provide a further platform to enhance communication and awareness; and at the same time greater convenience for patients to access the vaccine during pregnancy.

A third option could be to fund an additional general practice team antenatal consultation to provide the Tdap maternal vaccination for the patients; this would be in addition to the current LMC funded visits. This also has the potential to increase the access convenience, and awareness for patients and providers. The additional consultation with the general practice has a further opportunity for early engagement with parents and has the possibility to improve early infant enrolment and early conversations about infant immunisation.

6.4.2 Recommendation for Health Professional Education

The findings from this study show that there are definite gaps and inconsistencies in the information being communicated to women during their pregnancy. It is crucial that all health care providers engage in ongoing immunisation education as a key aspect to increase providers’ awareness, understanding of current recommendations in order to provide their patients with confident, supportive messaging about the importance of immunisation during pregnancy (Eppes et al., 2013; Hayles, et al., 2015; Wiley et al., 2013b; Wiley et al. 2013c).

Currently immunisation education training in NZ is predominantly attended by registered nurses from a variety of work place settings, with the focus on a process of fulfilling requirements needed to apply for authorisation to administer vaccines on the national immunisation schedule without a prescription or standing order (MoH, 2014a). Other health professionals who attend vaccinator training include pharmacists, enrolled nurses, general practice receptionists, antenatal educators and midwives; however, general practitioners and doctors in general are poorly represented.

Unless there is a requirement, incentive or compulsion for all health professionals to attend immunisation education on a regular basis it seems unlikely that sufficient uptake to achieve the level of knowledge, awareness and confidence to improve the current clinical practice will occur. Therefore, further research needs to be undertaken to include health professionals’ knowledge and understanding of maternal vaccination to establish where they learn, and the barriers to education opportunities to increase
their current knowledge. This would offer information to provide the best way of presenting ongoing learning opportunities in the future.

6.4.3 Recommendations for Future Research

Further research is required in order to draw more accurate conclusions about the type of information pregnant women received from health professionals in more detail, and needs to include a focus on the specifics of encouraging or discouraging information, which was only broadly covered in this study. Such research needs to include exploring the health professionals’ attitudes, beliefs, and confidence about recommending and administering vaccines in pregnancy, and potentially enable comparative analysis.

Finally, further research to explore the factors influencing women’s decisions about having the pertussis vaccine during pregnancy in other regions of NZ, outside an epidemic and include a larger sample for greater representation of both subgroups of women. Even with the study limitations, it is likely that the findings in this study exist in other areas of practice in NZ.
7  CHAPTER SEVEN: Research Methods Study Two

This chapter outlines the research methods in Study Two titled “Acceptance and timeliness of infant vaccination of mothers who received the Tdap vaccine during pregnancy”. This will include the study sample, data collection process, and ethical considerations identified throughout the research process.

7.1  Research aim

The aim for Study Two was to explore whether the acceptance of the Tdap vaccine during pregnancy is associated with infant immunisation status and timeliness for the national immunisation scheduled events of six weeks, three months and five months of age.

7.1.1  Hypothesis

Women who are vaccinated during pregnancy are more likely, than those unvaccinated, to ensure their child received timely vaccination.

7.2  Research Method

Infants of mothers who accepted vaccination during pregnancy and enrolled the SMART VIP study, mentioned earlier, had their immunisation status and timeliness data compared with the total CDHB area birth cohort. The data was obtained utilising the infant’s National Health Index\textsuperscript{11} (NHI) number to confirm data recorded on the National Immunisation Register\textsuperscript{12} (NIR) for the six weeks, three months and five months immunisation milestone events. Overdue vaccinations were deemed to be greater than four weeks after the national immunisation schedule due date; to measure timeliness of the vaccine administration for the recommended NZ national immunisation schedule.

\textsuperscript{11} National Health Index number; is a unique number that is assigned to each person using health and disability support services.

\textsuperscript{12} National Immunisation Register (NIR) – is a computerised information system that has been collecting New Zealand Childhood Immunisation Scheduled vaccine information for children born from 2005; and since 2014 will collect some adult immunisation information. The main purpose of the NIR is to provide an accurate record of an individual’s immunisation history (MoH, 2014). The NIR data is securely held by the New Zealand Ministry of Health and District Health Boards.
7.3 Sample Method

Study Two was one of convenience cohort sampling of the SMART VIP study. This enabled the opportunity to explore whether vaccination received during pregnancy had any effect on the timeliness of their infant’s immunisations without further consent or further contact with postnatal mothers.

7.3.1 Inclusion Criteria

The study participants were infants of women in the CDHB area who had received the Tdap vaccine during pregnancy from April 2012 until December 2013. These women were enrolled in the SMART VIP study at the time of their vaccination. The population of Study Two is one of convenience to the SMART VIP study, and observed the same inclusion criteria.

7.3.2 Sample Size

Preliminary statistical calculation for comparing the proportions of women with on-time vaccination in the Tdap group and Canterbury birth cohort, has suggested that: if timeliness is 79% overall (rates as of 2011), with a sample size of 300 women who received Tdap, the study would have 90% power to detect a significant difference if the timeliness in the Tdap group is 88%.

A total of 363 infants of women who were enrolled in the SMART VIP study, and had received Tdap vaccine during pregnancy, with 355 infants included in the study. Eight infants were excluded as they had moved overseas and their vaccination status was incomplete. Statistical calculation will compare the proportion of women who had received the Tdap vaccine during pregnancy with the Canterbury birth cohort to detect any difference of timeliness and completion of infant vaccination.

7.4 Data Collection Procedures

The infant vaccination statuses were confirmed on the NIR, and the timeliness of their receipt of vaccines were compared to that of the CDHB area birth cohort for the same time period. The vaccination data statuses were received from the NIR as a password protected Excel spreadsheet. The data was checked using Excel formulas to indicate the time period and spacing when the six week, three month and five month events were due, and the dates when the vaccines were actually administered as recorded on
the NIR. Any dates seen as outliers within the data set were sent back to the NIR for verification.

7.5 Ethical Considerations

The SMART VIP study had prior approval to access the vaccination records of infants for the woman enrolled in the study; this was confirmed prior to the collection of data occurred for the vaccination status and timeliness research. Ethics approval application had been made to the Upper South A Regional Ethics Committee as part of the SMART VIP safety study conducted by Dr Tony Walls, Christchurch Paediatrics Department (see appendix one).

7.5.1 The Right to Self-Determination

As mentioned earlier, participants enrolled in the SMART VIP study gave their consent, at the time of receiving their Tdap vaccination, and included the consent for their infant’s vaccination details to be accessed. Participants were fully informed of the study and an emphasis that participation was their choice and voluntary, and that they could withdraw their participation at any time.

7.5.2 Maintaining Confidentiality

The participants NHI number was needed to access the NIR for the infants’ immunisation records. Prior to data analysis, the NHI number was removed from the database, and only the study identification number was used.

As mentioned earlier, the data collected has been stored on a password protected database. The research data will be kept for ten years at the Centre for Postgraduate Nursing Studies, University of Otago, Christchurch; and then destroyed in accordance with the University of Otago guidelines.

7.6 Data Analysis

The Excel programme was utilised for data collection and analysis of raw numbers were then consulted with the University of Otago, Christchurch Campus Biostatistician. All stages of analysis were supported and verified with the University of Otago, Christchurch campus Biostatistician for accuracy.
7.7 Summary

This chapter has described the methods and collection processes of the data to explore the aim of Study Two. The results and analysis of the Study Two will be discussed in the following chapter.
8  CHAPTER EIGHT: Results and Analysis - Study Two

This chapter describes the results of Study Two which explored whether the acceptance of immunisation during pregnancy, impacts on infants’ vaccination status and timeliness on the national immunisation scheduled. It will outline key findings of Study Two.

8.1  Sample included

There were a total of 363 infants of women who were enrolled in the SMART VIP study. The SMART VIP infants included in the study represented 355, eight infants were excluded as they had moved overseas and their vaccination statuses were incomplete on leaving the country; therefore, not able to be confirmed. The SMART VIP infants’ vaccination statuses were confirmed using the NIR and the timeliness of their receipt of vaccines was compared to that of the overall CDHB area births for the same period of time. This data set is not directly linked to, but separate from, the survey data set presented in Study One.

8.2  Prevalence of On-time Immunisation Coverage by Inclusion in the SMART VIP Study Cohort

Overall, 94.6 percent of the SMART VIP infants born of women who had received the Tdap vaccine during pregnancy received their five-month immunisations on-time, measured at six months of age (95% CI, 90.4%-95.6%). This was significantly higher than the overall vaccination proportion for the CDHB area infant cohort of 82.3 percent (p-value <0.001). Timeliness of the SMART VIP study group was also analysed at ten weeks, reflecting the six week vaccination event; and at four months, reflecting the three months vaccination event. At ten weeks and four months the SMART VIP study cohort coverage was 98.6 percent for both events, whereas the CDHB area infants at ten weeks were 91.5 percent and at four months 86.3 percent; see table 8.1.
Table 8.1: Prevalence of on time immunisation coverage by inclusion in the SMART VIP study cohort

<table>
<thead>
<tr>
<th>Age</th>
<th>No (n=5824)</th>
<th>Yes (n=355)</th>
<th>Proportion difference</th>
<th>Prevalence ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Week 10</td>
<td>91.5%</td>
<td>98.6%</td>
<td>7.09 ( 5.67, 8.51)</td>
<td>1.08 (1.06, 1.09)</td>
</tr>
<tr>
<td>Month 4</td>
<td>86.3%</td>
<td>98.6%</td>
<td>12.29 (10.78, 13.80)</td>
<td>1.14 (1.12, 1.16)</td>
</tr>
<tr>
<td>Month 6</td>
<td>82.3%</td>
<td>94.6%</td>
<td>12.35 (9.81, 14.89)</td>
<td>1.15 (1.12, 1.18)</td>
</tr>
</tbody>
</table>

A number of the infants in both infant cohorts received their vaccinations more than five days earlier than the recommended national immunisation schedule. This was an unexpected finding and is not recommended.

Table 8.2: Infant Immunisation given early (>5 days early)

<table>
<thead>
<tr>
<th>Due date</th>
<th>CDHB infant cohort</th>
<th>Infants in SMART VIP study cohort</th>
</tr>
</thead>
<tbody>
<tr>
<td>Week 6</td>
<td>0.8%</td>
<td>1.8%</td>
</tr>
<tr>
<td>Month 3</td>
<td>15.6%</td>
<td>18%</td>
</tr>
<tr>
<td>Month 5</td>
<td>7.3%</td>
<td>6.5%</td>
</tr>
</tbody>
</table>

8.3 Summary

This chapter has presented the results of Study Two. The data obtained from Study Two provided information relating to the status and timeliness of infant’s vaccinations. The key findings, limitations and recommendations will be discussed in the following chapter.
9 CHAPTER NINE: Study Two—Discussion, Limitations and Recommendations

This chapter will discuss the key findings identified in the previous chapter, followed by the limitations. The recommendations are offered at the end of the chapter based upon the findings of Study Two.

9.1 Discussion

9.1.1 Vaccination Timeliness

A significant finding was that SMART VIP study infants, of women who had received Tdap vaccine, were more likely to be vaccinated on-time at every scheduled immunisation event compared to the CDHB area infant cohort. This was despite overall high rates of coverage for CDHB area infant vaccinations in general. As mentioned earlier, the necessity for women to visit their GP during pregnancy, to receive the Tdap vaccine, may have enabled opportunistic discussion about the importance of on-time infant vaccination and early enrolment; this additional engagement with a key health professional may have contributed to the greater timeliness in the study population.

It is essential that infants receive the primary series on-time for the protection of infants from pertussis, and is currently a key national Health Target of the NZ Ministry of Health. On-time infant immunisation is a key public health intervention recommended to reduce pertussis in infants during an epidemic (Mitchell et al., 2014). Calarco et al. (2012; see page 32) reported a similar finding in their study, mothers (n=900) who accepted a pertussis-containing vaccine postpartum and influenza vaccine during pregnancy were 82 percent and 63 percent higher, respectively, to have fully vaccinated infants than women who had not accepted the vaccine/s, or had received a vaccine in previous years.

9.1.2 Early Vaccinations

An unexpected finding from this study was the early administration of infant vaccinations seen in both the SMART VIP infant study group and the overall CDHB area infant cohort. Early vaccinations were defined as a vaccine administered five days or more prior to the date recommended on the NZ national immunisation schedule. Early administration of a scheduled vaccine was observed more frequently for the
scheduled vaccines due at three months of age; which represented 18 percent of the SMART VIP study infant group and 15.6 percent of the CDHB area infant group.

The main aim of a national immunisation schedule is to provide guidelines for administration of vaccines to ensure the optimal protection against the diseases included (Centers for Disease Control and Prevention (CDC), 2011). Most vaccines in the childhood immunisation schedule require two or more doses to develop optimal protective antibodies; also known as a primary course. Therefore, decreasing the interval between doses of the vaccine may interfere with individual’s immune system to provoke an adequate immune response to the antigens being administered (CDC, 2011).

It may be necessary in some circumstances to administer a dose of vaccine at an interval shorter that indicated on a schedule, for example: when an infant or child is behind the scheduled guidelines and needs to be brought up to date quickly, or when international travel is imminent, or in the event of a disease outbreak. In these circumstances an accelerated or catch up course may be used; but not routinely recommended.

The CDC outlines recommended minimum intervals and ages for administration of the vaccines based on the United States of America National Immunisation Schedule (Atkinson et al., 2009b), which includes many of the vaccines used within the NZ immunisation schedule. The recommendations clearly state that the vaccine doses should not be administered earlier than the “recommended minimal ages and intervals” indicated on the national immunisation schedule (CDC, 2011).

Infants in the current study, who received their vaccinations early, based on the NZ national immunisation schedule intervals, did not exceed the recommended minimal intervals or ages (Atkinson et al., 2009b), with the exception of the vaccines scheduled at six weeks of age; 1.8 percent in the SMART VIP study cohort and 0.8 percent of infants in the CDHB area cohort who received their six week immunisation event early. Reasons for early administration could have been due to: the child being brought to the GP early in error or convenience by the parents; having an appointment not specifically for vaccination and offered vaccination at the time of the visit; the clinician or parent counting the intervals incorrectly, for example: in days or weeks and not months; or due to pending travel and therefore advised by a clinician, or vaccinated early on request by
a parent. However, without further research the true reasons for early vaccine administration are unknown.

9.2 Limitations

There are several limitations of Study Two for consideration and discussion. The first of which is a potential selection bias as the mothers of the infants were enrolled in the SMART VIP study and may have been particularly pro-vaccination, and more infection risk-adverse compared to other postpartum mothers within the CDHB area; therefore the results may not be representative of the overall CDHB area population.

The second limitation is of potential bias of women actively enrolled and participating in a study (SMART VIP), with on-going follow up as part of the SMART VIP study; this may have increased the women’s knowledge about pertussis and vaccination in general. Therefore, these factors may have led to better infant vaccination rates for this cohort.

Finally, the ability to measure the CDHB area population over time is limited as the population will fluctuate in real time as people move into and out of the CDHB area. Therefore the comparative data captured coverage at a specific time point. Therefore the findings are limited to the CDHB area, and not representative of the overall NZ population.

9.3 Summary

Study Two provides valuable data on the positive effect of maternal vaccination for on-time vaccinations of the infant primary series. This study identified that infants of women who had received Tdap vaccine during pregnancy, were significantly more likely to receive their infant immunisation events on-time. This could have a significant positive effect for on-time infant immunisation coverage nationally.
9.4 Recommendations

9.4.1 Extension of the Tdap Vaccine on the National Immunisation Schedule

The value for maternal Tdap vaccination is multifaceted for example for the protection of the mother, protection of the newborn infant in the first months of life, the positive effect for infant vaccination timeliness, and an opportunity for GP contact with their patient during their pregnancy. Therefore, it is beneficial for the national immunisation schedule to include the Tdap vaccine for pregnant women routinely and not only as a response to an epidemic, as it is currently.

9.4.2 Future Research

The unexpected finding of the early administration of infant vaccinations seen in both the study infant cohort and the CDHB infant cohort needs further research to understand the true reasons for the early administration of vaccines, and explore the extent of this occurring. The currently focus of vaccination being monitored and reported on, is on completed immunisation events based on the immunisation schedule events. The timing of the vaccine is not actively monitored unless the vaccines are overdue. Therefore vaccines administered early may currently go undetected for the majority of the time.

Finally, further research is needed to explore infant status and timeliness, of mothers who accepted vaccination during pregnancy. Such research needs to include other regions of NZ, outside an epidemic and outside of a study, to establish whether this finding truly exists or whether the other factors involved contributed to this outcome.
10 CHAPTER TEN: Conclusion – Study One and Study Two

The attitudes to, and knowledge of, a vaccine preventable disease will influence the acceptance of vaccines during pregnancy. The four main factors reported by women who received the Tdap vaccine during pregnancy being; to protect their baby from pertussis, the recommendation from a health professional, the threat of pertussis in the community, and the vaccine being fully funded. In comparison, women who did not receive the vaccine identified main factors to be: they were not aware the vaccine was available, fear of side effects during pregnancy, and doubtful of the vaccine effectiveness. The barriers for women, who did not receive the Tdap vaccine, may have been overcome by the supportive recommendation from a health professional regarding immunisation during pregnancy (Eppes et al., 2013; Hayles et al., 2015; Meharry et al., 2013; Wiley et al., 2013c).

The most important influencing factor from Study One was that a health professionals’ recommendation for vaccination is crucial, and may significantly influence the uptake of the Tdap vaccine in this population. In the absence of relevant information, and recommendations patients are unable to make an informed decision about of their current options to prevent pertussis in their infants (Eppes et al., 2013; Hayles et al., 2015; Tong et al., 2008; Wiley et al., 2013a).

Administration of Tdap vaccine during pregnancy and on-time infant vaccination offers the best strategy to protect infants against pertussis. Study Two identified that at every immunisation milestone, infants of women vaccinated against pertussis during pregnancy were more likely to be vaccinated on-time. There are definite benefits and evidence emerging for health professionals to provide support for recommendations of vaccinating during pregnancy with the Tdap vaccine.

All efforts need to be made to prevent pertussis, as the disease continues to evade the best planned strategies and efforts. Pertussis is a major issue for public health specialists, largely due to the complexities of the disease with the recurring epidemics. One significant challenge is the waning immunity from the vaccine and infection, and the limited effectiveness of the current vaccine in preventing the disease (Cherry, 2012; Poolman et al., 2011).
As this study occurred during an epidemic it reveals the importance to actively communicate and strongly promote on-time infant vaccination, increase coverage and uptake of Tdap vaccination during pregnancy. And the importance for on-going promotion of booster doses for adults, especially healthcare professionals working in paediatric, gynaecologic, and obstetric health areas (Edwards & Decker, 2013; MoH, 2014a). The coverage needs to extend to anyone employed to care for preschool children; and if possible include vaccination of family contacts of infants, to fully incorporate a cocooning strategy (Bechini et al, 2012; Castagnini et al., 2012; Healy & Baker, 2013; Healy et al., 2015; Quinn et al., 2013).

As the nature of immunity is not constant and community coverage can never be complete, eradication is never reached. How health policy makers respond to variations in immunity and the event of epidemics is vital. Therefore, if vaccines are temporarily added to the national schedule and then later discontinued, there is a risk that such changes in schedules lead to confusion for both health professionals and the general public. Furthermore, this may be wrongly interpreted that discontinuation equates to eradication or that the strategy failed. Without being fully aware of the complexities of the disease, the changes to immunisation schedules could be seen as the experts grasping for solutions. Therefore health professionals may find communicating the changes difficult and, confidence and credibility for a programme could be undermined or lost.

As mentioned earlier, Mitchell et al. (2014) highlighted the benefit of maternal Tdap vaccination to reduce the expected number of infant notifications by 41.7 percent. There are obvious benefits and growing evidence for Tdap vaccination during pregnancy. Vaccinating pregnant women should be given high priority when determining public health policy to protect young infants from pertussis.
REFERENCES:

Advisory Committee on Immunisation Practices. (2011). *Updated recommendations for Use of Tetanus Toxoid, reduced Diphtheria Toxoid and Acellular Pertussis Vaccine (Tdap) in pregnant women and persons who have or anticipate having close contact with an infant aged <12 months, Morbidity and Mortality Weekly Report, 60*(41), 1424-1426.


Joint Committee on Vaccination and Immunisation. *Minutes of Teleconference*. Joint Committee on Vaccination and Immunisation: United Kingdom; August 20, 2012.


Appendix One: Ethics Approval

28 February 2013

Dr Tony Walls
Paediatric Department, University of Otago, Christchurch
PO Box 4345, Christchurch Mail Centre
Christchurch
8140

Dear Dr Walls

<table>
<thead>
<tr>
<th>Re:</th>
<th>Ethics ref:</th>
<th>URA/12/EXP/021/AM01</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study title:</td>
<td>SMART VIP Study - Safety Monitoring for Adverse Reactions to Tdap Vaccine in Pregnancy</td>
<td></td>
</tr>
</tbody>
</table>

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

- Women in Canterbury who have received Tdap vaccine will be identified through Pegasus Health Records. Their GP will be contacted by phone or email to ask for permission for researchers to contact the woman directly. A letter will be sent to the woman 5 days before the initial phone contact outlining the study, and the reasons for the study, and giving them the opportunity to decline participation. If they do not decline they will be contacted by study staff and verbal and then written consent will be obtained for participation in the study.

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

Yours sincerely,

Ms Raewyn Idoine
Chairperson
Southern Health and Disability Ethics Committee

Encl:  appendix A: documents submitted  
appendix B: statement of compliance and list of members

A - URA/12/EXP/021 – Approval of Amendment – 28 February 2013
## Appendix A

### Documents submitted

<table>
<thead>
<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post Approval Form</td>
<td></td>
<td>05 February 2013</td>
</tr>
</tbody>
</table>
Appendix B
Statement of compliance and list of members

Statement of compliance

The Southern Health and Disability Ethics Committee:

— is constituted in accordance with its Terms of Reference
— operates in accordance with the Standard Operating Procedures for Health and Disability Ethics Committees, and with the principles of international good clinical practice (GCP)
— is approved by the Health Research Council of New Zealand’s Ethics Committee for the purposes of section 25(1)(c) of the Health Research Council Act 1990
— is registered (number 00008713) with the US Department of Health and Human Services’ Office for Human Research Protection (OHRP).

List of members

<table>
<thead>
<tr>
<th>Name</th>
<th>Category</th>
<th>Appointed</th>
<th>Term Expires</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ms Raewyn Idoine</td>
<td>Lay (consumer/community perspectives)</td>
<td>01/07/2012</td>
<td>01/07/2015</td>
</tr>
<tr>
<td>Mr Doug Bailey</td>
<td>Lay (the law)</td>
<td>01/07/2012</td>
<td>01/07/2015</td>
</tr>
<tr>
<td>Mrs Angelika Frank-Alexander</td>
<td>Lay (consumer/community perspectives)</td>
<td>01/07/2012</td>
<td>01/07/2014</td>
</tr>
<tr>
<td>Dr Sarah Cunningham</td>
<td>Non-lay (intervention studies)</td>
<td>01/07/2012</td>
<td>01/07/2015</td>
</tr>
<tr>
<td>Ms Gwen Neave</td>
<td>Lay (consumer/community perspectives)</td>
<td>01/07/2012</td>
<td>01/07/2014</td>
</tr>
<tr>
<td>Dr Nicola Swain</td>
<td>Non-lay (observational studies)</td>
<td>01/07/2012</td>
<td>01/07/2014</td>
</tr>
<tr>
<td>Dr Martin Than</td>
<td>Non-lay (intervention studies)</td>
<td>01/07/2012</td>
<td>01/07/2014</td>
</tr>
<tr>
<td>Dr Matthew Zacharias</td>
<td>Non-lay (health/disability service provision)</td>
<td>01/07/2012</td>
<td>01/07/2015</td>
</tr>
</tbody>
</table>

http://www.ethics.health.govt.nz
19 April 2013

Dr Tony Walls
Paediatric Department, University of Otago, Christchurch
PO Box 4345, Christchurch Mail Centre
Christchurch
8140

Dear Dr Walls

Re: Ethics ref: URA/12/EXP/021/AM02
    Study title: SMART VIP Study - Safety Monitoring for Adverse Reactions to Tdap Vaccine in Pregnancy

I am pleased to advise that this amendment has been approved by the Southern Health and Disability Ethics Committee. This decision was made through the HDEC Expedited Review pathway:

- This is an additional arm of the study, using the same cohort of pregnant women, and looking at the factors that influence their choices about having Tdap vaccine during pregnancy. This amendment allows the team to answer additional important questions arising from the use of this vaccine during pregnancy.

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

Yours sincerely,

[Signature]

Ms Raewyn Idoine
Chairperson
Southern Health and Disability Ethics Committee

Encl: appendix A: documents submitted
      appendix B: statement of compliance and list of members
# Appendix A

## Documents submitted

<table>
<thead>
<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post Approval Form</td>
<td></td>
<td>11 April 2013</td>
</tr>
</tbody>
</table>
Appendix B
Statement of compliance and list of members

Statement of compliance

The Southern Health and Disability Ethics Committee:

— is constituted in accordance with its Terms of Reference
— operates in accordance with the Standard Operating Procedures for Health and Disability Ethics Committees, and with the principles of international good clinical practice (GCP)
— is approved by the Health Research Council of New Zealand’s Ethics Committee for the purposes of section 25(1)(c) of the Health Research Council Act 1990
— is registered (number 00008713) with the US Department of Health and Human Services’ Office for Human Research Protection (OHRP).

List of members

<table>
<thead>
<tr>
<th>Name</th>
<th>Category</th>
<th>Appointed</th>
<th>Term Expired</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ms Raewyn Iden</td>
<td>Lay (consumer/community perspectives)</td>
<td>01/07/2012</td>
<td>01/07/2015</td>
</tr>
<tr>
<td>Mr Doug Bailey</td>
<td>Lay (the law)</td>
<td>01/07/2012</td>
<td>01/07/2015</td>
</tr>
<tr>
<td>Mrs Angelika Frank-Alexander</td>
<td>Lay (consumer/community perspectives)</td>
<td>01/07/2012</td>
<td>01/07/2014</td>
</tr>
<tr>
<td>Dr Sarah Cunningham</td>
<td>Non-lay (intervention studies)</td>
<td>01/07/2012</td>
<td>01/07/2015</td>
</tr>
<tr>
<td>Ms Gwen Neave</td>
<td>Lay (consumer/community perspectives)</td>
<td>01/07/2012</td>
<td>01/07/2014</td>
</tr>
<tr>
<td>Dr Nicola Swain</td>
<td>Non-lay (observational studies)</td>
<td>01/07/2012</td>
<td>01/07/2014</td>
</tr>
<tr>
<td>Dr Martin Than</td>
<td>Non-lay (intervention studies)</td>
<td>01/07/2012</td>
<td>01/07/2014</td>
</tr>
<tr>
<td>Dr Mathew Zacharias</td>
<td>Non-lay (health/disability service provision)</td>
<td>01/07/2012</td>
<td>01/07/2015</td>
</tr>
</tbody>
</table>

http://www.ethics.health.govt.nz
Appendix Two: Survey Questionnaire

Factors influencing women’s decisions about having the pertussis-containing (Tdap) vaccine during pregnancy research survey

The questions in this survey are intended to gather information to increase our understanding about what factors may influence decisions of women offered vaccines during pregnancy. Specifically, we are interested to know about the factors you may have considered regarding having or not having the pertussis (whooping cough) vaccine during your recent pregnancy. You may skip any questions you don’t feel comfortable answering.

The survey will take about 15-20 minutes. All information provided will be treated anonymously. Participation in the survey is completely voluntary (your choice).

Section One: Vaccination status

1. Did you receive the pertussis-containing vaccine during pregnancy?  
   *Please circle one*
   
   Yes (go to question 4.)  No  Don’t remember

   **If YES**, please include the name of your Doctor and Medical Centre:

   ……………………………………………………………………………………………………………………………

2. Were you aware the pertussis-containing vaccine was available to you during pregnancy?  
   *Please circle one*
   
   Yes (go to question 4.)  No  Don’t remember

3. Would you have considered having the pertussis-containing vaccine during pregnancy if you had been offered it (or aware the vaccine was available)?  
   *Please circle one*
   
   Yes  No  Don’t know

4. Did you receive the influenza vaccine during pregnancy?  
   *Please circle one*
   
   Yes  No  Don’t remember
5. Who administered the vaccination/s? (Pertussis-containing vaccine or influenza vaccine)
   - General Practitioner/ Doctor
   - Midwife
   - Practice Nurse
   - Other (please specify) ..............................................................
   - Don’t remember
   - Did not receive a vaccine during pregnancy

6. If you received both the pertussis-containing vaccine and influenza vaccine. Did you receive the vaccines:
   - Both at the same time (on the same day)
   - On separate days (different visits)
   - Don’t remember
   - Did not receive a vaccine during pregnancy

7. Do you feel the facts about the vaccination/s you received were clearly explained to you?
   Please circle one
   - Yes
   - No
   - Did not receive a vaccine
   Any additional comments: ......................................................................................
   ................................................................................................................................

8. When deciding whether or not to receive the pertussis-containing vaccine, please indicate the information sources that were most helpful? Tick as many as required/apply
   - Information from the midwife
   - Information from the doctor
   - Information from the practice nurse
   - Discussion with spouse/other relative/friend
   - Made my own decision/own research
   - Posters ...........................................................................................
   - Internet ..........................................................................................
   - Other reading material (TV, Radio, Newspaper etc) ..........................
   - Other healthcare professional source (please specify) ..................
   - Didn’t know the vaccine was available
9. Who was your lead maternity care (LMC) provider?
   - [ ] General Practitioner (GP) / Doctor
   - [ ] Independent Midwife
   - [ ] Hospital Midwife
   - [ ] Obstetrician
   - [ ] Shared care
   - [ ] Other

10. Is your baby “enrolled” with a general practitioner (GP) / Doctor?  
    Please circle one
    - [ ] Yes
    - [ ] No
    - [ ] Don’t know

11. During your pregnancy did you receive any information encouraging you to receive the pertussis-containing vaccine?  
    Please circle one
    - [ ] Yes
    - [ ] No
    - [ ] Don’t remember

12. Where did you receive this (encouraging) information from?  
    Tick any many as required
    - [ ] General Practitioner (GP) / Doctor
    - [ ] Practice Nurse
    - [ ] Independent Midwife
    - [ ] Hospital Midwife
    - [ ] Obstetrician
    - [ ] Whaanui/partner/family
    - [ ] Antenatal class
    - [ ] Written material (please specify)
    - [ ] Internet
    - [ ] Other (please specify)
    - [ ] Did not receive any encouraging information
13. During your pregnancy did you receive any information *discouraging* you to receive the pertussis-containing vaccine during pregnancy?  
*Please circle one*

- Yes
- No
- Don’t remember

14. Where did you receive this *(discouraging)* information from?  
*Tick any many as required*

- General Practitioner (GP) / Doctor
- Practice Nurse
- Independent Midwife
- Hospital Midwife
- Obstetrician
- Whānau/partner/family
- Antenatal class
- Written material (please specify)......................................................................
- Internet.............................................................................................................
- Other (please specify).....................................................................................
- Did not receive any discouraging information

15. How concerned are you that a vaccine would not prevent the pertussis (whooping cough) disease?  
*Please circle one*

- Very concerned
- Somewhat concerned
- Don’t know
- Not too concerned
- Not at all concerned

16. From the following list below:
   
   What concerned you the *most* when deciding whether or not to accept the pertussis-containing vaccine?  
*Only tick ONE please*

- Safety/side effects for yourself
- Safety/side effects for your baby
- Effectiveness of the vaccine to prevent the disease
- Pain/anxiety
- No concerns
- Threat of whooping cough infection/affects
- Other (please specify).....................................................................................

17. Have you ever known anyone to be affected by the pertussis (whooping cough) disease?  
*Please circle one*

- Yes
- No
Only answer questions on this page if you did receive the pertussis-containing vaccine during pregnancy.

(If you did not receive the pertussis-containing vaccine, go to question 21)

With the following four questions, choose one statement that you consider being the “most important” to you:

18. I decided to have the pertussis-containing vaccine: Please tick one only
   - [ ] To prevent the pertussis disease circulating in the community
   - [ ] To protect myself from the disease
   - [ ] To protect my baby from the disease

19. I decided to have the pertussis-containing vaccine, because it was: Please tick one only
   - [ ] Recommended by a health professional
   - [ ] Recommended by my spouse/family/friends
   - [ ] I knew others who had, had it

20. I decided to have the pertussis-containing vaccine because: Please tick one only
   - [ ] The vaccine was free and available
   - [ ] There is a lot of pertussis in the community
   - [ ] Of the convenience and ease to receive it

21. I decided to have the pertussis-containing vaccine because of the: Please tick one only
   - [ ] TV coverage (news, ads)
   - [ ] Information I received about it
   - [ ] Other, please specify: ........................................................................................................................................
Only answer questions on this page if you did not receive the pertussis-containing vaccine during pregnancy.

(If you did receive the pertussis-containing vaccine, go back to question 17).

With the following four questions, choose one statement that you consider being the “most important” to you:

22. I decided not to have the pertussis-containing vaccine because it was:  
   Please tick one only
   [ ] Too expensive
   [ ] I was unable to get to the practice (or it was inconvenient)
   [ ] I didn’t know about the vaccine or that it was available

23. I decided not to have the pertussis-containing vaccine because of:  
   Please tick one only
   [ ] The low risk of pertussis in Canterbury
   [ ] Fear of side effects
   [ ] Fear of needles/injections

24. I decided not to have the pertussis-containing vaccine due to being:  
   Please tick one only
   [ ] Doubtful of the vaccine’s effectiveness
   [ ] Anti-vaccines (do not believe in/against vaccines)
   [ ] Mistrust of the information

25. I decided not to have the pertussis-containing vaccine because:  
   Please tick one only
   [ ] It was not recommended by anyone
   [ ] I do not know anyone who has had whooping cough
   [ ] Other, please specify.................................................................
Section two: Knowledge statements:

Please read the following statements about immunisation. Select and circle only one.

26. Pertussis (whooping cough) disease can be a serious disease for young children and babies.
   Agree    Somewhat agree    Don’t know    Somewhat disagree    Disagree

27. Vaccination is more likely to make us sick rather than keeping us healthy.
   Agree    Somewhat agree    Don’t know    Somewhat disagree    Disagree

28. If you keep yourself, well fed, and otherwise healthy, you will not catch pertussis (whooping cough).
   Agree    Somewhat agree    Don’t know    Somewhat disagree    Disagree

29. Parents/caregivers have a responsibility to ensure they and their children are immunised to prevent diseases spreading.
   Agree    Somewhat agree    Don’t know    Somewhat disagree    Disagree

30. I am confident about having myself/child/children immunised.
   Agree    Somewhat agree    Don’t know    Somewhat disagree    Disagree

31. Childhood diseases are no longer around much so you don’t have to worry about immunising against them.
   Agree    Somewhat agree    Don’t know    Somewhat disagree    Disagree

32. Canterbury is currently having high numbers of pertussis (whooping cough) cases (also known as an outbreak).
   Agree    Somewhat agree    Don’t know    Somewhat disagree    Disagree
Section three; General Information

32. Please enter your National Health Index Number (NHI), which can be found in your maternity notes: ..........................................................

33. Which of the following age group do you fall into?
   - [ ] < 18 years
   - [ ] 18 - 21 years
   - [ ] 22 - 25 years
   - [ ] 26 - 29 years
   - [ ] 30 - 33 years
   - [ ] 34 - 37 years
   - [ ] 38 - 41 years
   - [ ] 42 - 45 years
   - [ ] 46 - 50 years

34. Which ethnic group/s do you belong to?  please tick as many as required
   - [ ] NZ European/Pakeha
   - [ ] NZ Maori/Iwi
   - [ ] New Zealander/Kiwi
   - [ ] Samoan
   - [ ] Tongan
   - [ ] Cook Island Maori
   - [ ] Fijian
   - [ ] Niuean
   - [ ] Other Pacific Island
   - [ ] Asian (Indian, Korean, Chinese, Japanese, Thai etc)
   - [ ] Other European (British, Irish, English, Scottish, Welsh)
   - [ ] Continental European (Dutch, German, Croatian, Russian etc)
   - [ ] Australian
   - [ ] North American (U.S.A., Canadian)
   - [ ] Middle Eastern
   - [ ] Other (please specify) .................................................................

35. Which of the following is your highest qualification?
   - [ ] Less than secondary school
   - [ ] Some secondary school (no exams passed)
   - [ ] Fifth form certificate or NCEA 1
   - [ ] Sixth form certificate or NCEA 2
   - [ ] Higher School Certificate
   - [ ] Bursary
   - [ ] Tertiary Qualification:
       - Undergraduate degree (Bachelors) e.g. BA, BSc
       - Postgraduate study e.g. Postgraduate diploma, Masters, PhD
   - [ ] Vocational qualification/certificate e.g. polytechnic, hairdresser, plumber etc

Thank you for your time, you have come to the end of the survey.

Please return the survey in the envelope provided.
Appendix Three: Survey Flyer

Pertussis (whooping cough) – Research Survey
You are invited to participate...

...in a survey to explore the factors influencing women's decisions about having the pertussis-containing (Tdap) vaccine during pregnancy

What would you need to do?
The study involves you completing a short survey.

If you are discharged home after the 1st of June 2013:
• all women will be sent an information pack
• it will include a copy of the survey
• the survey will be available online – pack includes "login" details

We are interested in your participation, regardless of whether or not you have received the pertussis-containing (whooping cough) vaccine during your pregnancy.

University of Otago
Study title: Factors influencing women's decisions about having the pertussis-containing (Tdap) vaccine during pregnancy
Principal Investigator: Linda Hill Phone: 021 847 737 Ethics ref: URA/12/EXP/021/AM02
Appendix Four: Participant Information Letter

Title: Factors influencing women’s decisions about having the pertussis-containing (Tdap) vaccine during pregnancy

Principal investigator:
Linda Hill
Postgraduate Masters Student, Registered Nurse
University of Otago, Christchurch

Research Supervisors:
Dr Beverley Burrell  Dr Tony Walls
Senior Lecturer  Paediatric Infectious Diseases
Centre for Postgraduate Nursing Studies  Senior Lecturer
University of Otago, Christchurch  University of Otago, Christchurch

What are the aims of this study?

Since August 2011, New Zealand has been experiencing an outbreak of pertussis (whooping cough), and the Canterbury region has had a significantly high number of reported pertussis cases. Pertussis can cause severe disease in infants, and most of the children hospitalised with pertussis have been younger than 8 weeks of age. Most of these infants have not received their first infant immunisations, and therefore have no protection against pertussis. If their mothers are vaccinated during pregnancy with Tdap vaccine (contains tetanus, diphtheria and acellular pertussis (Tdap) components) this may provide some protection for them in the first few months of life.

The New Zealand Ministry of Health Technical Advisory Forum on vaccines reviewed the available information on the safety and effectiveness of the Tdap vaccine and recommended its use during pregnancy in New Zealand.

In 2012 during the pertussis outbreak, the Canterbury District Health Board (CDHB) agreed to fund the administration of Tdap to pregnant women who had not received a previous pertussis booster with Tdap. The aim of this intervention was to prevent pertussis in small babies who are most at risk of severe infection. In January 2013, Pharmac began funding the use of the Tdap vaccine during pregnancy nationally.

The purpose of this study is to explore the factors influencing women’s decisions about having the pertussis-containing (Tdap) vaccine during pregnancy. By understanding these factors it may be possible to improve the way messages are communicated to individuals, whānau and communities.

Please note: We acknowledge that you may have recently been approached for a pertussis study, we would like to clarify that this is a different study and we would very much appreciate your participation.
What does this study involve?

Regardless of whether you have or have not received the pertussis-containing vaccine during pregnancy, we are interested in your participation in a short survey.

The survey is about the pertussis vaccine and immunisation in general and will take no more than 15-20 minutes. If you would like assistance filling in the survey, please contact Linda Hill (details below). You can complete the survey attached, and return it in the envelope provided, or online at: https://www.surveymonkey.com/s/whooping

If you did receive the vaccine during pregnancy, with your permission, we will contact your General Practitioner’s team for the details of the vaccine given i.e.:

- Batch number
- Expiry date
- Date administered

Do you have to stay in the study?

You may choose to leave the study at any time, without giving a reason. If you do give a reason, then it may be recorded. Your choice will not change the medical care or other benefits you receive outside of this study.

What about your personal and medical information?

It is very important that your personal and medical information is kept confidential and secure.

The personal and medical information collected about you during the study will be labelled with a code number. The research team will be the only people who have access to this information. The study data base will not include any information that would allow people not involved in the study to identify you e.g. your name, address or date of birth.

Who should you contact if you have questions?

If you have any questions please contact:
Linda Hill by email: hilli241@student.otago.ac.nz or by phone: 021 847 737

If you have any queries or concerns regarding your rights as a participant in this study, you may wish to contact a Health and Disability Advocate:
Free phone: 0800 555 050
Free fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@hdc.org.nz

This study has received ethical approval from the Southern Health and Disability Ethics Committee, ethics reference number: URA/12/EXP/021/AM02
Appendix Five: Consultation Letter To The Lead Maternity Carers

16 May 2013

Dear Lead Maternity Carer,

Research Study: Factors influencing women’s decisions about having the pertussis-containing (Tdap) vaccine during pregnancy.

As you will be aware pregnant women are being offered the Tdap vaccine (contains tetanus, diphtheria and acellular pertussis (Tdap) components) during their pregnancy. The aim of this intervention is to prevent pertussis (whooping cough) in small babies who are most at risk of severe infection. Approximately 40% of pregnant women in Canterbury have chosen to be vaccinated.

The purpose of this study is to explore the factors influencing women’s decisions about having the pertussis-containing (Tdap) vaccine during pregnancy. By understanding these factors better it may be possible to improve the way messages are communicated to individuals, whanau and communities, from the results identified in this study.

Canterbury women will be approached to participation in a short survey after the birth of their baby; in order not to influence decisions of those who have not received the vaccine during pregnancy. Whether or not the women have received the pertussis-containing vaccine during pregnancy, we are interested in their participation.

The survey is about the pertussis-containing vaccine and immunisation in general, and will take no more than 20 minutes; the survey may be completed in hard copy (returned it in an envelope provided) or online. Posters will be placed in the postnatal ward introducing the research, and informing women discharged within the CDHB area during this time that they will be contacted by mail.

As the LMC for these women, it is important that you are aware of the research being conducted, and that you have the opportunity to specifically exclude any of your clients you feel should not be contacted. If this is the case please advise me directly with the NH1 number either by email hili241@student.otago.ac.nz or by phone 021 847 737.

If you would like to see the information sheet and short survey that will be sent out, please contact me (via the contact details above).

Please feel free to contact me if you have any questions.

Best regards

Linda Hill
Principal Investigator
Postgraduate Masters Student,
Registered Nurse
University of Otago
Christchurch

Dr Beverley Burrell
Research Supervisor
Senior Lecturer
Centre for Postgraduate Nursing Studies
University of Otago
Christchurch

Dr Tony Walls
Research Supervisor
Paediatric Infectious Diseases
Senior Lecturer
University of Otago
Christchurch

Ethics ref: URA/12/EXP/021/AM02
# Locality Authorisation for Canterbury District Health Board

Locality authorisation is a standard condition of HDEC approval for the conduct of a study at a given locality. Locality review is the process by which a locality assesses its suitability for the safe and effective conduct of a study.

## Part one: General

<table>
<thead>
<tr>
<th>Project title:</th>
<th>Factors influencing women’s decision about having the pertussis-containing (Tdap) vaccine during pregnancy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Locality to be assessed:</td>
<td>CDHB maternity wards</td>
</tr>
<tr>
<td>Brief outline of study:</td>
<td>The purpose of this study is to explore the factors influencing women's decisions about having the pertussis-containing (Tdap) vaccine during pregnancy. By understanding these factors better it may be possible to improve the way messages are communicated to individuals, whānau and communities. Permission is requested to place posters in the maternity wards introducing the proposed research within the CDHB area during the time of the study. Canterbury women will be approached to participation in a short survey after the birth of their baby; in order not to influence decisions of those who have not received the vaccine during pregnancy. Whether or not the women have received the pertussis-containing vaccine during pregnancy we are interested in their participation. The survey would be posted with an on-line log-in access included.</td>
</tr>
</tbody>
</table>

### Local Principal Investigator:

<table>
<thead>
<tr>
<th>Name</th>
<th>Linda Hill</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title</td>
<td>Registered Nurse, Health Sciences Masters Student</td>
</tr>
</tbody>
</table>

### Contact person & contact details:

<table>
<thead>
<tr>
<th>Name</th>
<th>Linda Hill</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phone</td>
<td>21 847 737</td>
</tr>
<tr>
<td>Email</td>
<td><a href="mailto:hill041@student.canterbury.ac.nz">hill041@student.canterbury.ac.nz</a></td>
</tr>
</tbody>
</table>

### Other local investigators:

- Dr Tony Watts, Paediatric Infectious Diseases Consultant, Senior Lecturer, University of Otago, Christchurch
- Dr Beverley Burrell, Senior Lecturer, Centre for Postgraduate Nursing Studies, University of Otago, Christchurch

## Part two: Locality Issues

1. **Suitability of the local researcher**
   - In the investigator(s) at the locality suitably qualified experienced registered and indemnified to take professional responsibility for the conduct of the study at the locality? [ ] Yes [ ] No

2. **Suitability of the local research environment**
   - Are all the resources and/or facilities that the study requires appropriate and available? [ ] Yes [ ] No

CDHB Locality Authorisation Form | June 2012 | 1
Would conducting the study at the locality impact on the provision of publicly funded health care at that locality? □ Yes □ No

Have all potentially affected managers of resources such as patient records or laboratory managers been notified? □ Yes □ No

3) Have issues such as cultural issues specific to this locality or to people being recruited at this locality been addressed? □ Yes □ No
SIGN OFF

I hereby certify that all information within this application is true and correct and I will ensure all consents and approvals are obtained and registered by the Research Office before research commences.

Principal Investigator: [Signature] [Date]

Recommendations: I hereby endorse this application to undertake this research on behalf of the CDHB and guarantee the availability of facilities, equipment and any special support which may be required as detailed in the application. I confirm that it is in accordance with current CDHB policy.

Service Manager: [Signature] [Date]

Clinical Director: [Signature] [Date]

Comments from Signatories: (Optional)

Research Office Use Only:

Finance Office: [Signature] [Date]

I am satisfied that suitable arrangements have been made for the safe and effective conduct of this study and therefore this study is authorised to be conducted within the CDHB.

General Manager: [Signature] [Date]
Appendix Seven: Letter From The Maori Research Advisor

05 February 2013

Dr Beverley Burrell
Centre for Postgraduate Nursing studies
University of Otago, Christchurch

Mā te rangahau Hauora e tautoko te whakapiki ake te Hauora Māori
All health research in Aotearoa New Zealand benefits the Hauora (health and wellbeing)
of tangata whenua

Tena Koe Beverley,

Thank you for arranging a meeting between your student Linda Hill and me at the University of Otago, Christchurch on the 25th February 2013, to discuss Linda’s research study titled:

Influencing factors considered by women regarding the pertussis-containing (Tdap) vaccine during pregnancy

I note that this research project will be undertaken by Linda with you as her Supervisor. I also understand from our meeting that Linda has applied to the NZNO research fund.

Commentary on Proposed research
From our meeting I established that this research project is a Master’s thesis and your research will be a retrospective convenience, two part study. 1. Recruitment of 300 participants over 9-12 months for participating in a telephone survey. 2. Compare immunisation status and timeliness of infant immunisation of mothers who received the pertussis vaccine during pregnancy, with the Canterbury birth cohort.

Specifically in your application we discussed the following:

1. I note that your research is a blinded study of pregnant women who will nominate themselves into the project via posters from Birthing units, midwives, and general practice.

2. The need to ensure that ethnicity data is collected from each participant (in accordance with the MOH guidelines, which involves the use of the Census 2006 question) alongside background details collected from each participant. If the participant identifies as Maori, but this was not recorded in their records, this should be reflected by informing the clerk and ensuring the participant is correctly recorded as being Maori.

3. It was agreed that there is a need to acknowledge the issues pertaining to ethnicity including age and to consider how this data will be collected in your study. Your study will involve a number of Maori participants. I note that the findings from your study may contribute to the development of future research hypotheses or projects.

4. Your application would be strengthened by including a clear profile of current rates of pertussis and highlighting current disparities between Maori and non-Maori, using descriptive statistics to highlight Maori and non-Maori incidence rates within the CDHB and nationally.
5. Your application should include a clear profile of current literature International /national rates of pertussis (including age and ethnicity) highlighting current disparities between ethnic women. This may be supported by looking at the robust data of Canterbury PHOs and look at the Population demographics for babies born in Canterbury.

6. Your application should highlight direct benefits for those participants who do participate in the study, and document direct health benefits/gain for individual (Maori) participants who consent to be part of this study. This research would also be strengthened if you sought Health professionals / Maori already working in this area to support Maori who have given birth over the last few months to participate in your survey/study.

Potential Further Support Resources
Further resources that you might want to access to strengthen your responsiveness to Maori within your research are: 1. HRC’s Nga Pou Rangahau Haurora Kia Whakapiki Ake Te Haurora Maori 2004-2008, 2. The Health Research Strategy to Improve Maori Health and Well Being 2004-2008. The other reference that is available is 3. Haurora Maori Standards of Health IV: A Study of the Years 2000-2005 by Bridget Robson and Ricci Harris, Maori Health Research Unit, Wellington School of Medicine, University of Otago, Wellington. All provide Maori specific information on a range of health issues.


It is also advisable that researchers review and refer to the District Health Board’s Annual Plan, www.dhbs.govt.nz/communications/documents/pdf/annualplan/annual_plan_2011_2012.pdf and/or the current Health Targets published by the Ministry of Health for 2011/2012, www.health.govt.nz/new-zealand-health-system/health-targets, Dr Matthew Reid’s “Haurora Waitaha”, CDHB.

Dissemination of Results
As stated in the HRC’s Guidelines for Researchers on Health Research Involving Maori, it is important that research results contribute to Maori health gain. This should occur not only in an academic forum, but also within the community from whence the data is drawn. Therefore the findings from this study should be further discussed with relevant Maori stakeholders. For your project this should involve a further discussion with the Maori managers/health workers who supported the study.

At the conclusion of your study, the Research Manager Maori will assist in facilitating this meeting. This will provide an appropriate forum for not only dissemination but consideration of community feedback into any discussion going forward.
Ethics

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 also be supplied to me at that time, as findings from this project may contribute to the development of future research hypotheses or projects. It is therefore important that appropriate Maori organisations, Maori health professionals and Maori researchers are aware of your findings. The Research Manager Maori would be willing to assist in the dissemination of your findings once your project has reached a successful conclusion.

I wish you well in your research

Ka nui tonu nga mihi

[Signature]

Wendy Dallas-Katoa
Acting research Manager – Maori