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Exploring the Association between Parental Concern about Vaccine Safety and Incomplete Childhood Immunization:

A Multivariate Model

by

Shannon Elizabeth MacDonald

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This thesis is dedicated to the memory of my father, Dr. J. Douglas Muir, PhD,
and my PhD supervisor, Dr. Christine Newburn-Cook, PhD, RN.

They are both greatly missed, but they left me a legacy of
honesty, integrity, and excellence.

Abstract

High levels of immunization coverage are required to maintain control of infectious diseases that previously caused significant illness and death in Canada. However, childhood immunizations have been so successful that many Canadians have never seen the impact of these diseases, with some parents becoming more concerned about the safety of vaccines than about the infectious diseases that they were designed to prevent. The purpose of this thesis was to determine if parental concern about vaccine safety is significantly associated with incomplete childhood immunizations, and whether other personal or systemic factors play a role in influencing uptake. The thesis consists of four related papers focusing on: (1) The value and challenges of applying the population health framework in nursing research; (2) The benefits and drawbacks of using postal surveys for public health nursing research; (3) Assessment of the accuracy of the immunization database utilized in this study in terms of immunization status classification, as compared to parent report; and, (4) The findings of the multivariate data analysis in the study. The main conclusions of this thesis are as follows: (1) The population health framework, while presenting challenges for nurse researchers, provides a valuable framework for assessing the multi-level factors influencing health behaviours, such as immunization uptake; (2) Awareness of the potential for survey error is essential when using postal surveys in research, and measures must be taken to minimize, assess, and control for non-response bias; (3) The immunization database used in this study had a low, but not inconsiderable, number of misclassification errors of immunization status, while

parent report had a greater number of errors; and (4) Parental concern about vaccine safety was indeed associated with incomplete immunizations, but other personal and systemic factors were also associated with vaccine uptake and/or mediated the relationship between parental concern and uptake.

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Chapter 1: Introduction

The aim of this thesis is to improve knowledge, and ultimately clinical practice, programs, and policies, that promote uptake of childhood immunizations in Canada. The central focus of the study was determining the impact of parental concern about vaccine safety on immunization uptake. In my clinical practice as a nurse in pediatric intensive care units in Canada and the United States I cared for children adversely affected by infectious diseases that could have been prevented through timely completion of their recommended immunizations. In some cases, lack of immunization was a conscious choice by the parents, while in others it was due to logistic or other challenges, such as difficulty accessing immunization services. These experiences motivated me to explore the reasons why children do or do not receive potentially life-saving immunizations.

The thesis consists of four papers prepared for publication: two already published, one under review, and one ready for submission. The papers constitute a unified whole presenting the conceptual framework underlying the study (Chapter 2), a methodological issue relevant to the study (Chapter 3), and the results of the study (Chapters 4 and 5). Chapter 6 presents a summary of the study and its recommendations, the contributions of the research, the limitations of the study, and the next steps in my program of research. The 'bookend chapters' (Chapters 1 and 6) will be written as a first person narrative, as these chapters represent my own reflections and decision-making regarding the thesis, whereas the chapters of publishable papers will be written from the perspective preferred by the journal publishing/reviewing the paper.

In this chapter, I will present: (a) the significance and context of the problem and the rationale for the study, (b) a review of the relevant literature, (c) the purpose, objectives, and research questions for the study, (d) the conceptual framework that guided the study, and (e) an overview and description of the linkage between the four papers that comprise the body of the thesis.

Background

Prior to the introduction of routine childhood immunizations, vaccine-preventable diseases were a significant cause of illness and death for children in Canada and worldwide (Canadian Public Health Association [CPHA], 2001). The overwhelming success of childhood immunizations has led to such dramatic declines in infectious diseases that many Canadians have become complacent about immunizations, because they rarely, if ever, see the impact of these diseases (Alberta Health, 2007; Canadian Nurses Association [CNA], 2001). Some parents, in fact, have become more concerned about the safety of vaccines than about the infectious diseases that they were designed to prevent (Alberta Health, 2007; CNA, 2001; Salmon et al., 2005). However, history has shown that populations that do not maintain high immunization rates see the resurgence of these deadly diseases, resulting in an increased burden on the health care system and numerous unnecessary deaths (Alberta Health, 2007; CPHA, 2001).

Understanding the factors that promote or inhibit high levels of immunization coverage, and, specifically, the role of parental concern about vaccine safety, is essential to protecting the health of Canadian children. Unimmunized and incompletely immunized children are at increased risk of contracting vaccine-preventable disease, and may transmit such disease to children too young to be vaccinated, to individuals unable to be vaccinated due to medical contraindications, or to those who fail to mount a protective immune response to the vaccine (Salmon et al., 2005).

Despite these risks, rates of immunization coverage for Canadian pre-school children are well below the recommended targets of 95-97% coverage (Public Health Agency of Canada [PHAC], 2008). In 2009, coverage for individual vaccines for Canadian children at two years of age ranged from only 55% to 92% (Laroche, Frescura, & Belzak, 2010). No Canadian data were provided in 2009 on the percentage of children up-to-date for all vaccines. However, in 2006, coverage for all vaccines was only 61% at two years old and 41% at seven years old (PHAC, 2006). These rates are clearly suboptimal, and it is possible that subgroups in the population have substantially lower rates. Coverage rates of less than 100% can still ensure the resistance of a population to spread of infectious disease through *herd immunity*, the protection provided to unimmunized individuals when a large enough proportion of the population is immunized to prevent person-to-person spread though a community (John & Samuel, 2000). However, the level of coverage required to maintain herd immunity is still very high; the target level set by the Public Health Agency of Canada is 95-97%, varying with disease (PHAC, 2008). In addition, the principle of herd immunity is dependent on an even distribution of susceptible individuals amongst a largely immune population. Outbreaks can still occur when susceptible clusters of individuals are exposed to an infectious case. Thus, there is the potential for outbreaks if the rates of coverage in the general population drop below the level required for herd immunity, or if there is clustering of incompletely immunized individuals within the larger population.

To improve immunization coverage in Canada, and to target programs toward high risk groups for incomplete immunization, it is necessary to determine the various factors leading to low immunization uptake, including the influence of parental concern about the safety of vaccines. Few studies have empirically tested the association between parental concern about vaccine safety and immunization status, and, of those that have, most have not simultaneously assessed the influence that other personal and systemic factors may play in mediating this relationship. The limited understanding that we have regarding this issue is derived mainly from studies conducted outside of Canada, where immunization programs differ significantly (as will be described later in this chapter).

The need to understand more about the factors influencing childhood immunization coverage in a Canadian context has been recognized by Immunize Canada (a Canadian coalition of professional, health, consumer, government, non-government, and private sector organizations that promote the uptake of vaccines), which has stated that, “there’s no valid Canadian data on why parents say no (to immunization)” (Peters, 2005, p. 1). The purpose of this study was, therefore, to determine the relationship between parental concern about vaccine safety and incomplete immunization of pre-school children, and to assess the influence of other personal and systemic factors on this relationship.

Literature Review

This review focuses on the factors influencing immunization of pre-school children in developed countries. I start with a brief overview of the personal, sociodemographic, and systemic variables hypothesized to influence immunization status. While sociodemographic characteristics are sometimes considered to be personal factors, they may also be considered systemic factors, due to their influence on social and environmental context (e.g., income, education, number of children). For the purposes of this literature review, I will discuss sociodemographic characteristics separately from personal and systemic factors. This overview of relevant factors is followed by an in-depth discussion of what is known about the impact of parental concern about vaccine safety and the limitations of previous research on the subject.

The State of Knowledge about Personal, Sociodemographic, and Systemic Factors

Personal factors. Personal factors thought to influence immunization uptake include knowledge, attitudes, and beliefs, as well as other individual-level variables. While there has been a considerable amount of research focussed on these factors, there have so far been inconsistent findings (Sturm, Mays, & Zimet, 2005).

Specific knowledge, attitudes, and beliefs thought to be associated with immunization completion include:

- Concerns about the safety of vaccines (Lannon et al., 1995; Lawrence et al., 2004; Mills, Jadad, et al., 2005; Mills, Montori, et al., 2005)

- The perception that children are not at risk from these diseases anymore or that the diseases are not serious, i.e. limited knowledge about vaccine-preventable disease susceptibility and severity (Lawrence, Hull, MacIntyre, & McIntyre, 2004; Salmon et al., 2005)
- Lack of belief in vaccine effectiveness (Lawrence et al., 2004; Salmon et al., 2005)
- Parental forgetfulness regarding when immunizations are due, which may be associated with the increasingly complex childhood immunization schedule (thus also a systemic factor) (Bond et al., 1998; Lannon et al., 1995; Lawrence et al., 2004; McWha et al., 2004; Miller, Hoffman, Baron, Marine, & Melinkovich, 1994; Mills, Jadad, Ross, & Wilson, 2005; Thomas, Kohli, & King, 2004)
- Distrust of the government or the mainstream medical community (Kulig et al., 2002; Mills, Jadad, et al., 2005)
- Religious beliefs that oppose immunizations (Kulig et al., 2002; Salmon et al., 2005)
- Ethical conflict, such as objection to animal testing in vaccine development or use of fetal cell lines in vaccine development (Salmon et al., 2005)
- Belief in alternative health practices (e.g., home birth, use of complementary/alternative medicine) (Kulig et al., 2002; Lawrence et al., 2004; Salmon et al., 2005)
- Belief that a child with a mild illness should not be immunized (Mills, Jadad, et al., 2005; Thomas et al., 2004)

In addition to these knowledge, attitudes, and beliefs, other personal factors thought to influence immunization uptake include:

- Competing demands at home (multiple children, a household member with a health issue requiring extra time and attention, mother's return to work) and/or insufficient social support to facilitate access to immunization services (Bond, et al., 1998; Lannon et al., 1995; Mills, Jadad, et al., 2005)
- Concern about immunization pain (Kennedy, Basket, & Sheedy, 2011; Taddio et al., 2012)
- Concern that the child is receiving too many needles in one visit (Bardenheier et al., 2004; Madlon-Kay & Harper, 1994; Mills, Jadad, et al., 2005; Thomas et al., 2004)

The latter two factors could equally be considered systemic factors, as they are personal experiences/beliefs that result from issues with the immunization delivery system (i.e. poor pain management and number of needles).

Unfortunately, evidence is inconsistent about the influence of these factors, with some studies reporting an effect (Lawrence et al., 2004; Salsberry, Nickel, & Mitch, 1993), while others suggesting that these factors do not differ between completely and incompletely immunized children (Bates, Fitzgerald, Dittus, & Wolinsky, 1994; Miller et al., 1994; Strobino, Keane, Holt, Hughart, & Guyer, 1996; Taylor & Cufley, 1996)

Sociodemographic factors. Sociodemographic characteristics may also influence or mediate behaviours regarding childhood immunizations. Although valuable, findings on sociodemographic associations with immunization status cannot explain underlying causes of the phenomenon. For instance, sociodemographic characteristics may actually influence children's immunization through parental beliefs or through access to services (Cushon et al., 2012; Santoli, Szilagyi, Rodewald, 1998); thus we need to understand the process by which these characteristics influence immunization practices. Regardless, these characteristics are non-modifiable covariates that should be assessed and controlled for in data analysis.

Sociodemographic characteristics such as younger or older maternal age, low education, low income, single marital status, and non-Caucasian race have often been shown to influence uptake of immunization (Avis, et al., 2007; Bobo, Gale, Thapa, & Wassilak, 1993; Boulianne et al., 2003; Cutts, Orenstein, & Bernier, 1992; Dombkowski, Lantz, & Freed, 2004; Gust, Darling, Kennedy, & Schwartz, 2008; Humiston et al., 1993; Li & Taylor, 1993; Luman et al., 2005; Miller et al., 1994; Prislin, Dyer, Blakely, & Johnson, 1998; Salsberry, Nickel, & Mitch, 1994; Zhang et al. 2008), but other studies have found no such association between these factors and vaccine uptake (Bigham, et al., 2006; Dummer, Cui, Strang, & Parker, 2012; Gust et al., 2004; Lieu et al., 1994). Large family size has consistently been found to be associated with uptake (Bardenheier et al., 2004; Boulianne et al., 2003; Dombrowski, Lantz, & Freed, 2004; Gust et al, 2004; Gust et al., 2008; Luman et al., 2005; Miller, Hoffman, Baron, Marine, & Melinkovich, 1994; Samad et al., 2006; Zhang et al., 2008). Canadian studies have also found that First Nations people living on reserves have lower rates of immunization coverage (Roberts, Poffenroth, Roos, Bebchuk, & Carter, 1994), and that immigrant status may be associated with higher rates of coverage (Guttmann et al., 2008). One often cited case-control study from the U.S. (Miller et al., 1994) found that in bivariate analysis, significant barriers to immunization by two years of age included maternal education of high school or less, more than two moves since the child's birth, maternal age <21 years, and ≥2 older siblings. After controlling for income, number of moves, maternal education, lack of insurance coverage, and maternal non-white race, only maternal age <21 years and ≥2 older siblings remained significant. Another seminal U.S. study utilizing multivariate analysis found that when race, gender, ethnicity, and geographic location were controlled, a one-parent household, large family size, and lower parental education were significantly related to increased odds of under-immunization (Dombkowski et al., 2004). However, it is noteworthy that neither of these studies included variables related to knowledge, attitudes, and beliefs and systemic factors in their analyses.

Systemic factors. Systemic barriers have been found to limit use of preventive health services in general, so it is conceivable that they play a role in use of immunization services. Systemic factors typically refer to characteristics of the social, physical, or economic environment that impact people's lives. These 'distal' factors often influence individuals' health choices by limiting access to services (Butterfield, 2002; MacDonald, Newburn-Cook, Allen, & Reutter, 2013). The evidence regarding systemic factors mainly comes from qualitative and descriptive studies; analytic exploration of these factors has been limited. Some factors suggested to negatively influence immunization uptake include: inner city or rural residence (Briss et al., 2000; Li & Taylor, 1993; Roberts et al., 1994); lack of access to reliable transportation (Lannon et al., 1995; Morrow et al., 1998); and employment conflicts or child-care availability (Lannon et al., 1995; Salsberry et al., 1993). Low income, or living in a low-income neighbourhood (which is also a sociodemographic characteristic), has consistently been shown to detrimentally influence receipt of immunization in both U.S. (Briss et al., 2000; Cutts et al., 1992; Roberts et al., 1994), and Canadian studies (Guttmann et al., 2006).

A number of provider issues have been suggested to act as systemic barriers/facilitators. Choice of vaccine provider or primary health care provider (e.g., family physician, paediatrician, naturopath) has been associated with immunization status (Alonso, Gonzalez, & Carbonell, 2001; Li & Taylor, 1993). It has also been suggested that a vaccine provider may fail to administer a vaccine dose to an eligible child due to lack of awareness that the vaccine is due; lack of knowledge regarding appropriate contraindications for immunization, such as withholding the vaccine when the child has a minor illness; or objection to providing multiple vaccines in one visit (Avis et al., 2007; Halperin, Eastwood, & Haperin, 1998; Lannon et al., 1995; Madlon-Kay & Harper, 1994). Such ‘missed opportunities’ have been associated with incomplete immunizations (Centers for Disease Control and Prevention [CDC], 1994). There are, however, mixed findings regarding the role of provider recommendation. Some studies have found that provider recommendation of vaccines did not correlate with high regional coverage rates (Szilagyi et al., 1994; Zimmerman, Schlesselman, Mieczkowski, Medsger, & Raymund, 1998); whereas others have found that provider recommendation was associated with positive attitudes of parents toward immunizations, although not with actual immunization behaviours (Freeman & Freed, 1999; Taylor & Newman, 2000). In one Canadian study (McWha et al., 2004), the failure of providers to present information regarding vaccine benefits was noted as a barrier to immunization.

Lack of an immunization registry or reminder system has also been shown to be associated with incomplete immunizations (Santoli, Szilagyi, & Rodewald, 1998). A particular problem is 'record scattering', which occurs when children receive their immunizations from multiple providers whose record-keeping systems are not linked. This phenomenon has been shown to contribute to incomplete immunization, as well as 'over-immunization' (receiving more than the recommended number of doses of a vaccine) (Santoli et al., 1998).

Issues related to clinic access and/or operations have been suggested to influence completion of immunizations (Gore et al., 1999; Orenstein, Atkinson, Mason, & Bernier, 1990; Roberts et al., 1994), although there has been little empiric investigation of these issues (Santoli et al., 1998). Possible factors include (a) long waiting times in the clinic, (b) insufficient or inconvenient clinic hours, (c) insufficient clinic staff, (d) visits by appointment only, (e) waits of several weeks for appointments, (f) lack of flexibility in scheduling appointments, and (g) inaccessible clinic locations (Gore et al., 1999; Lannon et al., 1995; Orenstein et al., 1990). One survey of American parents found that the most commonly reported clinic-related barriers to completion of immunizations were no appointment being available, the clinic not being open at a time they could go, dislike of clinic staff, and long waiting times in the clinic (Thomas et al., 2004). This study did not, however, correlate these factors with children's immunization status. One study (Prislin et al., 1998) did find that difficulty getting to the clinic (transportation and weather issues) and inconvenient clinic hours were correlated with incomplete immunizations.

There is mixed evidence regarding whether the cost of vaccines limits immunization coverage. Some American studies show that uninsured children exhibit lower coverage (Dombkowski et al., 2004; Gore et al., 1999; Zimmerman & Janosky, 1993), whereas others show that low immunization coverage also exists among individuals with HMO or military insurance coverage for the cost of vaccines (Lieu et al., 1994; Weese & Krauss, 1995). Surprisingly, even in Canada, where there is no direct cost to the public for most recommended childhood vaccines, one survey found that parents cited cost of the vaccine as a reason why they did not immunize their child (Ipsos-Reid, 2004). In settings where cost is in fact an issue, this barrier is likely to increase as more vaccines are added to the childhood immunization schedule.

Relevant research in Canada. There has been limited investigation of the factors influencing immunization coverage in Canada. The 2002 National Immunization Coverage Survey (NICS) (McWha et al., 2004) is the most recent NICS to report data about parental knowledge, attitudes, and beliefs, but it did not correlate these factors to children's immunization status. The same is true of a 2011 survey conducted for the Public Health Agency of Canada (EKOS Research Associates Inc., 2011). The survey asked parents about the factors influencing uptake, but only assessed parents whose children had not received all of the recommended vaccines, i.e. no comparison group.

Other Canadian studies have assessed the influence of a variety of factors, but few simultaneously assessed personal, sociodemographic, and systemic factors that might be influencing immunization coverage. Relevant studies in Canada include:

- A study in Manitoba (Roberts et al., 1994) that determined that the lowest rates of immunization completion were amongst residents of inner-city neighbourhoods and Aboriginals living on reserves.
- A study in Ontario (Guttmann et al., 2006) that found that providers with a high volume of children in their practice had higher rates of immunization.
- An Ontario study (Guttmann et al., 2008) that reported that children of immigrant mothers had slightly higher rates of immunization coverage than the general population.
- A study of premature infants in Ontario (Wilson et al., 2012) that determined that extremely and very premature infants who were hospitalized during the first 6 months of life had lower immunization rates.
- A study in Saskatchewan (Avis, Tan, Anderson, Tan, & Muhajarine, 2007) that assessed a number of sociodemographic variables and found that single mothers and people with less access to a personal vehicle had lower rates of immunization.
- A study in British Columbia (BC) (Bigham et al., 2006) that assessed parents' health beliefs about the Hepatitis B vaccine and found that concern about

vaccine safety was a significant predictor of uptake in bivariate analysis. In a multivariate model only health care provider and family recommendation were significant.

- A Québec study (de Courval, De Serres, & Duval, 2003) of the influence of provider recommendation on uptake of the varicella vaccine (before it was publicly funded) that reported that uptake was increased when providers strongly recommended the vaccine and when they provided parents with information on vaccine safety.
- A study from Nova Scotia (Dummer, Yunsong, Strang, & Parker, 2012), which found that parents with *low* income and education were more likely to complete immunizations.
- A qualitative study in southern Alberta (Kulig et al., 2002) that found that reasons for parents' refusal of vaccines included religious beliefs (in Dutch Reform and Hutterite communities) and concern about vaccine safety (in Hutterite communities and among users of alternative health care).

The only study conducted in Canada that assessed a wide range of potentially influential factors was a cross-sectional study of parents of two-year-old children in the province of Québec (Boulianne et al., 2003). It used a postal survey to assess parents' knowledge, attitudes, and beliefs, socio-demographic characteristics, and selected systemic factors. The authors report that the strongest predictor of incomplete immunization was failure to administer the two vaccines scheduled for 18 months on the same day (explaining 46% of the incompletely immunized children). They also concluded that the following factors were associated with incomplete immunization status: delaying initiation of immunization until >3 months; single parenthood; maternal employment outside the home; and ≥2 children in the home. Unfortunately, the lack of a centralized immunization registry and use of multiple providers (a mixture of physicians and public health nurses) in this setting meant that information contained in the registry was often incorrect. In fact, 53% of the children initially classified as ‘incomplete’ in the registry were reclassified as ‘complete’ based on parental report, leaving the potential for misclassification of immunization status to influence study findings.

Parental Concern about Vaccine Safety

Parental concern about vaccine safety appears to be on the rise (Benin, Wisler-Scher, Colson, Shapiro, & Holmboe, 2006; Gust et al., 2008). Thus, it is important to consider its influence on immunization coverage levels. The concerns of parents include fear that vaccines will overwhelm or weaken children’s immune systems; fear that vaccines will cause the diseases they are meant to prevent; or concern that vaccines will result in other serious illnesses, such as autism or asthma (Kulig et al., 2002; Mills, Jadad, et al., 2005; Salmon et al., 2005). One particular concern that has gained prominence of late is that the measles, mumps, and rubella (MMR) vaccine will lead to the development of autism (Wakefield et al., 1998). Although this assertion has been discredited by multiple well-designed and executed studies, it has had a profound impact on parents’ decision to immunize their children (MacIntyre & Leask, 2003; Madsen et al., 2002; Offit & Coffin, 2003; Peltola et al., 1998; B. Taylor et al., 1999).

Despite its potentially important role, the evidence to support an association between parental concern about vaccine safety and incomplete immunization is inconclusive, often due to limitations in study design.

In order to draw causal associations between the exposure (concern about vaccine safety) and the outcome (immunization uptake), it is essential to have data on both levels of exposure (i.e. concerned and not concerned) and both levels of outcome (i.e. immunized and not immunized). An ideal study design would be a prospective cohort study that assessed parents' level of concern and then followed the parents over time to determine if they immunized their children. In the absence of such lengthy and expensive studies, a case-control study design is a feasible alternative, as it retrospectively assesses the level of parental concern amongst immunizers (controls) and non-immunizers (cases). Another element of a strong study design is the ability to control for other variables that might be the true explanation for an observed association between the exposure and outcome. For example, parents with a low level of education may be disproportionately concerned about vaccine safety because they lack knowledge about the benefits and risks of vaccines. Thus, an observed association between vaccine safety concern and vaccine uptake might actually be due to the parents' level of education. If a study only assesses the one-on-one relationship between each exposure and immunization status (using bivariate analysis), without including other possible exposures/explanations in the model (using multivariate analysis), the results will be potentially invalid and misleading. It is also important to note that variables that are not significant in bivariate analysis may in fact become significant in multivariate analysis, due to the effect of the other variables in the model. Important and interesting results can emerge from determining which variables become significant or non-significant when other variables are entered into a model. Such information is useful in determining possible direct and indirect causes and which variables act as mediators of effect.

Studies that have suggested an association. The relationship between parental concern about vaccine safety and incomplete immunization has been suggested in a number of studies which did not or could not test the association. Qualitative investigation of the issue has suggested that parental concern about vaccine safety may be responsible for incomplete immunizations (Bond, et al., 1998; Kulig et al., 2002; Lannon et al., 1995). A systematic review of 15 qualitative studies regarding parental beliefs and attitudes about vaccines found that concern of potential harm was the barrier most commonly identified by parents; it was, in fact, the only barrier that was identified in every interview or focus group included in the review (Mills, Jadad, et al., 2005). However, one-on-one (Mills, Jadad, et al., 2005) and focus group (Raithatha, Holland, Gerrard, & Harvey, 2003) interviews with parents of young children have found that "even parents who immunize their children appear to have grave concerns regarding vaccine safety" (Raithatha et al., 2003, p. 163). In most cases, children begin the immunization series; the major problem is failure to complete it (Cutts et al., 1992). Vaccine safety concern does not seem a likely explanation for this behaviour (Tickner, Leman, & Woodcock, 2006). While it is possible that parents have had time to consider the implications of immunizing, or conferred with family and friends (Tickner et al., 2006), it seems as likely that other barriers have arisen that have impeded them from returning for recommended booster doses (Bond et al., 1998).

A number of quantitative studies provide descriptive data suggesting, but not testing, the association between vaccine safety concern and low immunization uptake. A British study found that the main reason parents reported for not completing their child's 18-month immunizations was concern about vaccine safety and side effects, with 34% of parents stating that some vaccines are riskier than the disease they are meant to prevent (Smailbegovic, Laing, & Bedford, 2003). Two studies in which vaccine providers in the U.S. were surveyed reported that fear of vaccine side effects was the main reason that parents refused immunization (Fredrickson et al., 2004; Freed, Clark, Hibbs, & Santoli, 2004). An Australian study also found that concern about vaccine safety was the main barrier cited by parents who did not complete their children's immunizations (Lawrence et al., 2004). However, none of these studies assessed the beliefs of parents who *did* complete immunizations, i.e. there was no comparison group to validly test the association.

There are limited data from Canada regarding the proportion of parents concerned about vaccine safety or the difference in concern between immunized and incompletely/unimmunized immunized groups. The 2002 NICS indicated that, of children who had received *no immunizations*, vaccine safety was the most commonly cited reason for refusal (48.0% ±19.6%). However, there was no indication of how prevalent this concern was among the rest of the sample, or whether this concern influenced the decision of parents of *incompletely* immunized children. A more recent Canadian study (EKOS, 2011) found that among 167 parents who reported that their child had not received all of the recommended vaccines, 17% stated that concern about vaccine safety influenced their decision. This study relied on parent report of immunization status, and neither of these studies assessed the beliefs of parents who *did* complete immunizations, to see if they differed.

There have been a number of postal and telephone surveys in the U.S. assessing both parents who did and did not complete their children's immunizations. These studies found that misperceptions that undermined belief in the safety of vaccines were widespread among parents of young children, including those who immunize (Gellin, Maibach, & Marcuse, 2000; Gust et al., 2005; Shui, Weintraub, & Gust, 2006). However, none of these studies actually tested the association between these beliefs and the immunization status of the child.

Studies that have tested the association. Studies using bivariate analyses of the association between vaccine safety concern and incomplete immunization status are inconclusive. One U.S. survey (Taylor et al., 2002) of parents of children 8-35 months old who visited pediatricians' offices (n=13,520) found that the most commonly cited barrier to immunizing their child was concern about vaccine safety. However, there was no significant difference between parents of completely and incompletely immunized children (22.4% and 23.7%, respectively). Although this study proceeded to multivariate logistic regression of variables, concern about vaccine safety was not included in the model, as it had not been found to be significant in bivariate analysis. Another study conducted in the U.S. found concern about vaccine side effects as the most frequently cited barrier of parents, but the level of concern was not statistically significantly different between parents of immunized and incompletely immunized children (Taylor & Newman, 2000). The previously mentioned Québec study (Boulianne et al., 2003) compared the proportion of completely and incompletely immunized children whose parents had concerns about vaccine safety. Although concern about vaccine safety was found to be twice as prevalent in parents of incompletely immunized children (13.9%) as compared to completely immunized children (7.0%), this association was not significant in bivariate analysis and thus was not included in their multivariate model.

A limited number of studies have conducted multivariate analysis of the association between parental concern about vaccine safety and children's immunization status. All of these were case-control studies conducted in the U.S. Three of these (Allred et al., 2005; Bardenheier et al., 2004; Gust et al., 2004) used data from the U.S. National Immunization Survey (NIS), a telephone-administered structured questionnaire of a nationally representative sample of parents of children 19-35 months of age (for further detail on the NIS see Smith et al., 2001). The one other study (Salmon et al., 2005) conducted a postal survey of parents of school-aged children (grades K-5) selected from schools in 5 U.S. states. The control group for each study was 'completely immunized children', but the case group varied, including missing ≥1 or ≥2 dose(s), or having filed a state-allowed exemption from immunizations. All of the studies found a relationship between parental concern about vaccine safety and incomplete immunization status. Each study controlled for different covariates (including socio-demographic characteristics and parental knowledge, attitudes, and beliefs), but none controlled for systemic factors which may have influenced parents' immunization behaviours (aside from Gust and colleagues (2004) who controlled for number and type of immunization providers).

Despite the inclusion of numerous variables in these four multivariate studies, the failure to control for systemic factors is a shortcoming recognized by many of the study authors (Allred et al., 2005; Bardenheier et al., 2004; Gust et al., 2004). Specifically, provider practices, interpersonal factors (doctor-patient relationship), community factors (social norms), and public policy factors (immunization laws) were not taken into account and may significantly impact vaccine coverage. Additionally, study authors noted that, while concern about vaccine safety was significantly associated with incomplete immunization status, it was also quite prevalent in the immunized group (Gust et al., 2004; Salmon et al., 2005), with no obvious explanation as to why these parents still proceeded to immunize their children. As stated by one of the study authors, "research designed to determine the reasons parents have their children vaccinated despite safety concerns would be beneficial" (Bardenheier et al., 2004, p. 574).

Summary of Limitations of Previous Research

In addition to the limitations specific to the multivariate studies about vaccine safety described above, there are a number of issues that relate to the entire body of literature about factors influencing immunization completion. These issues include failure to simultaneously assess the broad range of personal and systemic variables and study populations/settings that limit relevance to the Canadian pre-school population.

The causes of low immunization coverage are likely multi-factorial, and thus require assessment of the broad range of variables potentially influencing parents' behaviour. The failure to collect data and conduct multivariate analyses which incorporate knowledge, attitudes, and beliefs, socio-demographic variables, other personal factors, and systemic factors is a shortcoming in the current literature (Cutts et al., 1992) . As one study's authors (Sturm et al., 2005) have stated in their recent review of the evidence:

> It would be helpful for future research to adopt a more integrative approach by examining multiple aspects of the model and how they may interrelate....Integrative multi-factorial research may provide insights into how providers can effectively engage parents in decision-making and clarify ways in which providers serve as links between public health policy recommendations and actual parental decisions (p. 448).

Clearly, future studies of barriers and facilitators to immunization should include both individual and broader system variables in the same model.

Another limitation of past research is that the vast majority of knowledge we have regarding the influences on children's immunization status is derived from research conducted outside of Canada, mainly in the U.S. and Australia. Unfortunately, the findings of these studies cannot be directly generalized to

Canada due to the vastly different health care and immunization delivery systems that may have unrecognized influences on study results. For instance, in the U.S. (where all four of the multivariate studies of vaccine safety were conducted), school entry laws mandate compulsory immunization in all 50 states, with varying options for exemption (based on medical, religious, or philosophical grounds) depending on state (Walkinshaw, 2011). Despite these exemptions, such legislation does promote completion of immunization coverage in school-aged children, as well as pre-schoolers (Gust et al., 2004; Omer, Salmon, Orenstein, DeHart, & Halsey, 2009). These laws demonstrate to parents the value of immunizations and the need to take action, and they place an administrative burden on parents seeking exemptions (Orenstein & Hinman, 1999; Stadlin, Bednarczyk, & Omer, 2012; Walkinshaw, 2011). In Canada, only Ontario, New Brunswick, and Manitoba have legislated comparable policies of mandatory immunization on school entry (Walkinshaw, 2011). Australia has not taken the approach of mandating immunizations, but the federal government has instituted an incentive scheme in which parents are financially rewarded for completing their children’s immunizations (Bond, 1999; Walkinshaw, 2011). This scheme is operationalized by linking child care assistance and maternity allowance payments to a child’s immunization status. It seems evident that laws or incentives that promote immunizations will have an impact on parents’ views, as well as their behaviours, regarding immunizations. Thus, studies in these other countries cannot be directly applied to the Canadian context.

Conclusion

It is evident from the literature that a straightforward association between parental concern about vaccine safety and failure to complete children's immunizations has not been clearly demonstrated, and that any such relationship may be mediated by other personal and/or systemic variables. Incomplete immunization does not necessarily mean that a parent has made an active decision not to immunize. As has been stated (Tickner et al., 2006), "forgetting appointments, lack of time after the mother returns to work, illness in the family, and having other childcare commitments can militate against attending vaccination appointments on time, despite the best of intentions" (p. 7033).

It is essential to understand which factors are important in determining immunization uptake in Canada, and which are unimportant or indirectly associated. In particular, it is critical to determine the role of parental concern about vaccine safety, as public confidence in the safety of vaccines is essential in maintaining high rates of immunization coverage (Salmon et al., 2005). Knowing more about the factors associated with parents who have immunization safety concern and what influences their decisions to immunize is critical for the design of effective interventions (Shui et al., 2006). The lack of relevant and reliable data to support the role of this factor in influencing the immunization status of Canada's pre-school children makes this study both important and timely. Research to fulfill this need will also help address the goals set forth in Canada's National Immunization Strategy (FPT ACPHHS, 2004) and the Alberta Immunization Strategy (Alberta Health, 2007), which call for measures to improve immunization coverage rates by evidence-based strategies to overcome barriers to immunization uptake.

Study Purpose, Objectives, and Research Questions

The purpose of this study was to assess the relationship between parental concern about vaccine safety and incomplete immunization of Alberta pre-school children. The specific objectives were: (a) to identify if parental concern about vaccine safety is associated with incomplete immunization of Alberta pre-school children, and (b) to assess whether other personal and/or systemic factors explain incomplete immunizations.

The research questions were as follows:

1) Is there an independent association between parental concern about vaccine safety and incomplete immunization of Alberta pre-school children?
2) Are there associations between additional personal factors and incomplete immunization of Alberta pre-school children?
3) Are there associations between various systemic factors and incomplete immunization of Alberta pre-school children?
4) Does the association between parental concern about vaccine safety and incomplete immunization remain after controlling for relevant sociodemographic, personal, and systemic factors?

Conceptual Framework and Theory Guiding the Study

In order to facilitate assessment of both personal and systemic factors, this study was guided by the population health framework. The population health framework asserts that health is determined by a wide array of individual and population-level ‘determinants of health’, including social, economic and physical environments, personal health practices, individual capacity and coping skills, human biology, early childhood development, and health services (Federal/Provincial/Territorial Advisory Committee on Population Health [FPTACPH], 1999; PHAC, 2002). The population health framework promotes an understanding and integration of the ‘distal’ systemic determinants of health (e.g. physical and social environments, health programs and policies, access to health services, income, housing) with more ‘proximal’ personal factors (nutrition, biology and gender, personal health practices, and coping skills) that determine health (Keller, Strohschein, Lia-Hoagberg, & Schaffer, 2004; Mechanic, 2007). The ultimate goal of research guided by the population health framework is to establish causal or associative relationships between broader upstream health determinants and the short- and long-term impacts they have on health outcomes (Kindig, 2007). The population health framework is also congruent with the values of the nursing profession and nursing research, as this broad perspective of the determinants of health fits well with the holistic view of humans espoused by nursing (Chinn & Kramer, 2011). A more detailed discussion of the population health framework and its relevance for nursing research is presented in Chapter 2 of this thesis.

Most previous studies of the factors influencing childhood immunization uptake do not have an explicitly stated conceptual framework or have frameworks that do not recognize the need to assess systemic variables along with personal factors. Most of these studies have used social-cognition models, such as the

Health Belief Model, to understand immunization behaviours (Bigham et al., 2006; Bond et al., 1998; Pielak & Hilton, 2003; Smailbegovic et al., 2003). These approaches do not adequately acknowledge population-level influences on parents' behavior (such as immunization policies and access to health/immunization services), instead focusing on individuals' perceptions, knowledge, attitudes, and beliefs. In contrast, the population health framework provides a sufficiently broad conceptual framework for investigating both personal (proximal) and systemic (distal) factors influencing immunization uptake.

Within the population health framework, Milio's Ecological Theory of Prevention (Milio, 1976) was the specific theory chosen to examine *how* the variables in the framework were related. Milio suggests that it is the *range of choices available* to people that is paramount in shaping their health behaviour. The availability of choice is in turn influenced both by an individual's personal resources (such as knowledge, beliefs, finances, time, and other competing priorities) and their societal resources (such as availability of health services, child care, and safe shelter) (Butterfield, 1990; Milio, 1976). As Milio states, "most human-beings…make the easiest choices available to them most of the time, and not necessarily because of what they know is most healthful" (p. 435). The key message is that dynamic and interactive pathways between population-level factors and one's psychological resources and coping strategies constrain one's autonomy, such that an individual cannot simply choose to be healthy or to freely undertake behaviours to increase health, due to factors beyond their control

(Frank, 1995; Schwartz & Diez-Roux, 2001). By utilizing the population health framework and Milio's ecological theory of prevention to guide this study, I recognize that individuals' health choices are dependent on the options available to them within the limitations placed by population-level factors.

Study Methods

While Chapters 4 and 5 of this thesis include brief descriptions of the study methods, a more comprehensive description of the methodology is provided here.

Study Setting and Population

This study took place in the city of Edmonton, Alberta, Canada and surrounding rural communities. This area includes approximately 1.1 million people living in Edmonton, St. Albert, Spruce Grove, Leduc, and the counties of Strathcona, Leduc, Parkland, Yellowhead, and Sturgeon (Capital Health, 2008). The annual birth cohort in the region is approximately 16,000 children. Publicly-funded public health care in this region is provided by Alberta Health Services (AHS)-Edmonton Zone.

The target population for the study was parents or primary caregivers of children between the ages of 24 and 35 months (i.e. two years old) who resided in the region. It is typical to assess immunization coverage at two years of age, as the infant immunization series is scheduled for completion at 18 months and, given a grace period of 6 months, should be complete by the age of two. After this point, many children do not have contact with the public health system until school entry, leaving incompletely immunized children at risk for more than three years, during which they are at high risk from many communicable diseases.

All routine childhood immunizations in the Edmonton region are provided free of charge exclusively by public health nurses in community-based clinics. Documentation of each vaccine dose administered is recorded on the child's hard-copy clinic record, the parent-held record (i.e. the immunization card parents are asked to bring to each immunization appointment), when available, and entered into a computerized immunization registry onsite by designated clerical staff. The accuracy and completeness of data entry is validated on a regular basis through auditing of randomly selected records, with an accepted error rate of <3% (personal communication, Anita Hanrahan, Director of Communicable Disease Control for AHS, September 25, 2008). The registry is a central administrative immunization computer database, known as 'Caseworks' (Zhang et al., 2008), which includes records of all routine childhood immunizations administered in the AHS-Edmonton region, as well as various sociodemographic characteristics of each child (see Appendix A). The database includes all children born in the region, as well as those who move to the region and make contact with the public health system. Children who move out of the region are inactivated in the database upon notification of the public health department. The database does not include Aboriginal children living on reserves, who receive their immunizations through Health Canada. Available immunization coverage rates for two year olds in the region for the year of the study (2009) range from 77-88%, depending on the specific vaccine (Alberta Health, 2013). Data are not available as to the proportion of children who have received *all recommended doses of all vaccines* by age two, a rate which is inevitably lower than for individual vaccines.

Study Design

This was a case-control study which compared the immunization views, experiences, and characteristics of parents of children whose immunizations were complete at two years of age (controls) to those who were not complete (cases). Determination of case and control status was based on the child's immunization status on the date of their 2nd birthday, as determined by the immunization database.

Sample selection. Potential participants were randomly selected from the registry using an algorithm to identify cases and controls, using a random number generation procedure. The algorithm accounted for variation in the number of doses required for children who were older at initiation of the series or due to individual clinical conditions. This process was conducted by an AHS epidemiologist who selected and anonymized the potential participants. Use of the immunization database for sample selection enabled cases and controls to be selected from a common administrative cohort of children, which ensured comparability of cases and controls and eliminated the problems that ensue when controls are selected from a different and potentially non-comparable source than cases. Inclusion criteria for this study were:

- Currently residing within the Edmonton health region
- Parent or primary care-giver for a child between the ages of 24 and 35 months, who is included in regional immunization database

- Having no other child in the household already included in the study sample

Case and control definitions. The recommended and publicly-funded immunizations for two year old children in Alberta at the time of the study (2009) included the following vaccines, commonly referred to as the ‘infant series’ (see Appendix B for order and age of administration):

- 4 doses of DTaP-IPV-Hib (diphtheria, acellular pertussis, tetanus, polio, haemophilus influenza type B)
- 1 dose of MMR (measles, mumps, rubella)
- 4 doses of pneumococcal conjugate
- 3 doses of meningococcal conjugate
- 1 dose of varicella (or history of disease)

Controls were defined as children in the database between the ages of 24 and 35 months who were *completely immunized* (i.e. had received all of the above vaccines) by their 2nd birthday. *Cases* were defined as children in the database between the ages of 24 and 35 months who were *incompletely immunized* by their 2nd birthday. This included children who had received some, but not all, vaccines (i.e. partially immunized) and those that had received no vaccines (i.e. unimmunized). Children whose immunizations were delayed at their 2nd birthday (i.e. were incompletely immunized at 24 months, but then completed their vaccine schedule at a later date) were categorized as incomplete.

Sample size. The sample size calculation for this case-control study was based on the findings of a previous cross-sectional Canadian study, conducted in Québec (Boulianne et al., 2003). Boulianne’s study analysed a sample of 430 completely immunized and 266 incompletely immunized children. They found that 13.9% of parents of incompletely immunized children had concerns about vaccine safety, as compared to 7.0% of parents of completely immunized children. Utilizing OpenEpi statistical software (Dean, 2009), the sample size for the present study was calculated from a power analysis using a 95% Confidence Interval, 80% Power (ß = 0.20), a 1:1 ratio of cases to controls, and a proportion of “exposure in ill” (vaccine safety concern in incompletely immunized) of 13.9% and “exposure in the not ill” (vaccine safety concern in completely immunized) of 7.0%. With an anticipated survey response rate of 50% (the Québec study found that surveys were returned from 53% of parents of incompletely immunized children and 58% of parents of completely immunized children) the calculated sample size was 671 cases and 671 controls. This was feasible to obtain with an annual birth cohort of 16,000 children, of which at least 12% would be incompletely immunized (based on earlier presented Alberta Health coverage data); there would be approximately 1,920 potential cases and 14,080 potential controls in the registry.

Data Collection

After extraction of immunization and sociodemographic data from the immunization registry, primary data collection proceeded through a postal survey administered to parents of the children chosen in the sample. The administration of the postal survey involved numerous steps according to Dillman’s ‘Tailored Design’ for postal survey administration (Dillman, 2007), in order to promote a high response rate and minimize the potential for non-response bias. In the spring of 2009, each of the cases and controls were mailed an advance notification letter (see Appendix C), which informed them about the study and provided them the opportunity to opt out of participating in the survey. This letter and all materials that followed were mailed by clerical staff at AHS, acting as an intermediary. This letter was followed by a packet containing an information letter (see Appendix D) and questionnaire (see Appendix E) one week later. The information letter described the purpose of the study, how the potential participants were selected, the time anticipated for participation, indication that completion of the survey implied consent to participate, and a statement that participants' responses to the questionnaire or decision to not participate would not influence their health care services in any way. Potential participants were provided with a phone number and e-mail address to contact if they had any questions or concerns regarding the study. Participants were asked to return the questionnaire in the postage-paid envelope provided. Participants who did not return the questionnaire or opt out within 3 weeks of the initial mailing were sent a reminder postcard (see Appendix F). This was followed by a replacement survey 3 weeks later and a final reminder letter another 3 weeks later (see Appendix G). Each potential participant was assigned a unique numeric identifier, which was entered on all mailed materials, enabling us to track response to the survey and allowing parents to opt out of the survey if they so wished, without having to share their identity.

Questionnaire Design

As this study assessed a broader range of personal and systemic variables than previous studies, there was no pre-existing validated questionnaire to adopt for use. Therefore, I developed and tailored a questionnaire based on a review of existing instruments, consultation with parents and relevant experts, validation, and pilot testing.

The design and testing of the questionnaire involved the following steps:

1. Extensive review of qualitative and quantitative research was undertaken to identify factors with potential influence on immunization uptake.
2. These factors were conceptualized according to the population health framework to ensure that the broad spectrum of multi-level influences on immunization uptake was considered.
3. Authors of all previously published studies utilizing potentially relevant questionnaires were contacted (n=37).
4. A total of 16 questionnaires were obtained and reviewed for relevance and validity.
5. Individual questionnaire items to address the variables identified in the literature review were borrowed or modified from the most validated tools available, with the permission of the authors (Bardenheier et al., 2004; Boulianne et al., 2003; CDC, 2000; Fredrickson et al., 2004; Gellin et al., 2000; Lieu et al., 1994; Salmon et al., 2005; Shui et al., 2006; Strobino et al., 1996; Thomas et al., 2004; Trauth, Zimmerman, Musa, Mainzer, & Nutini, 2002).
6. Parents (n=2) and practitioners and researchers in public health and pediatrics (n=4) were consulted to ensure the relevance of the identified questions for this population and setting, and to identify any themes not yet included.

7. The questionnaire was developed and formatted according to the guidelines set out by Dillman's Tailored Design Method (Dillman, 2007), which has been shown to maximize participant response rate. Examples of some of the strategies used include ensuring pages are clear and uncluttered, using appropriate level of language, and asking the most relevant questions first. The length of the questionnaire was kept to the minimum possible, while still including the relevant content.
8. The validation process involved review of the instrument for content and face validity by parents (n=5) and experts in the fields of epidemiology (n=2), family medicine (n=2), pediatrics (n=1), public health nursing (n=3), survey methodology (n=1), and immunization programming (n=4).
9. The revised questionnaire underwent a cognitive interviewing[1] process with two parents of preschool children to ensure ease of use and face validity.
10. The questionnaire was pilot tested with six parents, including both those that did and did not immunize their children.
11. Final revisions were completed.

The final questionnaire (see Appendix E) consisted of 49 questions (some with sub-questions), took approximately 15 to 20 minutes to complete, and was at a grade 6 reading level (Flesch-Kincaid Grade Level Score 6.1; Kincaid, Fishburne, Rogers, & Chissom, 1975). Response formats included Yes/No, 5-

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[1] Cognitive interviewing is a process used to identify problematic questions that may elicit response error to survey questions. While in the presence of the researcher (or their designate), subjects are asked to read each question on the survey and describe out loud how they perceive and interpret questions. This enables the researcher to understand how each question in the survey is perceived from the respondents' perspective rather than that of the researchers (Drennan, 2003).

point Likert-type scale (Likert, 1932), and some narrative responses. The survey asked parents questions about their views and experiences with immunizations, including knowledge, attitudes, and beliefs about immunizations and vaccine-preventable disease; other personal factors (e.g., daycare use and residential moves); and systemic factors (e.g., parents' experiences with the immunization delivery system and access to services). The questionnaire also asked about a number of sociodemographic characteristics. Parents were asked to report their child's immunization status according to parent-held records or recall (complete, incomplete, or unimmunized); parents were not required to consult the parent-held record due to concerns that excessive participant burden might adversely impact the response rate. To ensure that no misclassification of cases and controls occurred due to errors in the registry, discrepancies in immunization status between the registry and parent report were adjudicated by review of the original clinic record by AHS personnel; clinic records are typically considered the 'Gold standard' for assessing immunization status (Stecher, Adelman, Brinkman, & Bulloch, 2008).

Data Entry and Analysis

Data entry was conducted by myself using the REDCap (Research Electronic Data Capture) data management system (Harris et al., 2009) to facilitate validated data entry, cleaning, and management. I also conducted double data entry of 10% of surveys (n=47) to assess data entry accuracy using the REDCap data comparison tool. The measured error rate was 0.13% (6 errors out of 4,371 data points). This rate was sufficiently low that a complete double entry was not pursued. Data analysis was conducted using SPSS version 20.0 (IBM Corp., 2011). Logistic regression was conducted to determine the association between the various exposure variables and the outcome variable (child's immunization status). Both bivariate analysis and multivariate regression analysis were conducted, with the outcome of interest being parents of children who were *not complete* (cases), as compared to those who were complete (controls). More details of the data analysis, including coding of variables and the model building process, are described in Chapter 5.

Ethics

Ethical approval for this research study was obtained from the Health Research Ethics Board (Panel B) at the University of Alberta, which also administered the ethics review for AHS-Edmonton (see Appendix H). This study complied with all ethical standards for research involving human subjects. Data collection for this study was not invasive in nature, consisting only of extraction of data from a database and administration of a questionnaire. The only inconvenience was the time required to complete the questionnaire. Parents were informed that consent to participate was implied by return of a completed survey and that they could withdraw from the study at any time. All survey mailings were sent by clerical staff at AHS-Edmonton, to ensure that the identity of study participants was not known by the research team.

Overview of the Manuscripts

The objectives and description for each of the four papers that comprise this thesis are presented below, along with the rationale for each paper and the linkage between the papers.

Paper #1: Embracing the Population Health Framework in Nursing Research

This paper has been published as:

MacDonald, S.E., Newburn-Cook, C., Allen, M., & Reutter, L. (2013). Embracing the population health framework in nursing research. Nursing Inquiry, 20(1), 30-41.

Objectives. (a) To propose the population health framework as a valuable, but underutilized, conceptual framework for guiding nursing research; (b) To describe the challenges and rewards of using the framework in nursing research; (c) To propose the steps that need to be taken for nurse researchers to fully embrace the framework.

Description. This paper starts by defining the concepts underlying the population health framework, outlining the evolution of the framework, and describing its relevance and current use in nursing research. The steps needed for nurse researchers to more effectively utilize the framework are discussed, including improved awareness of the processes that link the multi-level determinants and the use of multi-level theory and methods. Examples of nursing studies that have effectively utilized the framework are presented. Lastly, the possible political, societal, professional, and organizational challenges that act as barriers to broader use of the framework in nursing research are discussed.

Rationale for the paper and linkage with other papers. Research I conducted prior to this study led me to a growing awareness of the role that systemic factors can play in the uptake of health-promoting practices. Specifically, I began to appreciate that individuals' knowledge, attitudes, and beliefs were not always direct predictors of health practices when population-level factors (e.g., access to services, poverty) limited access, availability, or awareness of optimal health choices. When considering the factors influencing immunization uptake, both from the literature and from my own personal experiences with parents, it became evident that parents' behaviours were being influenced by more than their knowledge and beliefs. Thus, I chose to apply the broader population health framework in my doctoral study. This paper describes the framework I used to guide this research, as well as the way I, as a developing nurse researcher, foresee approaching my future program of research.

Paper #2: Addressing Non-response Bias in Postal Surveys

This paper has been published as:

MacDonald, S.E., Newburn-Cook, C., Schopflocher, D., & Richter, S. (2009). Addressing nonresponse bias in postal surveys. Public Health Nursing, 26(1), 95-105.

Objectives. (a) To describe the benefits of using postal surveys in public health nursing research; (b) To outline the various potential sources of survey error; (c) To describe the implications of low survey response rates; and (d) To describe strategies to minimize non-response bias.

Description. This paper starts by describing the value of postal surveys in nursing/public health research, as well as the potential challenges of this approach. It focuses on the potential for survey error, particularly survey non-response. The paper presents a number of recommendations for preventing and addressing non-response, both before and after data collection. These include recognizing the reasons for non-response, implementing strategies to reduce non-response through response-enhancement strategies, assessing for non-response bias after data collection, and conducting post-survey adjustment of data, as needed and when possible. A case study is presented to exemplify how these strategies can be applied.

Rationale for the paper and linkage with other papers. When considering the various approaches for data collection in my study, I determined that a postal survey was the most valid and feasible tool. However, in reviewing the literature on postal survey methodology, I discovered that there were a number of pitfalls to using this approach of which I had previously been unaware. I also discovered that there was a gap in the nursing literature regarding the use of postal surveys and the considerations for doing so. This paper was prepared to outline for myself, and for other nurse and public health researchers, the issues requiring attention in the preparation, administration, and analysis of postal surveys.

Paper #3: The Pot Calling the Kettle Black: Accuracy of Classifying Immunization Status by Registry Versus Parent Report

This paper is under review as:

MacDonald, S.E., Schopflocher, D.P., & Golonka, R. The pot calling the kettle black: Accuracy of classifying immunization status by registry versus parent report. Submitted to Vaccine.

Objectives. (a) To identify any misclassification of immunization status by the immunization registry used in my study; (b) To compare the frequency of misclassification by parent report in my study; (c) To determine the types of errors occurring in each source.

Description. This paper describes the strengths and limitations of various sources of immunization coverage data, and highlights the need to understand more about the accuracy of immunization registries, which are being used more commonly for administrative, clinical, and research purposes. Children's immunization status according to the registry used in my study was compared to their status as reported by parents in the postal survey. Discrepancies in immunization status between the registry and parent report were adjudicated by review of the clinic record. The amount of error and the reasons for the errors from each source were compared. Our study found that while more children were misclassified due to errors in parent reporting than due to registry errors, the error rate in the registry was not insignificant. The direction of the errors from the two sources were opposite, with most of the parent errors being misclassification of the child as being complete, whereas the registry tended to misclassify children as incomplete. These finding and the reasons for the errors identified in our study have important implications for program administration, clinical follow-up of individual children, and vaccine research.

Rationale for the paper and linkage with other papers: Misclassification of outcome status in a case-control study is a serious methodological flaw that can call into question the validity of study findings.

Despite assurances from registry administrators that data entry audits ensured the accuracy of the registry utilized in our study, we determined that it was essential to conduct independent assessment of data accuracy. Time limitations and expense precluded us from assessing/confirming immunization status for every study participant from the original clinic record (the Gold standard for assessing status). Thus, we decided to utilize parental report of children's immunization status as a confirmatory step. We asked each participant to report their child's immunization status, and when there was disagreement between the registry and parent report, we checked the original clinic record. Confirmation of immunization status improved the validity of our study findings by minimizing outcome ascertainment bias. This paper also adds to the existing published literature on the issue; while many studies have reported on the accuracy of parent report, few have assessed the accuracy of computerized registries, which are being used more commonly.

Paper #4: The Role of Parental Concern about Vaccine Safety in Determining Immunization Coverage: A Multivariate Model of Personal and Systemic Factors

A version of this paper will be submitted to the journal *Pediatrics*.

Objectives. (a) To present the bivariate and multivariate analysis of the relationship between children's immunization status and the numerous variables of interest; (b) To determine if parental concern about vaccine safety had a bivariate association with immunization status, and whether such a relationship changed when other variables were included in the model.

Description. This paper presents the results of the bivariate and multivariate analyses for the association between each variable and the outcome variable, i.e. the child being incompletely immunized. The variables included: (a) knowledge, attitudes, and beliefs about vaccines, including concern about vaccine safety; (b) other personal factors, such as social support and daycare use; (c) sociodemographic characteristics; and (d) systemic factors, such as the parents' experiences with the immunization delivery system. Our study found that concern about vaccine safety was indeed a significant factor in determining immunization status, even after other personal, sociodemographic, and systemic variables were included in the model. It also identified a number of important variables that play a role in influencing uptake, some of which have not been well described in the literature previously.

Rationale for the paper and linkage with other papers. This paper reports the findings from the main analysis of the thesis study. While there are other aspects of the study that can and will be explored further in future analysis of the data (as described in Chapter 6), we felt that it was most important to present the complete multivariate model in the thesis. This is also the study's most significant contribution to the literature, which to date, has lacked a comprehensive assessment of the personal and systemic factors influencing immunization uptake. It also provides a complete picture of the study process and enables identification of future avenues to be explored in my program of research.

Conclusion

These four papers all add new knowledge to the published literature, in addition to their contribution to my substantive, theoretical, and methodological education. Paper #1 presents the conceptual framework underlying the study, which was utilized throughout the study development, conduct, and analysis process. Paper #2 addresses a key methodological issue relevant to the study, namely the benefits and challenges of using postal surveys in public health research. Both of these papers provide context and background for the results papers that follow. Paper #3 is a critical assessment of a key aspect of my study validity, namely the accuracy of assessment of the study outcome (child's immunization status). Without knowledge of this issue, the results of any further analysis could be called into question. Paper #4 presents the culmination of the work presented in the earlier papers, namely the results of the regression analysis of factors influencing children's' immunization uptake. These four papers individually, and as a unit, make what I believe to be important contributions of new knowledge to the field of immunization research and provide a firm foundation for my future program of research.

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Chapter 2: Paper #1

Embracing the Population Health Framework in Nursing Research

Shannon E. MacDonald RN, PhD Candidate [a]
Christine V. Newburn-Cook RN, PhD
Marion Allen RN, PhD, Professor Emeritus [a]
Linda Reutter RN (Retired), PhD, Professor Emeritus [a]

[a] University of Alberta Faculty of Nursing

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Background

> The call to the nurse is not only for the bedside care of the sick, but to help in seeking out the deep-lying basic cause of illness and misery, that in the future there may be less sickness to nurse and to cure (Wald, 1915, p. 65).

This statement by Lillian Wald, one of the founders of public health nursing, challenges nurses to look beyond individuals and their immediate environment toward the more distal causes of health and illness. While many nurse researchers have taken up the challenge to adopt this broader view of health and its influences, there is more to be done to fully embrace this approach in nursing research.

In this paper we argue that ‘population health’ is a valuable conceptual framework for guiding nursing research, but that there are further steps to take and distinct challenges in adopting the framework. We first describe the concepts and evolution of the population health framework and its relevance to nursing research. We then discuss the next steps for nurse researchers to more effectively utilize the framework, including attention to the processes that link the multi-level determinants and applying appropriate multi-level theory and methods. We then identify various political, societal, professional, and organizational challenges to using the framework in nursing research. We contend that by taking the appropriate steps to more fully embrace this framework, nurse researchers will be better equipped to explore the broad range of determinants of health and to explain their influence on health.

The Population Health Framework

Although many nurses are familiar with the population health framework, it is useful to briefly review the concepts and evolution of the framework as a foundation to this discussion. The population health framework asserts that health is determined by a wide array of individual and population-level ‘determinants of health’ (listed in Table 2-1), ranging from personal and interpersonal factors to broader physical and social environments (Kindig & Stoddart, 2003; Public Health Agency of Canada [PHAC], 2002). Key to the population health framework is an understanding of the complex relationships between factors at different levels; population-level factors are foundational to the individual-level factors, and complex processes connect these levels and contribute to health outcomes.

The History and International Relevance of the Framework

The history and development of the population health framework are well described in government and academic literature, especially in the fields of health and social psychology (see Table 2-2). The population health framework has particularly strong roots in Canada and Britain, but is of relevance worldwide, as it enables integration of contextual factors, such as geographic and political variables that often vary by country or region. International adoption of the population health concepts occurred at the first International Conference on Health Promotion, culminating in the Ottawa Charter for Health Promotion (World Health Organization [WHO], 1986). The ongoing global relevance of this broader scope for health research has been reaffirmed by the WHO in recent years

(WHO, 2008). Population health is a universal, non-discipline-specific framework that can facilitate interdisciplinary research and promote the collaboration necessary to advance understanding of the complex pathways contributing to health outcomes of individuals and populations (Diez-Roux, 2007; Edwards, 2009; WHO, 2008).

How the Framework Relates to the ‘Social Determinants of Health’

Since the terms ‘social determinants of health’ (SDH) and ‘population health framework’ are sometimes used interchangeably, it is important to articulate the distinction. The SDH have been defined as ‘the social, economic, and political contexts in which people live and work and which contribute to the health of individuals and populations’ (WHO, 2008). They include social and political contexts, such as education, economic status, employment and working conditions, and social support; physical environment, such as water, sanitation, and housing; and early child development (Niederdeppe et al., 2008; WHO, 2011). The SDH do not include personal health behaviors (lifestyle choices such as diet and physical activity), individual capacity and coping skills, medical services (although some models do include this in SDH), genetics, or biology (Gollust et al., 2009; NCCPH, 2008; Niederdeppe et al., 2008; Raphael, 2011).

The population health framework can be seen as an overarching framework that includes both the broader social determinants, as well as the inter- and intra-personal determinants of health (NCCPH, 2008), as seen in Figure 2-1. This distinction between the population health framework and the SDH is in no way a criticism of the value of the SDH. It is merely clarification that, while the

SDH may be commonly recognized language, the term does not reflect the full range of multi-level health determinants (Canadian Nurses Association [CNA], 2009). The population health framework, therefore, is seen as a more inclusive approach that includes multi-level influences (from SDH right down to biology) and the interactions between them.

Relevance of the Framework for Nursing Research

If the promotion of human health is nursing’s central concern (Kikuchi, 2004; Schlotfeldt, 1987), and the role of the nurse is to facilitate, support, and assist individuals, families, and communities to enhance, maintain, and recover health (Thorne et al., 1998), then attention to the multi-level determinants of health is crucial. Nursing research that is focused only on the individual, rather than this broader perspective, is more likely to conclude that lack of knowledge or motivation on the part of the individual is the reason why people do not adopt healthy behaviours (Butterfield, 1990; Morgan & Marsh, 1998). This ‘lifestyle-oriented’ approach to health and health research can result in ‘blaming the victim’, rather than examining the political, economic, social, and cultural context that fostered those attitudes and behaviours (Morgan & Marsh, 1998; Pender et al., 2010). This prevailing emphasis on personal responsibility for health, excluding population-level influences, has been strongly criticized as an outdated modernist approach to health (Lupton, 1998).

The population health framework provides a broader framework for nursing research and fits well with the holistic view of humans espoused by the nursing profession (Chinn & Kramer, 2011; Morse, 1982). This framework is highly relevant for nurses, enabling them to identify not only personal factors, such as knowledge, attitudes, and beliefs that facilitate or hinder motivation for change, but also resources or barriers that help/hinder desired behavioural and environmental changes (Cohen & Reutter, 2007; Radzyminski, 2007). This approach is congruent with Chinn and Kramer's (2011) concept of Emancipatory Knowledge, which calls nurses 'to recognize social and political problems of injustice or inequity' (p. 64) and to create change that improves people's lives.

The broader perspective of the population health framework is not unknown to many nurses, having been discussed in the nursing literature under the banners of '*upstream thinking*' and '*reconceptualising the environment*'. 'Upstream thinking' (McKinlay, 1979) has been promoted by nurse researchers like Patricia Butterfield (1990) as a way for nurses to understand the complex social, political, economic, and environmental (i.e. 'upstream') forces that shape people's lives and then to address these distal factors known to be precursors of poor health outcomes (Butterfield, 1997 & 2002; Kearney, 2003). Nurses have also discussed the need to 'reconceptualise the environment' by moving beyond the traditional understanding of 'environment' (namely the immediate physical and psychosocial environment of individuals in the hospital, home, or community) (Dallaire et al., 1999; Kleffel, 1991 & 1996; MacDonald, 2004) to an expanded definition that encompasses the social, political, and economic structures and underlying ideologies that influence the individual's everyday realities (Butterfield, 2002; Cohen & Reutter, 2007). The approaches of 'upstream thinking' and 'reconceptualising the environment' are compatible with a holistic vision of nursing (Dallaire et al., 1999), fulfill nursing's individual and societal mandates (Thorne et al., 1998), and parallel the perspective now described by the term 'population health'.

Next Steps for Nursing Research

It is important to remember that the population health framework posits that population-level factors are foundational to individual-level factors and that *complex intermediate-level processes link them to each other and to health outcomes* (see Figure 2-1). Attention to these intermediate processes is an area where nurse researchers have the potential to make considerable strides in contributing new knowledge. While it is encouraging that the SDH are being incorporated into more nursing research, there is a need to fully embrace the broader population health framework by focusing on multi-level influences and the processes that connect them. Research that focuses only on distal factors, i.e. only the SDH, with little understanding of the intermediate-level processes that link them to health outcomes, is not truly enacting the population health framework (Coburn et al., 2003). Lack of attention to this aspect of the framework has developed because population health research has historically depended on epidemiologic methods operating according to the 'black box paradigm' or 'risk factor epidemiology'. This problematic paradigm refers to the tendency to focus on identifying associations between exposures and outcomes, without any understanding of the processes linking them (Coburn et al., 2003; Susser & Susser, 1996). There is a clear need to explore the processes by which distal factors interact with proximal factors to influence health. Understanding these intermediate processes is important because, while we cannot always easily intervene on distal factors (e.g. geography or poverty), we may be able to influence intervening variables (e.g. access to transportation, food security, social support services). Understanding how social and physical contexts interact with individual-level factors to influence health is important in designing effective interventions to improve health outcomes, and, increasingly, nurse researchers are advocating for this approach (Clark et al., 2008; Edwards et al., 2004).

Use of Multi-Level Theories

An important part of the step forward in population health nursing research is application of appropriate theoretical foundations to guide multi-level studies. While population health is a valuable *framework* for conceptualizing research, a *theory* (or often multiple theories) is needed to understand how the concepts within the framework are related (Dunn, 2006; Labonté et al., 2005; O'Campo, 2003). These theories, while less comprehensive than the framework, are more specific and concrete, and help to explain a logical set of relationships among variables, including direction of associations and possible hypotheses (Carpiano & Daley 2006). Raphael (2011) attributes the current 'lack of theory' in population health research to the positivist and epidemiological orientation of the population health approach to date, 'which results in an emphasis on data rather than theory' (p. 230). Adoption of appropriate theory is thus a critical component in identifying inter-relationships or *processes* that connect concepts identified in the framework (Chinn & Kramer, 2011).

We propose that ecological theories, many of which have their foundation in the fields of sociology and social psychology (Bandura, 1986; Glanz & Bishop, 2010; McLeroy et al., 1988), provide an ideal theoretical foundation for the population health framework. Ecological theories acknowledge that health behaviours have multiple levels of influences, often including intrapersonal, interpersonal, organizational, community, policy, and physical environment. They further posit that it usually takes the combination of both individual-level and population-level interventions to achieve substantial changes in health behaviour (Sallis et al., 2008). Such theories 'embrace population-level thinking without discarding biology or rejecting the notion of human agency' (MacDonald, 2004, p. 387). Thus, ecological theories can be used to explore the multiple and specific pathways and processes which explain and predict the relationship between social environment, individual response, and health (Carpiano & Daley, 2006; MacLean et al., 2010). Ecological theories provide a promising approach that is often mentioned in the literature, but as of yet, have been little used in guiding public health practice and research (Glanz & Bishop, 2010). Some of the more well known ecological theories are presented in Table 2-3. An excellent review of these and other ecological theories and their use can be found in a paper by Sallis and colleagues (2008).

Nurse researchers are well situated to use such theories to examine the processes that link human health to broader population-level determinants. Nurses' 'connectedness' with clients' and their environment puts them in an ideal position to listen to clients' stories, recognize the 'clues' to upstream etiology, look for patterns 'at the intersection of the personal and political' (Reutter &

Kushner, 2010, p. 275), and examine proposed etiological links (Macdonald, 2004; Morgan & Marsh, 1998; Radzyminski, 2007; Rafael, 1999). By drawing their research questions from their clinical practice and experience, and by connecting with clients in the collection of research data when appropriate, nurse researchers are better able to view and recognize the broad array of factors influencing their clients' health. Nurse researchers can use this unique perspective to identify immediate needs; upstream factors including social, economic, and environmental threats to health; and the intermediate processes that connect them (Kearney, 2003).

Use of Multi-Level Methods

While multi-level theory is essential to conceptualizing the relationship between multi-level factors, *multi-level methods* are also often useful for nursing research guided by the population health framework (Diez-Roux, 2000). 'Multi-level analysis' typically refers to various methods for analysing hierarchical data involving individual-level factors nested within population-level contexts (Diez-Roux, 2002). In recent years, epidemiology, particularly public health epidemiology, has developed a number of advanced *quantitative* techniques, such as hierarchical linear modelling, for analysing such multi-level relationships (Blakely & Woodward, 2000; Diez-Roux, 2008). Discussion of specific multi-level analyses is beyond the scope of this article, but Subramanian (2004) provides an excellent introduction to multi-level statistical modelling and analyses. Diez-Roux's (2000) work is also an excellent source of information regarding the strengths and limitations of multi-level methods.

In addition to quantitative multi-level methods, *qualitative* methods are a valuable option for investigating research guided by the population health framework. Given that the population health framework asserts that *context* (e.g. population-level factors) influences human behavior and health outcomes, it is an important focus of any study (McGrath & Johnson, 2003). Qualitative research is, by its very nature, ‘research in a natural context’ or ‘context-aware’, and thus well-suited to investigate multi-level factors and the intermediate processes that connect them (Denzin & Lincoln, 2000).

Another, and sometimes preferable, approach is a combination of qualitative and quantitative methods in a ‘mixed-methods’ approach. This approach involves collecting and analysing data, integrating results, and drawing inferences using both qualitative and quantitative methods in a given study (Creswell & Plano Clark, 2007). ‘The complexity of human phenomena mandates more complex research designs to capture them’ (Sandelowski, 2000, p. 46), and mixed-methods research has the potential to produce more complete, reliable, and insightful findings than depending on one method alone (McEvoy & Richards, 2006; Risjord et al., 2002). This is particularly true when examining factors at multiple levels and across sectors (e.g. health, education, environment), as is common in population health research. A mixed-methods approach also facilitates interdisciplinary collaboration by allowing the methodological traditions of multiple disciplines to be accommodated and valued. Although there is still some debate as to whether it is valid to combine methods from diverse philosophical paradigms (Bryman, 2007; Giddings & Grant, 2007; Morgan, 2007; Sale et al., 2002), this eclectic approach is becoming more accepted and common in nursing research (Clark et al., 2008; Doyle et al., 2009; Lewin et al., 2009; Sandelowski, 2000).

Examples of Nursing Research Guided by the Population Health Framework

It is useful to consider examples of nursing research that are congruent with the population health framework to illustrate how the framework can guide a more comprehensive investigation of health determinants and outcomes. Although the studies described here do not specifically identify the population health framework, the researchers very effectively utilize multi-level theory and methods in their research.

One such example is Browne et al.'s work (2010) on public health nursing practice with families at risk. Browne used a 'relational approach', which recognizes that health outcomes are shaped by people's social, economic, cultural, family, historical, and geographical contexts (population-level factors), as well as by their biology, gender, age, ability (individual-level factors). This 'relational view of nursing' acknowledges that personal, interpersonal, and contextual elements, including socioenvironmental limitations, are shaping peoples' health and illness experiences, and thus should be the target of nursing investigations. Browne's study used a hermeneutic qualitative methodology to investigate the relationship between public health nurses and high risk families, using focus groups and individual interviews. This multi-level study discerned that 'working relationally enabled the public health nurses to simultaneously recognize, contextualize, and respond to risks and capacities, and attend to the multidimensional ‘whole’ of the family’ (p. 29).

Another excellent recent nursing research study that exemplifies the population health framework is Sword et al.’s (2012) study exploring the mechanisms involved in the development of post-partum depression. The authors display an excellent grasp of the complexity of nursing research that explores causal mechanisms. The critical realism approach utilized in their study is clearly ecological in nature. They articulate that ‘critical realism acknowledges the causal importance of personal or agency factors (e.g. motivation, experience, meaning) and contextual or structural factors (e.g. place, cultural norms, gender inequalities) in influencing health outcomes, and the interplay of these factors’ (p. 52). Qualitative analysis of in-depth personal interviews with post-partum women enabled them to identify personal influences, situational or contextual influences, and the interplay between these factors that contribute to post-partum depression.

Although both of these studies exemplify qualitative methods, nursing research utilizing *quantitative* multi-level analysis techniques is also valuable in addressing many complex interrelationships among individuals/families, communities, or systems and their environments (ACHNE, 2009). This is a necessary area of growth for nursing research. As is aptly stated by Clark et al. (2008), ‘researchers should acknowledge the complexity of the world and its open systems and let methodological choice be led by the nature of the research question and the conceptualization of the phenomena under study’ (p. E72).

Challenges to Using the Population Health Framework in Nursing Research

Despite discussion in the literature about how the concepts of the population health framework could guide nursing research (Edwards et al., 2004; Reutter & Kushner, 2010) and the works of nurse researchers who have explicitly utilized the framework in their investigations (e.g. Davidson et al., 2006; Krewski et al., 2007; MacLean et al., 2010; Stewart et al., 2005), there exist a number of challenges to the framework's widespread adoption by nurse researchers. These include political, societal, professional, and organizational barriers.

Political and Societal Barriers

A significant barrier to population health-focused nursing research is the constraint imposed by the 'silo' structuring of government departments (Collins & Hayes, 2007), making interdepartmental collaboration on health-related policies and research a challenge. By their very nature, population health-focused activities require addressing distal factors outside the 'domain of health', such as transportation, housing, and education. Even within the realm of 'health', there is often a 'disconnect' between the goals, strategies, and resources of acute care, primary care, and public health. These limitations necessitate effective interdepartmental, intergovernmental, and intersectoral collaborative mechanisms (Keon, 2008a) that are typically beyond the control of an individual or team of researchers. What is needed are partnerships and 'intersectoral action for population health', with both horizontal and vertical dimensions (Keon, 2008b). The horizontal dimension links different ministries, such as education, health, and transportation. The vertical dimension links different levels of government (federal, regional, and local) and groups, institutions, and organizations in the community (Keon, 2008b). Clearly, such intersectoral action requires significant collaboration and substantial funding. Thus government buy-in and support is needed to support an agenda conducive to population health research. Unfortunately, this may be a difficult barrier to address as there is often a lack of political will by governments to allocate sufficient funding to population-level research and interventions, especially if it means reducing acute/clinical care dollars (Collins & Hayes, 2007; Raphael, 2003). Another barrier impeding political support for population health research initiatives are the long timelines involved in population health-focused endeavors. As stated in the report 'Population Health Policy: International Perspectives', the timelines to achieve measurable changes in population health 'extend well beyond the political horizons of even the most far-sighted of governments. It is difficult to reorganize or reformulate population health policy in successive governments' (Keon, 2008a, p. 50); with the same challenge applying to the conduct of population health research endeavors. This has led some experts to contend that a step-by-step approach to population health-focused activities is the only feasible strategy (Keon, 2008a).

Interlinked with this lack of political support is the dominant societal belief that health is only a personal responsibility (Niedderdeppe et al., 2008). This societal ideology is a daunting barrier to researchers in nursing and other health disciplines wishing to adopt a population health framework, as it limits societal support, or even awareness, of the need to address population-level health determinants (Daghofer, 2011; Raphael, 2011). Knowledge and understanding of the broader determinants of health is strikingly deficient in the general public. In many cases, there is wide public awareness of the influence of personal lifestyle behaviours (such as diet, activity, and smoking) and access to health care, but little understanding of the role of broader social determinants, such as education, income, and social support (Keon, 2008b). To some extent this ‘public blind spot’ (Raphael, 2003, p. 400) can be blamed on the media focus on lifestyle behaviours and the health care system (Keon, 2008b). To address this issue, supporters of public health and population health research need to become more savvy in utilizing the media to share messages that educate the public about population health.

Nurse researchers have an ‘unrealized opportunity... to improve health and reduce disparities’ (Williams et al., 2008, p. 815) by playing a part in shifting policymakers’ and the public’s focus away from the dominant medical and lifestyle-oriented health approaches (Chinn & Kramer 2011; Raphael et al., 2008; Reutter & Kushner, 2010). Increasing recognition that multi-level interventions are legitimate targets and activities for researchers is essential, rather than focusing on ‘weak but politically palatable programs in health education’ (Hawe, 2009, p. 292). Knowledge production in this area can be applied to design interventions that promote not only lifestyle changes, but also to influence the environment through consumer demand, collective action, or political advocacy (Radzyminski, 2007). Nursing research, as with any area of medical or scientific research, is not immune from prevailing social values and ideologies (Nettleton, 1997). Given the influence of public opinion on government policy decisions, generating a better appreciation for the determinants of health amongst the general public can foster political will for population health research, generate the conditions necessary for action, and sustain those actions over the long term (Keon, 2008b).

Professional and Organizational Barriers

Nurse researchers cannot help but be influenced by the social context described above, which largely accepts the dominant societal ideology of individual responsibility for health. This ideology is often perpetuated by the education and professional socialization to which nurses are exposed, including many of the popular nursing models, texts, course content and clinical placements in nursing curricula (Cohen, 2006). This prevailing emphasis on the 'nurse–person relationship rather than on a population health approach' (Reutter & Kushner, 2010, p. 276) does not adequately prepare most nurses to engage in research addressing multi-level causative factors or population-level interventions, such as community development and advocacy for policy change (Cohen, 2006; Spenceley et al., 2006). This challenge is not unique to nurses; other health researchers and practitioners 'are still socialized into believing that they can only influence lifestyle domains, and that housing, employment, or poverty are 'not health'' (Hawe, 2009, p. 292). Clearly, undergraduate and, to a greater extent, graduate nursing curricula need to include education on the broad range of health determinants and development of research skills needed to identify multi-level determinants of health (Browne & Tarlier 2008; Reutter & Kushner, 2010).

Research identifying policy-level factors consequently necessitates development of additional skills related to policy analysis and advocacy (Cohen & Gregory, 2009; Duncan & Reutter, 2006; Falk-Rafael, 2005; Keller et al., 2004; Reutter & Kushner, 2010; Sistrom et al., 2011; Spenceley et al., 2006).

Even with the necessary preparation and skills, there are often organizational barriers preventing nurse and other health researchers from targeting broader systemic factors in their research (Falk-Rafael & Betker, 2012). Raphael (2011) has suggested that researchers may feel that taking a critical stance on health and public policy issues can be a ‘career threatening move’ (p. 231), given that funding of the researcher’s department and/or research project grants are often dependent on the very government whose policy they are criticizing. Academic researchers are somewhat more protected than government employees, but may still have difficulty securing approval from health care administrators in whose agencies they are conducting research, when tackling politically sensitive issues, such as the impact of health care spending cuts. Moreover, the emphasis (and in some cases, even requirement) by granting agencies for more intersectoral team research poses additional problems as research collaborators in the public/government sectors may be reticent to tackle politically contentious issues due to possible career implications.

Even without such real or perceived obstacles, nurse researchers are often prevented from examining the broad system-level influences on health due to the absolute limitations of available data. As has been recognized in a recent Canadian Senate report:

> More complete data and information are needed to understand better the factors that affect population health.... The nature of the relationships between health and its determinants is complex; it cannot be explained in terms of single, commonly-used measures of socioeconomic status, such as income, education, or occupation. We need to ask: do we have enough and sufficiently sensitive indicators to track and assess the extent of health disparities; where are the gaps in knowledge and how can we fill them; what can be done to improve the information available on health disparities (Keon, 2008b, p. 12).

The ability to conduct population health research is clearly constrained if adequate information systems are not available to provide data on population-level variables of interest. An alarming example of this has occurred in Canada, where the federal government has recently abolished the mandatory long-form census, which had been a valuable source of population-level data on Canadians, including data on many of the social determinants of health.

Conclusion

The foundation of any study, the plan and organization of inquiry, and the emergence of knowledge begin with a conceptual framework (Carpiano & Daley, 2006). The choice of framework directs the research questions, determines ‘what we know, what we consider knowable, and what we ignore’ (Krieger & Zierler, 1996, p. 109). Our understanding of health and the role of nursing are largely determined by our perspective, and population health provides a conceptual framework well-suited to guide nursing research. If we understand the central concern of nursing to be the promotion of human health, then it is necessary to improve our understanding of the interrelations between individuals and the broader context in which they exist, and the processes that connect them.

Understanding the complex mechanisms that connect the multi-level determinants of health should be a priority for nursing research, contributing knowledge that will tackle current and future healthcare challenges (Clark et al., 2008). Such work could address clinical, service delivery, and policy issues, and inform healthcare decision-making (Edwards, 2008). Nurse researchers, working alongside their interdisciplinary partners, operating within the population health framework, have the potential to significantly impact the health of individuals and their communities by targeting social contexts, not just behaviour. To fulfill this worthy mandate, nurse researchers are encouraged to attend to the broad range of health determinants and the processes that connect them. Undertaking interdisciplinary and intersectoral collaboration utilizing the population health framework in nursing research will help ensure that population-level factors do not unduly constrain healthy options available to individuals in society.

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Table 2-1: Determinants of Health in the Population Health Framework

Determinants
Social and economic environments
Physical environments
Early childhood development
Health services
Personal health practices
Individual capacity and coping skills
Biology and genetics

(Federal/Provincial/Territorial Advisory Committee on Population Health [F/P/TACPH] 1999)

Table 2-2: Seminal Documents in the Evolution of the Population Health Framework

Seminal Documents
A new perspective on the health of Canadians (Lalonde 1974)
Inequalities in health: Report of a research working group (The Black Report) (Department of health and social security 1980)
Sick individuals and sick populations (Rose 1985)
Social foundations of thought and action: A social cognitive theory (Bandura 1986)
Ottawa charter for health promotion (WHO 1986)
Achieving health for all: A framework for health promotion (Epp 1986)
Producing health, consuming health care (Evans and Stoddard 1990)
The determinants of health (Mustard and Frank 1991)
Policies and strategies to promote equity in health (Dahlgren and Whitehead 1992)
Why are some people healthy and others not? (Evans, Barer and Marmor 1994)
Strategies for population health: Investing in the health of Canadians (F/P/T ACPH 1994)
Why "population health"? (Frank 1995)
Unhealthy societies: Afflictions of inequality (Wilkinson 1996)
Taking action on population health (Health Canada 1998)
Independent inquiry into inequalities in health (The Acheson Report) (Acheson 1998)
Population health in Canada: A systematic review (Hayes and Dunn 1998)
Population health: Concepts and methods (Young 1998)
Toward a lexicon of population health (Dunn and Hayes 1999)
Population health in Canada: A working paper (Frankish, Veenstra and Moulton 2002)
Towards a common understanding: Clarifying the core concepts of population health (PHAC 2002)
What is population health? (Kindig and Stoddart 2003)
The population health approach in historical perspective (Szreter 2003)
Population health approach (PHAC 2005)
Beyond the divides: Towards critical population health research (Labonte et al. 2005)

Speaking theoretically about population health (Dunn 2006)

Understanding population health terminology (Kindig 2007)

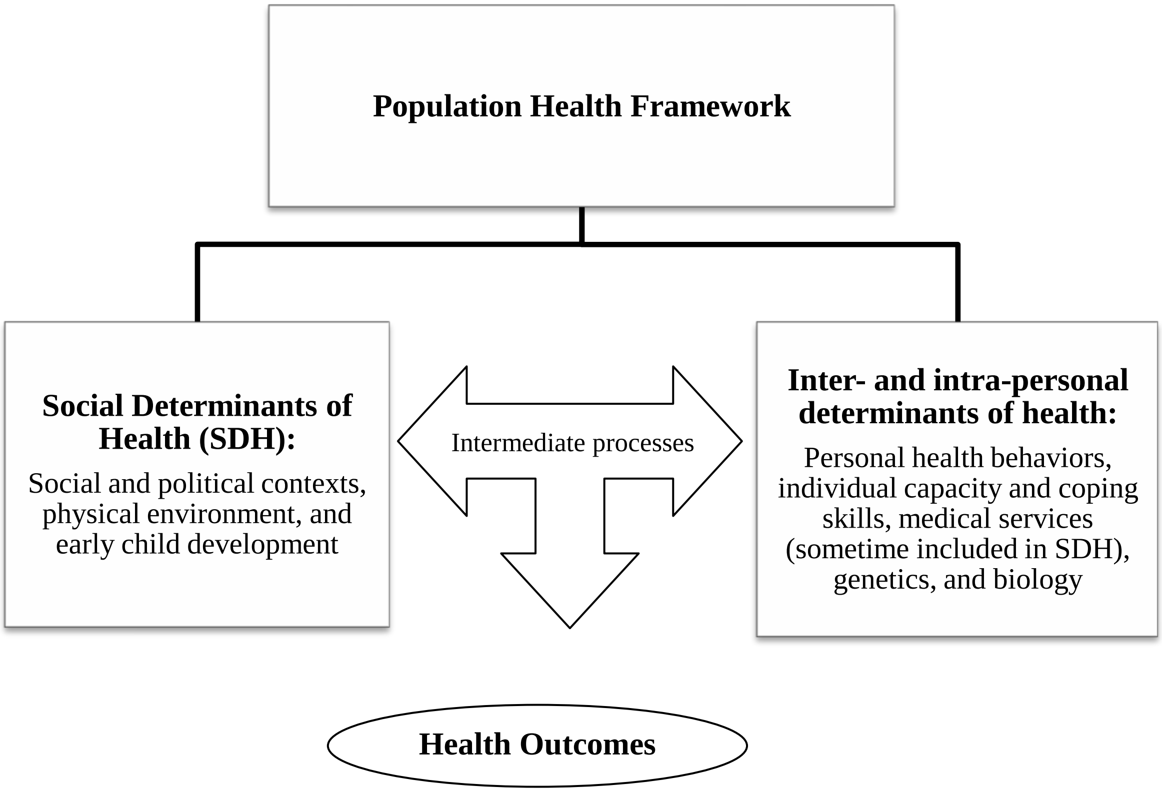
Population health: Challenges for science and society (Mechanic 2007)

Closing the gap in a generation: Health equity through action on the social determinants of health. Commission on Social Determinants of Health - Final report (WHO 2008)

Table 2-3: Selection of Ecological Theories

Ecological Theories
Ecosocial theory (Kreiger 1994)
Eco-epidemiology (Susser and Susser 1996)
Socio-ecological systems perspective (Human ecology) (McMichael 1999)
Milio's ecological theory of prevention (Milio 1976)
Critical social theory (Allen 1985)
Social ecology (Moos 1980)
Bronfenbrenner's ecological systems theory (Bronfenbrenner 1979)
Theory of triadic influence (Flay and Petratitis 1994)
Critical caring theory (Falk-Rafael 2005, 2012)

Figure 2-1: How the 'Social Determinants of Health' Relate to the Population Health Framework



Chapter 3: Paper #2

Addressing Non-Response Bias in Postal Surveys

Shannon E. MacDonald, RN, MN[a]
Christine V. Newburn-Cook, RN, PhD[a]
Donald Schopflocher, PhD[a,b]
Solina Richter, RN, DCur[a]

[a] University of Alberta Faculty of Nursing
[b] School of Public Health, University of Alberta

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Background

It is not uncommon for postal surveys to be viewed as a quick and easy option for data collection, with the potential for non-response bias often being under-appreciated (Kelley, Clark, Brown, & Sitzia, 2003; McColl et al., 2001). In particular, the belief that *a high response rate protects against non-response bias* is not uncommon amongst those unfamiliar with conducting or reading postal survey research (Asch, Jedrziewski, & Christakis, 1997; Groves, Couper, Presser, & Singer, 2006). Unfortunately, lack of sufficient attention to non-response in the design, implementation, and analysis of a study can have a significant impact on both the precision and the generalizability of study findings. In order to ensure the effective use of postal surveys in public health nursing research, it is essential that there be a full appreciation of the complex phenomenon of non-response bias.

This article discusses the issue of non-response bias in research that utilizes postal surveys for data collection. The potential benefits of postal surveys in nursing research are presented, followed by a discussion of survey non-response and its implications for the precision and generalizability of sample survey estimates, with emphasis on non-response bias. Recommendations for addressing non-response are presented, including: recognizing the reasons for non-response, implementing strategies to reduce non-response through judicious use of response-enhancement strategies, assessing for non-response bias, and executing post-survey adjustment of data. The importance of considering these issues in the initial design of the study is highlighted in a case study that describes possible procedures for sample selection, survey administration, data analysis, and reporting of study results.

Potential Benefits of Using Postal Surveys in Nursing Research

Postal surveys are a valuable tool for nurse researchers to use when collecting data from the general public and clients in the community. This method is particularly useful for research involving large and/or geographically dispersed populations, being more cost-effective than telephone or face-to-face interviews (Edwards et al., 2002; Hoffman, Burke, Helzlsouer, & Comstock, 1998; Kelley et al., 2003; McColl et al., 2001; Perneger, Etter, & Rougemont, 1993). The self-administered questionnaires utilized in postal surveys may also induce more honest answers to sensitive questions, and result in less interviewer bias and social desirability bias, as the interviewer does not directly influence the respondents' answers (Bowling, 2005; McColl et al.; Parker & Dewey, 2000; Perneger et al., 1993; Siemiatycki, 1979). It has also been argued that postal surveys are easier to implement and require fewer personnel, thus allowing individuals and small organizations to conduct their own research, rather than relying upon outside research organizations (Dillman, 1991; McColl et al.); although the wisdom of this approach has been debated (Hill, 1996). Despite the proposed benefits of postal surveys, there are a number of potential sources of survey error which nurse researchers should appreciate in order for this strategy to yield valid and reliable data.

Sources of Survey Error

A well-conducted postal survey has the ability to estimate the distribution of one or more variable(s) of interest in a population by obtaining data from only a small proportion of that population -- i.e., the sample (Dillman, 2007). However, the estimates provided through such surveys are only valid if they offer a relatively close approximation to the true population value. The failure of the sample survey estimate to closely approximate the actual population value is termed “survey error” (Locker, 2000). There are four potential sources of error to consider before confidence can be placed in the sample findings (Dillman, 1991).

Sampling error is the difference between the estimate, based on the sample, and the true parameter, based on the total population from which the sample was drawn (Biemer & Lyberg, 2003). Sampling error is the result of surveying an inadequate number of individuals in the survey population (Dillman, 2007). As the sample size decreases, the sampling error generally increases. Thus, increasing the sample size is generally the best way to minimize this form of error.

Non-coverage error, also commonly called *sampling frame error*, is associated with the sampling frame -- i.e., the list of target population members from which the sample is drawn (Biemer & Lyberg, 2003). If the sampling frame omits some individuals of the population, either accidentally or deliberately, all individuals in the population will not have an equal or known chance of being included in the sample, resulting in non-coverage error (Barriball & While, 1999b; Dillman, 2007). To protect against such error, every member of the survey population must be represented in the sampling frame (Dillman, 2007).

Measurement error occurs when respondents' answers to survey questions do not accurately reflect the variable that the survey intended to measure, often as a result of poor question wording (Dillman, 1991, 2007). The best approach to minimize this form of error is through careful attention to questionnaire construction, including confirming the validity and reliability of questions through focus groups and pilot testing.

Non-response error occurs when "a significant number of people in the survey sample do not respond to the questionnaire and have different characteristics from those who do respond, when those characteristics are important to the study" (Dillman, 2007, p. 10). While response rates are the generally accepted indicator of non-response error (Dillman, 1991), the most important aspect of the definition is that the people who respond to the survey are different from those who do not respond, *in a way relevant to the study*. Non-response error, the bias it can lead to, and the ways of identifying and addressing it, are the focus of this article.

It should be noted that non-response is not in itself one entity, but includes both item non-response and unit non-response. *Item non-response* occurs when the sampled individual returns the questionnaire, but omits information on one/some of the questionnaire items, either intentionally or unintentionally. In contrast, *unit non-response* occurs when the questionnaire is not returned, and thus no information is collected from the sampled individual (Barriball & While, 1999b; Biemer & Lyberg, 2003; Kessler, Little, & Groves, 1995). Discussion of response rates and non-response error and bias in this article will refer exclusively to unit non-response.

Implications of Survey Non-Response

Survey non-response can have significant implications for both the precision and the generalizability of sample survey estimates. In particular, low response rates can result in decreased study power, increased standard error, and non-response bias. Figure 3-1 provides a framework for viewing these implications within the broader context of survey error.

One effect of survey non-response is that a lower than anticipated response rate reduces the effective sample size, thereby reducing the number of subjects providing data for analysis. This decreases the statistical power of the study, making it more likely that a real effect will not be detected, i.e., Type II error (Gore-Felton, Koopman, Bridges, Thoresen, & Spiegel, 2002; Parker & Dewey, 2000). An inadequate sample size also increases the random error around a given measurement, thereby increasing the standard error of the estimate (Gore-Felton et al., 2002). Both of these processes decrease the precision of the sample survey measurement, resulting in wider confidence intervals around the value, and ultimately, less confidence in the estimate (Biemer & Lyberg, 2003).

Non-response bias differs from these other implications in that it is not based on the absolute number of research subjects, but, rather, on the proportion of potential subjects in the sample who respond (Gore-Felton et al., 2002). Non-respondents introduce bias when they would have systematically answered survey questions differently from respondents (Gore-Felton et al., 2002; Halpern & Asch, 2003; Kessler et al., 1995; Locker, 2000). When this occurs, the distribution of values of a given variable in the measured sample (based on the respondents) will not accurately represent the distribution of values of that variable in the larger population, thereby decreasing the generalizability of study findings (Gore-Felton et al., 2002).

Since it is relatively easy to assess response rates, and more challenging to identify bias, many researchers use response rates as a simple proxy for the measurement of bias and/or an indicator of data quality (Asch et al., 1997; Groves et al., 2006; Halpern & Asch; Locker; McFarlane, Olmsted, Murphy, & Hill, 2007). However, it is "the *risk* of non-response bias – not non-response bias itself – [which] is reduced with decreasing non-response rates" (Groves, 2006, p. 663). This is exemplified by Halpern and Asch (2003), who state:

> There is no necessary relation between low response rates and bias. A 10% response rate in a survey of 100,000 (individuals) would introduce no bias if the 10,000 responders were similar to the underlying target population in the behaviours or beliefs being evaluated. By contrast, a 90% response rate in this survey might introduce considerable bias if the 10,000 non-responders differed in some important way from the responders (p. 637).

Non-response bias is more accurately seen as a function of both the non-response rate and the magnitude of the difference between respondents and non-respondents on a key variable of interest in the study (Biemer & Lyberg, 2003; Groves, 2006; Locker, 2000).

Non-Response Bias in Nursing Research

Although non-response bias has been widely explored in public opinion and marketing research, it has been little discussed in the nursing research literature. This deficiency increases the potential that researchers unfamiliar with the challenges of survey research may adopt the simplistic view that *increasing response rates will decrease non-response bias*. Thus, it is clearly important for nurses intending to utilize postal surveys in their research to consider the occurrence of non-response bias in study design, and to knowledgeably weigh the relative benefits and limitations of implementing strategies to address it.

Addressing Non-Response

In any study utilizing a postal survey for data collection, the researcher should consider a number of factors related to non-response, beyond merely the achieved response rate. These include recognizing the reason(s) for non-response, implementing strategies to reduce non-response through judicious use of response-enhancement strategies, assessing for non-response bias, and executing post-survey adjustment of data.

Reasons for Non-Response

The reasons for non-response generally fall into two categories, non-contacts and refusals (Singer, 2006). Distinguishing between these is methodologically important, as the characteristics of each group differ within a given research situation. These differing characteristics may alter the nature of the potential bias they introduce, in turn altering the approach required to address them (Barriball & While, 1999a). It has been suggested that the situational variables contributing to non-contact (e.g. method of contact) may be more amenable to manipulation by researchers, enabling these variables to be minimized in a well-managed study, thereby reducing the overall level of non-response. In contrast, refusal to participate in a survey is affected by both situational factors and subject factors (e.g. subject age, salience of the study topic to the subject), requiring more diverse and creative strategies to address them (Barriball & While). Strategies for addressing non-response fall into two categories, those aimed at reducing the non-response rate (response-enhancement strategies), and those that adjust for non-response after survey completion (post-survey adjustment) (Biemer & Lyberg, 2003).

Response-Enhancement Strategies

Much of the methodological literature related to postal surveys, both nursing and otherwise, focuses on reducing non-response through response-enhancement strategies. These strategies are considered generally easier to implement than post-survey adjustment techniques (Biemer & Lyberg, 2003), and much effort has been expended gauging the effectiveness of the various approaches. Table 3-1 presents a number of response-enhancement strategies judged to be effective in a meta-analysis of randomized-controlled trials (Edwards et al., 2002). The details of these and other strategies are well described elsewhere in the literature (Dillman, 2007; Hoffman et al., 1998; McColl et al., 2001; Perneger et al., 1993; Siemiatycki, 1979).

Although achieving high response rates is thought to *decrease* the potential for bias, it is important to recognize that aggressively implementing measures to improve response rates can actually lead to an *increase* in non-response bias. Such a phenomenon occurs if the strategies used to increase response are more effective for some subgroups in the population than others, particularly if those subgroups differ on key study variables from those who still do not respond (Groves, 2006; Kessler et al., 1995; Locker, 2000; McColl et al., 2001). For instance, financial incentives may introduce systematic bias by disproportionately increasing responses from low-income subjects, who may vary from other subjects in terms of the key variables under investigation in the study (Groves, 2006). Thus, although response-enhancement strategies have the potential to reduce non-response bias, the researcher should exercise caution in tailoring a package of strategies that is "guided by some knowledge of how groups likely to be affected by the efforts relate to key survey variables" (Groves, 2006, p. 668).

Assessing Non-Response Bias

Despite appropriate efforts to increase survey response rates through judicious use of response-enhancement strategies, the researcher should still assess for the presence of non-response bias. The magnitude of such bias is a function of both the level of non-response and the extent to which non-respondents differ from respondents (McColl et al., 2001). Thus, assessment of bias necessitates having data available on some or all of the non-respondents. Such "auxiliary data" is essential for both assessing the presence and magnitude of bias, as well as for carrying out statistical adjustment techniques if bias is identified (Brick & Kalton, 1996; Groves, 2006).

There are various approaches for assessing non-response bias, each with its own strengths and limitations (see Table 3-2). The choice of strategy largely depends on the availability of data, as well as time and financial constraints. Upon comparing measures of the variable (obtained from data provided only by respondents) to estimates based on non-respondents, a determination can be made as to whether the respondents are representative of the target population, or whether the sample measure is biased in one direction or another (Barriball & While, 1999a; Locker, 2000). This decision is based on a subjective judgement, as there are no standardized guidelines for determining how large the difference between measurements must be before bias is considered to be of importance (Locker, 2000). Examples of such judgements can be found in the published literature, with Table 3-2 identifying examples of peer-reviewed publications using each strategy of non-response bias assessment.

Studies often utilize more than one method of assessing non-response bias. For example, Jenkins et al. (2004), in their study assessing health status through a self-administered postal survey, compared respondents and non-respondents on (a) key demographic variables present in the sampling frame database, and (b) health status indicators assessed through double-sampling (a random sample of non-respondents were re-contacted and offered a monetary incentive to participate). The response rate to the initial mailing was 37.5%, with a 60.3% response rate to re-sampling. Subgroup comparisons of demographic variables between respondents, non-respondents (those that responded to the incentive), and never-respondents found “no consistent, meaningful demographic differences” (p. 128). However, when researchers compared health outcomes, they found that chronic disease prevalence rates were generally higher among respondents; for example, 10.26% of female respondents reported heart disease, compared to 6.76% of female non-respondents, a statistically significant difference (p=0.0025). The authors concluded that “finding similarities in demographic characteristics between survey responders and non-responders does not guarantee that analogous similarities on study endpoints will also be observed” (p. 129), although they do not comment on whether post-survey adjustment is warranted.

Post-Survey Adjustment

Once it has been judged that non-response bias is present, post-survey adjustment of data is recommended. Data can be adjusted using either weighting or imputation techniques, both of which can improve the analysis by incorporating partial information on non-respondents to produce estimates of missing data (Kessler et al., 1995). Imputation, in which missing values are replaced by proxies (Lundström & Särndal, 1999), is generally used to manage *item* non-response, although it is occasionally used to address *unit* non-response (Durrant, 2006; Särndal & Lundström, 2005). Weighting is the standard means of compensating for bias in estimates resulting from unit non-response (Biemer & Lyberg, 2003).

The main objective of weighting is to reduce bias in survey estimates by adjusting the estimate provided by respondents to more closely represent the target population (Biemer & Lyberg, 2003). Weighting uses available auxiliary data to calculate and apply the appropriate weights to the observed values for respondents to compensate for non-respondents (Brick & Kalton, 1996; Särndal & Lundström, 2005). “The general strategy is to identify respondents who are similar to the non-respondents in terms of auxiliary information that is available for both respondents and non-respondents, and then to increase the base weights of respondents so that they represent similar non-respondents” (Kalton & Flores-Cervantes, 2003, p. 82). Specific methods of weighting include weighting class adjustments, raking, calibration, propensity models, and post-stratification (Durrant, 2006; Holt & Elliot, 1991; Kalton & Flores-Cervantes; Kessler et al., 1995; Särndal & Lundström, 2005). The choice of method, and the statistical calculation of such adjustment techniques, can be highly complex and technically demanding, usually requiring the services of an experienced statistician and/or survey methodologist (Biemer & Lyberg, 2003).

As with response-enhancement strategies, caution must be exercised in using post-survey adjustment techniques. All such techniques involve assumptions about respondents, non-respondents, and/or the relationship between response propensity and the survey variable of interest (Biemer & Lyberg, 2003; Groves, 2006; Groves, et al, 2006; Locker, 2000). Such assumptions vary with the strategy adopted, but common assumptions include: Non-respondents about whom information is available are representative of all non-respondents; respondents and non-respondents with similar characteristics are also similar on key survey variables; and non-respondents are a homogeneous group (Groves 2006; Locker, 2000). If any of the relevant assumptions are not met, post-survey adjustment strategies may further compound the bias in measurement. Thus, efforts to reduce bias can in turn lead to an increase in the standard error of the estimates, leading to a trade-off between bias and the precision of the estimate (Groves 2006; Kessler et al., 1995; Locker, 2000).

In summary, although postal surveys are a valuable tool for data collection in public health nursing research, nurse researchers should remain cognizant of the potential limitations of this approach. In particular, caution must be exercised in the indiscriminate use of response-enhancement strategies and post-survey adjustment of data. Use of the various approaches for reduction of non-response bias should be applied in a thoughtful, rather than a mechanical, manner (Kessler et al., 1995). In particular, it is essential that the issue of non-response not be an afterthought, but be considered in the initial design of the study.

Addressing Non-Response Bias in Study Design: A Case Study

The following case study highlights the measures taken to minimize non-response bias in the design of a study using a postal survey for data collection. There are numerous other issues related to the design of such a study, which will not be addressed in this example.

In this case study, a team of public health nurse researchers seeks to assess the influence of parents' knowledge, attitudes, beliefs, and demographic characteristics on the completion of their children's routine immunizations. They have decided that a postal survey is the most time and cost-effective manner of collecting such data from a sample of clients in their geographically large health region. The research team includes an experienced survey methodologistbiostatistician, who ensures that the issue of non-response is considered in the initial design of the study, including establishing procedures for sample selection, survey administration, data analysis, and reporting of study results.

Sample Selection

The research team has access to a database containing contact information for all children born in the health region, along with their immunization status and a number of socio-demographic characteristics. They decide to use this database for sample selection, as it includes most members of the target population and contains auxiliary data on all potential survey participants.

Survey Administration

The research team develops various strategies to increase the likelihood of response from potential participants; Strategies are selected from those presented in Table 3-1. Although they aim to maximize response rates, the team’s resources, as well as practical issues, limit their choice of strategies to the following:

1) The content and format of the questionnaire are tailored to promote participant response. It is a “user-friendly questionnaire”, with pages that are clear and uncluttered, using appropriate level of language, and asking the most relevant questions first. The length of the questionnaire is kept to a minimum, in order to encourage completion. Although research has shown that limiting the questionnaire to factual questions may increase response rates, this is not possible in this case, as the team is particularly interested in parents’ knowledge, attitudes, and beliefs. In addition, although coloured ink has been suggested to increase response rates, budget limitations preclude this strategy.

2) A cover letter is included with the questionnaire, highlighting the salience of the subject to the target population. Unfortunately, a personalized greeting cannot be used, as the researchers have not been directly provided with potential participants' contact information, due to privacy legislation.

3) While potential participants will be receiving a stamped return envelope, recorded delivery or first-class outward mailing are not being used, due to budgetary limitations.

4) In order to promote recruitment of low-income parents, who are known to have lower rates of immunization and lower rates of response to postal surveys, an incentive in the form of a grocery voucher is sent to all potential participants along with the questionnaire. The team realizes that offering this incentive may lead to systematic bias by disproportionately increasing responses from low-income subjects, but they believe the risk is warranted, as their express aim is to ensure adequate representation of this group.

5) Potential participants are being contacted by postcard prior to receiving the questionnaire, as pre-contact has been shown to improve response rates. Follow-up reminders, along with a second questionnaire, are being sent to all subjects who have not returned their questionnaire within three weeks.

Data Analysis

The database used for sample selection provides a 'rich sampling frame' which will assist in identifying and measuring non-response bias, as it contains identical measurements for both respondents and non-respondents on some of the socio-demographic characteristics of interest to the researchers (e.g. maternal age, low-income status, geographic location, number of children). Although these are not all the key variables of interest, the team recognizes that there are limitations to every method of bias assessment (see Table 3-2), and accepts the compromises implicit in using this particular method. The team decides that if bias is identified, they will apply the calibration method of weighting to adjust for non-response and to determine the final estimation of values for the variables, as this method makes use of the auxiliary variables available in the database.

Reporting and Conclusions of Case Study

The reporting of this survey study will include the achieved response rate, and if less than ideal, a description of the differences between respondents and non-respondents. The team will also report the possible implications of any bias and describe the post-survey adjustment of data that was conducted, if needed.

The research team has adhered to the belief that “the principal objective should always be to collect reliable, valid and unbiased data from a representative sample, in a timely manner and within given resource constraints.” (McColl et al., 2001, p. iv). As is evident from this case study, there is no universal recommendation on how to conduct a postal survey, as it is always necessary to balance *the ideal* with *the possible* (McColl et al., 2001).

Conclusion

This article should enable the novice survey researcher to identify the common pitfalls associated with non-response bias and will prompt researchers to be mindful of non-response bias when planning their study. As with the use of any research tool, planning and rigour are necessary in the conduct of postal surveys.

As Kelley et al. (2003) notes, “Survey research should not be seen as an easy, ‘quick and dirty’ option… [otherwise] it will not stand up to academic scrutiny and will not be regarded as having much value as a contribution to knowledge” (p. 266).

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Table 3-1: Effective Response Enhancement Strategies

Strategy	**Odds Ratio (95% CI)**
Incentives	
Monetary incentive	2.02 (1.79-2.27)
Non-monetary incentive	1.19 (1.11-1.28)
Length	
Shorter questionnaire	1.86 (1.55-2.24)
Appearance	
Coloured ink	1.39 (1.16-1.67)
Personalized greeting	1.16 (1.06-1.28)
Delivery	
Recorded delivery	2.21 (1.51-3.25)
Stamped return envelope	1.26 (1.13-1.41)
First-class outward mailing	1.12 (1.02-1.23)
Contact	
Pre-contact	1.54 (1.24-1.92)
Follow-up contact	1.44 (1.22-1.70)
Postal follow-up includes second questionnaire	1.41 (1.02-1.94)
Content	
Interesting/relevant content	2.44 (1.99-3.01)
User friendly questionnaire	1.46 (1.21-1.75)
Factual questions only (versus attitudinal)	1.34 (1.01-1.77)
More relevant questions first	1.23 (1.10-1.37)
Origin	
University sponsorship	1.31 (1.11-1.54)
Communication	
Explanation for not participating requested	1.32 (1.05-1.66)

Note. Includes response-enhancement strategies found to be effective, as determined by a statistically significant odds ratio in a meta-analysis of randomized-controlled trials (Edwards et al., 2002)

Table 3-2: Selected Strategies for Assessing Non-Response Bias in Postal Surveys

Strategy	Description and Example of Strategy[a]	Strengths[a]	Limitations[a]	Selected Examples of Published Study Using this Strategy[b]
No assessment of bias	• No assessment of bias is possible when auxiliary data is not available for the comparison of respondents and non-respondents (e.g. Sample drawn from a list of names & addresses with no other information available)	• No benefits	• Lack of auxiliary data makes assessment of potential bias impossible	
Subgroup comparison	• Compares response rates across subgroups of the target population (e.g. Comparing response rates by age, gender, or race)	• Useful when have reason to suspect that response rates differ by subgroup • Easy to perform	• Requires theoretical knowledge of what sub-groupings may be associated with differences in response rate • Makes assumption that response rates are constant within subgroups	• Hill, Roberts, Ewings, & Gunnell (1997) • Jenkins, Scheim, Wang, Reed, & Green (2004) • Locker & Grushka (1988) • Paganini-Hill, Hsu, Chao, & Ross (1993) • Perneger, Chamot, & Bovier (2005)
Benchmark comparisons	• Compares characteristics of the survey sample with a "benchmark survey" of the same sample; a survey of the larger population from which the sample was drawn; or supplemental matched data (e.g. Comparing characteristics of respondents and non-respondents in the survey sample to characteristics in a government census or	• Useful if no auxiliary data is available on the sample, but a previous benchmark survey includes some of the variables of interest in the current survey • If benchmark survey is from a highly credible source, such as a government census,	• A relevant benchmark survey of the sample must exist, and be accessible to the researchers • Only enables estimates of non-response bias on variables available in the benchmark survey, which are not necessarily the key survey variables • The benchmark data may be subject to errors or missing values • Census data may be out of date	• Barchielli & Balzi (2002) • Cohen & Duffy (2002) • Paganini-Hill et al. (1993)

Strategy	Description and Example of Strategy[a]	Strengths[a]	Limitations[a]	Selected Examples of Published Study Using this Strategy[b]
	linking to available medical records)	then comparable estimates in the new survey are viewed with more confidence.		
Rich sampling frame	• The list from which the sample was drawn contains auxiliary data, which can be used to compare respondents and non-respondents (e.g. Sample is selected from a database which contains some of the variables of interest in the study)	• Identical measurements are available for both respondents and non-respondents • Enables comparison of respondents and non-respondents with minimal additional effort or expense, that is, no need to collect additional auxiliary data or link to other data sources	• Not all sampling frames contain auxiliary data • Only enables estimates of non-response bias on variables available in sampling frame, which are not necessarily the key survey variables • The sampling frame data may be subject to errors or missing values	• Etter & Perneger (1997) • Jenkins et al. (2004) • Lin & Schaeffer (1995) • Locker & Grushka (1988) • Perneger et al. (2005)
Level of effort analysis / Multi-phase approach	• Uses the responses of subjects who require additional time or effort to recruit, so-called “late respondents”, to model the responses of non-respondents (e.g. The responses of non-respondents are extrapolated from a linear regression of responses from each successive wave of respondents)	• Enables comparison of respondents and non-respondents by extrapolating responses of late respondents to non-respondents • Does not necessarily require an external data source or extraordinary data collection measures	• Makes the assumption that “non-respondents” will answer similarly to “late respondents” • Measurement error may increase along with the increase in recruitment efforts	• Etter & Perneger (1997) • Locker & Grushka (1988) • Paganini-Hill et al. (1993) • Perneger et al. (2005)
Double-sampling / Resampling	• Obtaining responses from a sample of non-	• Useful when auxiliary data is not	• Requires the ability to identify and contact non-respondents	• Hill et al. (1997) • Jenkins et al. (2004)

Strategy	Description and Example of Strategy[a]	Strengths[a]	Limitations[a]	Selected Examples of Published Study Using this Strategy[b]
	respondents, in order to estimate the measure of key variables in the target population. • The decision to resample is not made until initial survey response has been determined (e.g. telephone follow-up of non-respondents to postal survey, or financial inducements offered in 2nd mailing in postal survey)	available from any other source • Substantial data can be obtained about non-respondents, including values of key variables of interest	through another mode (e.g. telephone) • Requires time and expense to re-contact and/or offer additional inducements • Assumes that those who never respond are similar to those “non-respondents” who eventually respond, in terms of their response to key variables	• Lahaut, Jansen, van de Mheen, & Garretsen (2002)

[a] Sources: Groves, 2006; Locker, 2000; Mosquin, Whitmore, Suerken, & Quackenboss, 2005; Olson, 2006

[b] Some articles are cited more than once, as studies often utilize more than one strategy to assess bias

Chapter 4: Paper #3

The Pot Calling the Kettle Black: Accuracy of Classifying Immunization Status by Registry Versus Parent Report

Shannon E. MacDonald MN [a]
Donald P. Schopflocher, PhD [a,b]
Richard P. Golonka, BSc [c]

[a] Faculty of Nursing, University of Alberta
[b] School of Public Health, University of Alberta
[c] Alberta Health Services, Health Protection, Communicable Disease Control

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Background

Correct classification of immunization status is essential for clinical care, administration and evaluation of immunization programs and policies, vaccine research, and tracking vaccine-associated adverse events (Freeman & DeFriese, 2003; Greene et al., 2009; Laroche & Diniz, 2012; Linkins & Feikema, 1998; Placzek & Madoff, 2011; Salmon et al., 2006; Wood, Saarlas, Inkelas, & Matyas, 1999). Accurate assessment of immunization coverage depends on having an accurate, comprehensive, and accessible source of data (Bentsi-Enchill, Duclos, Scott, MacIsaac, & Halperin, 1996). While hard-copy provider records (typically clinic charts) are a trusted source of immunization status (Dorell, Jain, & Yankey, 2011; Stecher, Adelman, Brinkman, & Bulloch, 2008), they are not a feasible, cost-effective, or easily accessible method of tracking individual or population level coverage (Suarez, Simpson, & Smith, 1997). Parent-held records or recall are commonly used in immunization research, but are often criticized as inaccurate; parent-held records typically underestimate coverage, while parent recall tends to overestimate it (Bentsi-Enchill et al., 1996; Bolton, Holt, Ross, Hughart, & Guyer, 1998; Dorell et al., 2011; Goldstein, Kviz, & Daum, 1993; Lister, McIntyre, Burgess, & O'Brien, 1999; Watson et al., 2006).

Population-based electronic immunization registries, also known as Immunization Information Systems (IIS), have been proposed as a valid, cost-effective, and accessible option for assessing immunization status (Davidson et al., 2003; Placzek & Madoff, 2011; Salmon et al., 2006). These registries are centralized electronic repositories for immunization data for a specified geographic location that can consolidate immunization records from multiple providers and settings (Placzek & Madoff, 2011). They have been promoted by immunization advisory bodies in the USA and Canada (Federal/Provincial/Territorial Advisory Committee on Population Health and Health Security [FPT ACPHHS], 2004; National Vaccine Advisory Committee [NVAC], 1999; Public Health Agency of Canada [PHAC], 2004a; US Department of Health & Human Services, 2010), and have been proposed as an alternative source of immunization status verification for the National Immunization Survey conducted annually in the USA (Khare, Piccinino, Barker, & Linkins, 2006). However, it is recognized that additional validation studies are needed to determine the accuracy of registry data (Davidson et al., 2003; Kelly, Zimmerman, Reed, & Enger, 2007; Khare et al., 2006; Placzek & Madoff, 2011).

The purpose of this study was (1) to determine the accuracy of immunization status classification in an immunization registry as compared to parent report, and (2) to determine the types of errors for both sources in order to identify areas for system improvement. This study was a sub-analysis of a larger research project utilizing a postal survey to investigate the personal and systemic factors associated with children’s immunization status. Necessary institutional ethics board approval and participant informed consent were obtained.

Methods

Study Population and Setting

The study population for this postal survey study was selected from the ‘Caseworks’ immunization registry operated by Alberta Health Services (AHS)-

Edmonton zone (population: 1.1 million) in Alberta, Canada. The registry includes immunization data on all children who were born in the Edmonton zone or moved to the zone and accessed public health services. All routine childhood immunizations in this zone are administered by nurses in community-based public health clinics, recorded on a hard-copy clinic record, and entered in the electronic registry onsite by designated clerical staff. Each child is assigned to a 'home' public health center where the clinic chart is stored. If an appointment is made at a different location, the chart is transferred prior to the visit, entered into the registry at the site of immunization, and then transferred back to the home clinic.

Determining Immunization Status

This case-control study compared children whose immunizations were up to date (UTD) at two years of age (6 months after the infant-series is due for completion) to those who were not UTD. The routine infant immunization schedule in Alberta at the time of the study was a series of five vaccines: Diphtheria, Tetanus, acellular Pertussis, Polio and Haemophilus influenzae type b (4 doses); Measles, Mumps, Rubella (1 dose); Varicella (1 dose or history of disease); Meningococcal C conjugate (3 doses); and Pneumococcal 7-valent conjugate (4 doses). This schedule is not consistent across Canada since each province and territory sets its own immunization schedule. The study accounted for variation in the number of doses required for children who were older at initiation of the series or due to individual clinical conditions.

Parents of children identified from the registry (671 UTD and 671 not UTD) were mailed an advance notice postcard, followed by the immunization survey a week later. If no response was received within 3 weeks, a reminder postcard was sent, followed by a final reminder and replacement survey 3 weeks later. The survey asked parents questions about their beliefs and experiences with immunization, as well as their child’s immunization status according to parent-held records or recall (i.e. received all immunizations; received some, but not all immunizations; or, has not received any immunizations). Parents were not required to consult the parent-held record due to concerns that excessive participant burden might adversely impact the response rate. When there was disagreement in immunization status (UTD vs. not UTD) between the registry and parent report, the clinic record (considered the ‘Gold standard’) (Stecher et al., 2008) was consulted. Proportions and confidence intervals for errors in reporting and frequencies of the types of errors were determined.

Results

Survey Response

Of the 1342 surveys that were mailed to potential study subjects, 461 were completed and returned (331 UTD and 130 not UTD). After removing undeliverable surveys from the denominator, the final response rate was 43%. Respondents were more likely to have children that were UTD for all vaccines, i.e. 71.8% (95% CI: 67.5% - 75.7%, 331/461) of respondents were UTD, as compared to only 50.9% (95% CI: 46.9% - 55.0%, 300/589) of non-respondents being UTD.

Amount and Reasons for Error

There were 60 discrepancies between the registry and parent report of immunization status among the 461 survey respondents. Clinic record review revealed that 9.5% (44/461) of the sample were misclassified due to parent reporting, while 3.5% (16/461) were misclassified due to registry errors. Table 4-1 indicates the number of misclassification errors from each source. None of the 315 children identified as UTD by the registry were misclassified, while 11.0% (95% CI: 5.9% - 16.0%) of the children recorded as not UTD by the registry (16/146) were misclassified, i.e. they were reported as UTD by parents and confirmed by chart review. The level of error for parent report was the inverse, 11.3% (95% CI: 8.1% - 14.5%) of children reported as UTD by parent report (42/371) were considered not UTD by the registry and confirmed by clinic chart review, while only 2.2% (95% CI: 0.8% - 5.3%) of the children reported as not UTD by parents were actually UTD (2/90). The specific reasons for misclassification from each data source are provided in Table 4-2.

Discussion

Differential Accuracy

The results of this study confirm previous findings that parent reporting of immunization status is not always accurate (Bentsi-Enchill et al., 1996; Bolton et al., 1998; Dorell et al., 2011; Goldstein et al., 1993; Lister et al., 1999; Watson et al., 2006), but also identifies potential limitations of immunization registry data. The level of error in the registry found in this study was 3.5%, which is likely somewhat reassuring to the registry administrators, who consider <3% to be an acceptable amount of error. However, if registries are to be heralded as the most accurate and reliable source for tracking immunization coverage in the future, this level of error is noteworthy when interpreting coverage calculations.

The differential accuracy of parent report versus the registry is of particular interest. Specifically, the results show that parents are generally accurate in reporting their child as not UTD (2.2% misclassification), but not for reporting them as UTD (11.3% misclassification); whereas the registry is very accurate when recording a child as UTD (no errors), but less so when not UTD (11% misclassification). Only two previous studies have simultaneously compared registry and parent reporting to a third Gold standard (Ortega et al., 1997; Stecher et al., 2008), and only one (Stecher et al., 2008) described the differential accuracy of UTD/not UTD for the registry versus parent report. In Stecher's study, parent report agreed with the provider record 62% of the time, with the majority of errors being due to parents misreporting children as complete when the provider record showed them to be incomplete. In comparison, the registry agreed with the provider record 59% of the time, with the majority of errors being due to data in the provider record not being entered in the registry. As compared to our study, Stecher's study found that there were more errors in the registry than in parent report, but that the direction of errors was the same as in our study (i.e. registry more typically underreported completion, whereas parents were more likely to over-report completion).

This finding has important implications for program administration, clinical follow-up of individual children, and vaccine research. From a population perspective, any child classified as not UTD in a registry may need to be verified by chart review before drawing conclusions about coverage levels for a given region or clinic. From an individual perspective, such verification is also needed before recall or reminder notices are generated and sent to parents. In terms of clinical care, a parent who presents their child for medical care and reports their child as not UTD for immunizations can be considered generally accurate and appropriate follow-up, including supplementary doses, should be pursued; whereas parents reporting their child as UTD are more liable to be in error. For research purposes, such as for vaccine effectiveness or adverse event studies, these findings indicate that a registry may be the best option for sample selection if the aim is to include both UTD and not UTD children in a study, given the lower overall error rate, 3.5% (16/461) as compared to 9.5% (44/461) for parent report. A registry is also preferable if only UTD children are being studied (no misclassification, compared to 11.3% for parent report), whereas parent report would be a more valid source for identifying subjects if the primary focus is not UTD children (2.2% misclassification, compared to 11% for registry).

Reasons for Misclassification

Perhaps the most valuable contribution of this study is new knowledge about the types of errors contributing to misclassification in immunization registries and parent report. Such information has important implications for parent education, quality control, and system improvements, yet few studies have reported this information. Knowledge of the specific types of errors, both in the registry and by parents, is necessary to target strategies to reduce misclassification and improve clinical follow-up of incompletely immunized children.

Types of registry errors identified in previous studies include errors in transcription of number/ dates of doses administered, and vaccine formulation, manufacturer, or lot number (Mahon, Shea, Dougherty, & Loughlin, 2008; Samuels, Appel, Reddy, & Tilson, 2002). It has been noted that non-transcribed data are sometimes found in locations not routinely transcribed (e.g. discharge summaries, encounter notes) or are in a format not conducive to transcription (e.g. stated as ‘up-to-date’, but no specific dates given) (Wilton & Pennisi, 1994). Our study is the first to identify failure to transcribe varicella disease history or factors that reduce the required number of vaccine doses, including late initiation of vaccine series and doses given out of the region. Errors due to children moving from another province and being considered complete by the other province’s schedule is a problem unique to the Canadian context, where immunization schedules can vary substantially between jurisdictions. The problems with transcription of charted data identified in ours and other studies (Mahon et al., 2008; Samuels et al., 2002; Wilton & Pennisi, 1994), suggest the need to assess optimal methods of charting to facilitate consistent and accurate data entry. This may involve improved format of paper-charting to facilitate recording of data in the appropriate location for ease and completeness of transcription or, alternatively, direct data entry into electronic devices.

The reasons for misclassification in parent reporting of immunization status are also of interest. The fact that some parents who refused varicella vaccine still considered their child to be UTD (n=6) seems to indicate that these parents did not see this vaccine as part of the ‘routine’ immunization series. It is also noteworthy that a number of parents (n=11) who had not completed their children’s immunizations did so after receiving the survey in the mail. Presumably the survey acted as a reminder mechanism for completion of the series, which speaks to the need for better follow-up of non-UTD children and the value of simple reminder/recall systems.

Strengths and Limitations

This study has a number of specific strengths that enable it to contribute new and valuable knowledge regarding the accuracy of immunization registries. This is one of the few studies comparing two alternate sources of data on immunization status to a third Gold standard and is the only published Canadian study to assess the accuracy of an immunization registry. The one-provider system for immunizations in this setting was a particular strength as it virtually eliminated the possibility that ‘record-scattering’ of provider records biased the Gold standard (Stokley, Rodewald, & Maes, 2001; Yusuf et al., 2002).

There were some limitations to this study, which need to be considered in the interpretation of the findings. As study subjects were selected on the basis of immunization status, we were unable to make inferences about prevalence of UTD/not UTD status, and since subjects were not selected on the basis of the Gold standard, reporting of sensitivity, specificity, and predictive values would be misleading. We accept this limitation since a case-control study was the best design to obtain a substantial number of cases in a population with relatively highly immunization coverage (Lawrence, MacIntyre, Hull, & McIntyre, 2004), and because there is a recognized need to assess data accuracy in immunization program research of all study designs, not merely cohort and cross-sectional studies (Placzek & Madoff, 2011). The fact that registry accuracy was only assessed for respondents to the survey suggests the potential for bias in this study. However, we can think of no reason why respondents should differ substantially from non-respondents in the accuracy of parent report or registry data. Finally, an assumption was made that only incongruent reports of immunization status between parent and registry data need be adjudicated. While this is a weakness of the study, as not all records were checked, this approach is not uncommon. It is reasonably safe to presume that only 'errors of omission' occur in the registry if registry software is designed to only accept dates of doses (Wilton & Pennisi, 1994), as in our study. There is also precedent for assuming that parents who report their child as not UTD are accurate (Irving, Donahue, Shay, Ellis-Coyle, & Belongia, 2009; Suarez et al., 1997), implying relevant records were confirmed appropriately.

Conclusions

Despite the significant benefits of population-based immunization registries, our study highlights the potential challenges in ensuring the accuracy of this data source. Clearly, registry records should not always be presumed superior to parent report. At the population level, coverage derived from the registry may *under*-estimate coverage rate, while parent reports tend to *over*-estimate coverage. At the individual level, parents are perhaps more accurate at identifying their child as incompletely immunized, while the registry is more accurate at identifying completely immunized children. Studies such as this one contribute knowledge needed to improve the quality, completeness, and regional comparability of immunization registries before they can be considered a valid and reliable source of data on immunizations status (Khare et al., 2006). We strongly recommend further targeted studies of registry data accuracy in other settings. We also suggest that researchers utilizing immunization registries conduct a quality assessment of their data source, including using appropriate algorithms to confirm classification of immunization status and/or assessing a random sample of subjects in the registry to ascertain the accuracy of the registry versus a Gold standard.

Administrators of immunization registries can aid in assuring data accuracy by adopting strategies to decrease the potential for misclassification, including direct electronic data entry (Adams, Conners, Mann, & Palfrey, 2000; Kolasa, Chilkatowsky, Clarke, & Lutz, 2006), electronic data transfer (Mahon et al., 2008; Stecher et al., 2008), double data entry (Samuels et al., 2002), and audit procedures (Davidson et al., 2003). The problems with transcription of charted data identified in ours and other studies, suggest the need to assess the format of paper charting forms to ensure that relevant data are consistently reported in the appropriate location for ease and completeness of transcription. It is also essential to ensure that registries are comprehensive, i.e. that they are fully inclusive of the target population. It is likely that the registry used in our study was more comprehensive than in other contexts, due to the one-provider system for immunizations in Alberta; thus errors identified in our study might be further compounded in multi-provider settings due to record-scattering (Stokley et al., 2001; Yusuf et al., 2002).

The ultimate goal of any immunization tracking system is to improve the protection of the population from vaccine-preventable disease. As childhood immunization schedules become more complex, parent reporting is likely to become less and less accurate. This is particularly important in the Canadian context where schedules vary by region. As provider records become more and more scattered due to our increasingly mobile society (Boyd, Linkins, Mason, Bulim, & Lemke, 2002), registries have the potential to be not only the best, but the only viable method for tracking individual and population level coverage. This increasing dependence on registries can lead to improvements in population and individual health if appropriate measures are instituted to ensure the accuracy of this data source.

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Table 4-1: Registry and Parent Report versus Clinic Record

		Clinic Record (Gold standard)		
		UTD	**Not UTD**	**Total**
Registry	**UTD**	315 [a]	0 [a]	**315**
	Not UTD	16[b,c]	130 [a]	**146**
	Total	331	130	
Parent Report	**UTD**	329 [a]	42[b,c]	**371**
	Not UTD	2[b,c]	88 [a]	**90**
	Total	**331**	**130**	

[a] Registry and parent report agreed, so no clinic record review conducted.
[b] Confirmed by clinic record review.
[c] Indicates misclassification errors

Table 4-2: Types of Misclassification Error

Reasons for Misclassification[a]	**n**
In registry (n=16)	
Dose not entered in registry	1
History of varicella disease not entered in registry	4
Fewer doses required due to age at first dose, but not noted in registry	2
Doses given out of region, but not entered in registry	5
Child moved from another province and considered complete by other province’s schedule, but not noted in registry	4
In parent report (n=44)	
Parent reported child UTD, although:	
Missed dose(s) (unexplained intentional or unintentional misreporting)	25
Refused varicella vaccine	6
Did not complete immunizations until after received survey	11
Parent reported child not UTD, although actually complete (unexplained intentional or unintentional misreporting)	2

[a] As compared to Gold Standard (clinic record)

Chapter 5: Paper #4

The Role of Parental Concern about Vaccine Safety in Determining Immunization Coverage: A Multivariate Model of Personal and Systemic Factors

Shannon E. MacDonald, RN, PhD Candidate [a]
Donald P. Schopflocher, PhD [a,b]
Wendy Vaudry, MD [c]

[a] Faculty of Nursing, University of Alberta
[b] School of Public Health, University of Alberta
[c] Faculty of Medicine, University of Alberta

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Background

There is growing evidence that parental concern about vaccine safety is on the rise (Benin, Wisler-Scher, Colson, Shapiro, & Holmboe, 2006; Gust, Darling, Kennedy, & Schwartz, 2008), with studies from the USA showing that more than half of parents report such concerns (Freed, Clark, Butchart, Singer, & Davis, 2010; Opel et al., 2011; Smith, Chu, & Barker, 2004). We also know that immunization coverage rates in most regions of the USA and Canada are suboptimal, well below the recommended 95-97% uptake needed to assure herd immunity from vaccine-preventable disease (Centers for Disease Control and Prevention [CDC], 2012a & 2012b; Public Health Agency of Canada [PHAC], 2006). What we do *not* know is if the growing level of concern is responsible for the low immunization coverage rates, or whether other factors are equally or more responsible.

Research from the USA does suggest that parental concern about vaccine safety is linked to outright *refusal* of vaccines, as evidenced by the increasing number of parents filing non-medical exemptions in regions where immunization on school entry is mandatory (CDC, 2012b; Omer, Salmon, Orenstein, DeHart, & Halsey, 2009; Smith et al., 2004). There are limited comparable data available in Canada, because most regions (Ontario, New Brunswick, and Manitoba being the exceptions) do not have mandatory immunization policies for school entry. However, we do know that in some provinces, such as Alberta, the number of children who have received no immunizations by age two has been gradually increasing in recent years, from 3.0% in 2008 to 4.6% in 2011 (personal communication D. Dover, Alberta Health, December 17, 2012). While such data are informative, we do not know:

1) Whether level of concern about vaccine safety is significantly different between parents of unimmunized, incompletely immunized (i.e. having received some, but not all of the recommended vaccines), and completely immunized children
2) Whether other personal factors, sociodemographic factors, or characteristics of the immunization delivery system are more/equally significant in determining immunization uptake.
3) Whether vaccine safety concern continues to be associated with incomplete immunizations, even after controlling for these other factors.
4) Whether vaccine safety concern is responsible for low uptake in jurisdictions where immunizations are not mandatory on school entry.

The purpose of this study was to address these gaps in knowledge by determining the association between children’s incomplete immunization status and a wide range of personal, sociodemographic, and systemic factors. These included: (a) knowledge, attitudes, and beliefs about vaccines (including concern about vaccine safety), (b) other personal factors, such as social support, return to work and daycare use, (c) sociodemographic characteristics, and (d) systemic factors, such as the parents’ experiences with the immunization delivery system. This study was guided by the population health framework, which asserts that individuals’ health-seeking behaviours are influenced not only by their knowledge, attitudes, and beliefs, but also by other personal, societal, and environmental factors that constrain/promote health-promoting behaviours (Butterfield 2002; MacDonald et al., 2013). Improving our understanding of the multi-level factors influencing completion of immunizations is essential in order to efficiently and effectively target intervention efforts to maintain/increase immunization uptake.

Methods

Study Setting

This study was conducted in the city of Edmonton, Alberta, Canada and its surrounding rural communities. The population of the Edmonton region is approximately 1.1 million, with an annual birth cohort of roughly 16,000 children (Capital Health, 2008). Publicly-funded public health care in this region is provided by Alberta Health Services (AHS)-Edmonton Zone. All routine childhood immunizations in the region are administered free of charge exclusively by public health nurses in community-based clinics run by AHS and entered into a centralized immunization registry computer database, known as ‘Caseworks’ (Zhang et al., 2008). The comprehensive registry includes all children born in the region and those who move to the region and make contact with the public health system, but does not include Aboriginal children living on reserves, who receive their immunizations through federally administered programs.

Target Population

The study population was parents or primary care-givers of children two years of age (24 to 35 months old) who resided in the region. Immunization coverage rates for two-year-olds in the Edmonton region for the year of the study

(2009) were 77.15% for DTaP-IPV-Hib (4 doses of Diphtheria, Tetanus, acellular Pertussis, Polio and Haemophilus influenzae type b) and 88.77% for MMR (1 dose of Measles, Mumps, and Rubella) (Alberta Health, 2013); data are not available for coverage levels for the other vaccines. These numbers are well below the target levels of 95% for DTaP-IPV-Hib and 97% for MMR (PHAC, 2008). Data on the proportion of children who received every dose of all the vaccines in the recommended immunization schedule are not available, but typically the number is considerably lower (CDC, 2012a; PHAC, 2006).

Study Design

This case-control study compared the immunization views, experiences, and characteristics of parents of children whose immunizations were up to date (UTD) at two years of age (controls) to those who were not UTD (cases). To be considered UTD, two year old children in Alberta at the time of the study received a series of five vaccines: Diphtheria, Tetanus, acellular Pertussis, Polio and Haemophilus influenzae type b (4 doses); Measles, Mumps, Rubella (1 dose); Varicella (1 dose or history of disease); Meningococcal C conjugate (3 doses); and Pneumococcal 7-valent conjugate (4 doses). This is a total of 13 injections, with up to 4 needles at a single visit (at 12 months). Assessing coverage at two years of age allowed a 6-month grace period from the time the infant series is due for completion at 18 months.

Sample Size and Selection

The sample size for the study (671 cases and 671 controls) was calculated from a power analysis using an effect size and response rate identified from an earlier Canadian study (Boulianne et al., 2003), a 95% Confidence Interval, 80% Power (ß = 0.20), and a 1:1 ratio of cases to controls. Both cases and controls were selected from the regional immunization registry using a random number generation procedure. Use of the immunization database for sample selection enabled cases and controls to be selected from a pre-existing common administrative cohort of children that ensured comparability of cases and controls. An algorithm to identify UTD and not UTD children was used, and accounted for variation in the number of doses required for children who were older at initiation of the series or due to individual clinical conditions. This process was conducted by an AHS epidemiologist who selected and anonymized the sample.

Data Collection

Data collection involved extraction of immunization and socio-demographic data from the immunization registry and primary data collection through administration of a postal survey of parents in the year 2009. Numerous steps were taken to promote a high response rate for the survey and to minimize the potential for non-response bias, as advised by Dillman (2007). Specifically, parents of children selected from the registry were mailed an advanced notice postcard, followed by the immunization survey a week later. If no response was received within 3 weeks, a reminder postcard was sent, followed by a replacement survey 3 weeks later, and a final reminder letter 3 weeks later. The parent could opt out of the study at any point by leaving a voicemail message and the survey number that was assigned to each participant for tracking purposes.

Questionnaire Design

As there was no pre-existing questionnaire that assessed the wide range of variables of interest, a questionnaire was developed to meet the needs of the study. This process involved the following steps: (a) Literature was reviewed to identify relevant variables to assess; (b) Authors of previous studies using a relevant questionnaire were contacted (n=37), and those that were obtained (n=16) were assessed for relevance and validity; (c) Individual questionnaire items were borrowed or modified from the most validated tools available, with the permission of the authors (Bardenheier et al., 2004; Boulianne et al., 2003; CDC, 2000; Fredrickson et al., 2004; Gellin, Maibach, & Marcuse, 2000; Lieu et al., 1994; Salmon et al., 2005; Shui, Weintraub, & Gust, 2006; Strobino, Keane, Holt, Hughart, & Guyer, 1996; Thomas, Kohli, & King, 2004; Trauth, Zimmerman, Musa, Mainzer, & Nutini, 2002); (d) Parents (n=2) and practitioners/researchers in public health and pediatrics (n=4) were consulted to identify any missing themes; (e) The questionnaire was formatted according to Dillman's Tailored Design Method (Dillman, 2007); (f) Validation of the questionnaire for content and face validity included review by parents (n=5), epidemiologists (n=2), family medicine physicians (n=2), pediatricians (n=1), public health nurses (n=3), a survey methodologist (n=1), and immunization program administrators (n=4); (g) Cognitive interviewing (Drennan, 2003) was used with two parents to confirm ease of use and face validity (h) The questionnaire was pilot tested with six parents, including both parents who did and did not immunize their children; and (i) Final revisions were completed.

The final questionnaire consisted of 49 questions (some with sub-questions), took approximately 15 to 20 minutes to complete, and was at a grade 6 reading level (Flesch-Kincaid Grade Level Score 6.1; Kincaid, Fishburne, Rogers, & Chissom, 1975). Response formats included Yes/No, 5-point Likert-type scales (Likert, 1932), and some narrative responses. The survey asked about a number of sociodemographic characteristics and about parents' views and experiences with immunizations, including: knowledge, attitudes, and beliefs about immunizations and vaccine-preventable disease (including concern about vaccine safety); other personal factors (such as daycare use, residential moves); and systemic factors (such as access to immunization services, parents' experiences with their children receiving immunizations and the immunization delivery system). The questionnaire also asked about children's immunization status according to the parent-held immunization card or parent recall (if the card was not available for reference); parents were not *required* to consult the parent-held record due to concerns that excessive participant burden might adversely impact the response rate. Discrepancies in immunization status (UTD versus not UTD) between the registry and parent report were adjudicated by review of the clinic record, considered the 'Gold standard' (Stecher, Adelman, Brinkman, & Bulloch, 2008). Parents were not made aware that the primary variable of interest was concern about vaccine safety, in order to minimize any intentionally biased response on that key variable.

Ethical approval for this research study was obtained from the Health Research Ethics Board (Panel B) at the University of Alberta, which also administered the ethics review for AHS-Edmonton. Return of the completed questionnaire was taken as implied consent to participate in the study, as was described in the information letter sent to participants.

Data Entry and Analysis

Data were entered by the first author using the REDCap data management system (Harris et al., 2009) to facilitate validated data entry, cleaning, and management. Double data entry of 10% of the sample found a sufficiently low level of error (0.13%) to confirm the accuracy of data entry. Data analysis was conducted using SPSS version 20.0 (IBM Corp., 2011). A logistic regression model was developed to model the effects of the variables in distinguishing parents of children who were *not UTD* from those who were *UTD*. For the purposes of model building, children with *no vaccines* were excluded from the ‘not UTD’ group, i.e. ‘not UTD’ consisted of children who had received some but not all of their recommended vaccines by age two. This enabled us to include variables regarding parents’ experiences with immunization services in our model, which parents of children with no immunizations could not answer, and is consistent with the evidence that non-immunizers are a group distinct from those who start but do not complete immunizations (Diekema, 2012). Data analysis included bivariate and multivariate analyses and testing for potential confounders and theoretically plausible interactions.

We chose to select the variables to enter into the statistical model, and the order in which to enter them, based on clinical and theoretical grounds (i.e. purposeful model building). All of these variables, and possible confounders, were maintained in the model regardless of their statistical significance at any stage. While this approach does not create as parsimonious a model as other strategies, which either choose variables for inclusion based upon relationships within the data and/or drop variables when they cease to be statistically significant, we chose this approach for two reasons: (a) Many earlier multivariate studies (Boulianne et al., 2003; Taylor & Newman, 2000; Taylor et al., 2002) which investigated concern about vaccine safety excluded this key variable in their full model due to lack of statistical significance in bivariate analyses, overlooking the possibility that the variable might have achieved significance in the multivariate model; and (b) A key strength of our study is its ability to include a wide range of potentially influential variables. Important and interesting results can emerge from determining which variables become significant or non-significant when other variables are entered. This information allows us to infer that certain variables have indirect effects on uptake, that is, have effects that are mediated through the new variables entered. Such knowledge can contribute to future theoretical model building of direct and indirect effects on immunization uptake, which can be tested through multi-level statistical analysis.

Questionnaire items that were answered on a 5-point Likert-type scale were treated as continuous variables in analysis, unless they exhibited a clear nonlinear relationship. In such an event, the responses were dichotomized at the natural breakpoint in the data (i.e. when a scatter plot of data points identified a clear point at which the responses of cases and controls differed); in most instances this was also the midpoint in the range of possible values.

Composite scores were created when a previously validated tool was used to measure a construct, (e.g., need for social support) (Seeman & Berkman, 1988), or when correlation matrices and factor analysis suggested that multiple questions might be measuring a single construct. Specifically, exploratory factor analysis was used to identify when variations in multiple observed questions/variables truly reflected variation in a smaller number of unobserved variables, called *factors* (Russell, 2002).

All of the knowledge, attitude, and belief (KAB) questions were scored on a 5-point Likert-type scale. A factor analysis was conducted on the 17 KAB items, and two factors were extracted based on the Kaiser eigenvalue > 1 criterion (Russell, 2002). A Varimax rotation (Russell, 2002) separated two distinct groups of items, each group loading on only one factor. The variable "concern about vaccine safety" is a composite measure derived from responses to the first group of items, consisting of five safety related questions[2]. Item responses were reflected (i.e. flipped) as needed to ensure that the valence of all responses was consistent for the composite scale. The range of possible scores for the new variable was 5 to 25, and because the responses exhibited a nonlinear relationship, the variable was dichotomized as Yes/No at the midpoint, which was also the natural breakpoint; No ≤12 and Yes >12. Nine other KAB questions from the second group of items identified in factor analysis created a second composite

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[2] The five safety related questions were: (c) I am scared of the possible long-term side-effects of vaccines, (d) I am scared of the possible short-term side-effects of vaccines, (g) Vaccines are safe for children, (n) The additives and preservatives in vaccines are safe, (s) Combining vaccines into one shot is safe (e.g. Measles-Mumps-Rubella)

measure, which we interpreted to measure “lack of belief in disease susceptibility and severity, and vaccine effectiveness”, based on a consideration of the item content. This composite score was also dichotomized at the natural breakpoint; No ≤ 33 and Yes >33.

“Don’t know” (DK) responses to any questions were either: (a) scored as a “No” when judged that DK reflected absence of the factor or lack of influence of the factor (e.g., “Have you ever had a bad experience with one of your older children when he/she was receiving their immunizations”); or (b) scored as “Missing” when DK was judged more indicative of indecisiveness (e.g., “I could use more help with daily tasks than I currently receive”).

Missing item responses were excluded for calculation of frequencies, but imputed with the mean for multivariate analysis, to enable inclusion of the subject in the full model. Whenever missing values were imputed for a given variable, a dummy variable was created (Missing value=1; Not missing=0) to test in the model to confirm that the mean was a reasonable imputation.

A number of measures were undertaken to minimize and assess for non-response bias. In addition to the strategies to promote survey response described earlier, we also compared respondents and non-respondents in terms of the variables available in the immunization registry, i.e. immunization status and designated local health centre, based on postal code. Although it would have been ideal to conduct more comprehensive follow-up and assessment of non-respondents by telephone (MacDonald, Newburn-Cook, Schopflocher, & Richter, 2009), we did not have access to participants’ phone numbers.

Results

Survey Response

Of the 1342 surveys that were mailed out, 274 were determined to be ineligible (see Figure 5-1) because the address on file was not current or valid (i.e. surveys were returned to sender by the post office with no forwarding address), so the subject was lost to follow-up (LTFU). There was a higher proportion of subjects LTFU in some of the inner city neighbourhoods (35.9% in Eastwood and 30.4% in NorthCentral), whereas the more rural areas had relatively lower numbers LTFU (10.3% in Strathcona County, 12.4% in Westview/Stony Plain, 8.8% in Leduc, 11.1% in Fort Saskatchewan).

Of the remaining 1068 eligible subjects, 461 questionnaires were completed and returned (331 UTD and 130 not UTD), 18 subjects requested to be withdrawn from the study (9 UTD and 9 not UTD), and 589 did not respond, i.e. either did not receive the survey (but it was not returned by the post office) or chose not to participate (300 UTD and 289 not UTD). The final response rate was 43% (461/1068). Non-response bias assessment indicated that 51.7% (331/640) of controls (UTD) responded to the survey, while only 30.4% (130/428) of cases (not UTD) responded. Differential response rates based on subjects' designated health centre indicated a higher rate of non-response from some of the lower income neighbourhoods in the region (Eastwood and North-Central), and higher response rates from the rural regions of Strathcona County, Sturgeon County, and Westview (Stony Plain). More details on non-response assessment are provided in Chapter 6.

Characteristics of Study Participants

Table 5-1 presents the characteristics of respondents to the survey, including those with complete immunizations, incomplete immunizations, and no vaccines. As noted in Figure 5-1, the latter group was not included in the analysis described in this paper for reasons previously mentioned. The accuracy of parents' reporting of their children's immunization status as compared to the immunization registry is reported in another publication (currently under peer review).

Concern about Vaccine Safety

Concern about vaccine safety varied considerably among the three groups, i.e. parents whose children were completely immunized, incompletely immunized, and who had received no vaccines. Specifically, 100% (n=17) of the parents who gave no vaccines indicated that they were concerned about vaccine safety, while 35.4% (n=40) of parents of incompletely immunized children reported concern, and only 6.9% (n=23) of parents of completely immunized children were concerned.

Regression Analysis

Table 5-2 presents the results of the bivariate analysis (unadjusted odds ratios) and multivariate analysis (adjusted odds ratios, including all other variables in the model) for each variable. The outcome variable in the regression model was the child's immunization status (Child not UTD=1; Child UTD=0).

In regards to parents' knowledge, attitudes, and beliefs (KAB), concern about vaccine safety was found to be strongly associated with being not UTD in bivariate analysis (odds ratio [OR] 7.338, 95% CI 4.138 – 13.012), although the effect was somewhat tempered when the other variables were added to the model (adjusted odds ratio [aOR] 2.829, 95% CI 1.151 – 6.957). The other composite KAB variable ‘lack of belief in disease susceptibility and severity, and vaccine effectiveness’ had a strong association in bivariate analysis (OR 6.001, 95% CI 3.717 – 9.690) and in the multivariate model (aOR 4.629, 95% CI 2.017 – 10.625). Distrust of medical professionals and the government were significant when no other variables were considered, but not significant when other variables were in the model.

Other personal variables had varying degrees of influence. Personal variables that had no significant association with immunization status included the need for more social support or having a member of the household with a serious health issue needing extra time or care. Having moved in the past two years (i.e. since the child was born) was significantly associated with being not UTD, both in bivariate (OR 2.471, 95% CI 1.564 – 3.904) and multivariate analysis (aOR 3.908, 95% CI 2.075 – 7.358). As compared to parents/primary caregivers that did not work, children whose caregiver both worked and used childcare outside the home were *more* likely to be UTD (OR 0.488, 95% CI 0.290 – 0.819), even after controlling for all other variables in the model (aOR 0.310, 95% CI 0.144 – 0.671).

The only sociodemographic characteristic of statistical significance was having three or more children under the age of 18 years, which was positively associated with being not UTD in bivariate analysis, but did not stay significant when other variables were added to the model. None of the other sociodemographic characteristics were found to be significantly associated with incomplete immunizations in either bivariate or multivariate analysis.

In regards to systemic factors (as measured by parents' experiences with immunizations and the immunization delivery system), variables found to have an association in bivariate analysis, but not multivariate analysis, included having experience with vaccine side effects (less likely to be UTD), having a positive experience with the immunization provider (more likely to be UTD), having received adequate information on immunizations (more likely to be UTD), having heard negative views about immunizations in media (less likely to be UTD), and having considered not getting immunizations because of needle pain (less likely to be UTD). Parents who had ever delayed their child's immunizations because there were "too many needles given at one visit" were much more likely to have a child who was not UTD (OR 15.100, 95% CI 6.391 – 35.675; aOR 7.734, 95% CI 2.598 – 23.025). Children with a regular family doctor/pediatrician were more likely to be UTD, even when all other variables were controlled for (OR 0.182, 95% CI 0.070 – 0.474; aOR 0.219, 95% CI 0.057 – 0.846).

The perception that getting immunizations was a big hassle was strongly associated with incomplete immunization in multivariate analysis; only the final category (getting immunizations was quite or very difficult) was associated with incomplete immunization (aOR 14.470, 95% CI 2.206 - 34.922), while the lower categories (slightly or somewhat difficult) were not. The overall significance of the variable (p=0.084) was borderline insignificant, likely due to the lack of significance of the lower hassle categories. Interestingly, this relationship only surfaced in the multivariate analysis, suggesting that being ‘very hassled' interacts with other variables in a mediating or moderating role and hence is not significant in a bivariate analysis. We tested whether there was an interaction between the specific or general hassle questions and the number of children the parent had, but found no effect modification. None of the specific ‘hassles’ of getting a child immunized, outlined in Table 5-2, were associated with immunization status.

Discussion

Knowledge, Attitudes, and Beliefs, including Concern about Vaccine Safety

Given the rising level of concern about vaccine safety among parents today, it is important to know the impact that this, and other knowledge, attitudes, and beliefs, have on immunization uptake. Determining whether parents who do not complete their children’s immunizations are *more* concerned than those that do complete them is essential, as there is evidence to suggest that even parents who immunize their children have concerns, yet still go on to immunize their children (Boulianne et al., 2003; Gangarosa et al., 1998; Raithatha, Holland, Gerrard, & Harvey, 2003; Strobino et al., 1996; Taylor & Newman, 2000). If this is the case, it is important to understand what factors lead one concerned parent to continue to immunize, while another concerned parent stops.

Our study found that, not surprisingly, all parents whose children had received no vaccines had concerns about vaccine safety. This is consistent with previous American studies of parents who file vaccine exemptions, in which the primary reason for refusing vaccines was concern about vaccine safety (Fredrickson et al., 2004; Salmon et al., 2005; Smailbegovic, Laing, & Bedford, 2003; Smith et al., 2004). In contrast, of the parents in our study who *started, but did not complete*, their children's immunizations (the incompletely immunized group), 35.4% reported concern about vaccine safety. Although this concern was significantly higher than among the fully immunized group (in which only 6.9% reported concern), it still suggests that this incompletely immunized group may be influenced in their immunization decision by factors other than vaccine safety (Tickner, Leman, & Woodcock, 2006).

There is growing recognition in the literature that other personal and systemic factors may influence vaccine uptake and/or mediate parental concern about vaccine safety (Allred, Shaw, Santibanez, Rickert, & Santoli, 2005; Bardenheier et al., 2004; Gust et al., 2004). Incomplete immunizations are not necessarily the result of a deliberate decision not to immunize; difficulty accessing services, competing time demands after the mother returns to work, illness in the family, and other childcare commitments can result in incomplete immunizations despite the best of intentions (Tickner et al., 2006). Unfortunately, few studies have conducted multivariate analysis of the association between children's immunization status and parental concern about vaccine safety, while including other potentially influential factors. In three relevant studies (Boulianne et al., 2003; Taylor & Newman, 2000; Taylor et al., 2002), concern about vaccine safety was assessed, but excluded from the multivariate model because it was not significant in bivariate analysis. In four other multivariate studies (Allred et al., 2005; Bardenheier et al., 2004; Gust et al., 2004; Salmon et al., 2005), vaccine safety concern remained in the model, but none of the studies included systemic factors which may have influenced parents' immunization behaviours (except for Gust et al. 2004, which controlled for number and type of immunization providers).

Our study addresses this gap in knowledge by determining that concern about vaccine safety remains a significant factor in determining uptake amongst parents who started, but did not complete immunizations, even after other personal, sociodemographic, and systemic variables were included in the model. After controlling for all other variables, the odds of having concern about vaccine safety were almost three times higher (OR 2.829, 95% CI 1.151 – 6.957) amongst parents of incompletely immunized children. It is noteworthy that in bivariate analysis the odds were much higher (OR 7.338, 95% CI 4.138 – 13.012), indicating that other variables in the model were moderating this relationship. It is also significant that the other composite KAB variable, 'belief in disease susceptibility and severity, and vaccine effectiveness', had a higher association (OR 4.629, 95% CI 2.017 – 10.625) than vaccine safety concern in the multivariate model. It is interesting to compare these findings with other multivariate studies that assessed vaccine safety concern and also assessed the role of other health beliefs, such as disease susceptibility/severity and vaccine effectiveness. Gust and colleagues (2004) identified that viewing the diseases as not serious was a common reason parents gave for withholding a vaccine, although they did not test this association with vaccine status. In Bardenheier and colleagues’ study (2004) they reported that reasons parents reported for withholding a vaccine included concerns about side effects and lack of belief in disease severity and susceptibility. In multivariate analysis, belief in disease severity had a significantly larger effect (aOR 4.5 - 31.7, varying with vaccine) than concern about vaccine side effects (aOR 2.5 - 10.0, varying with vaccine). Salmon and colleagues (2005) also reported on the influence of these variables. They found that, in addition to the association with vaccine safety concern (aOR 3.76, 95% CI 2.52-5.59), the other factors influencing uptake included belief in disease susceptibility (aOR 4.06, 95% CI 2.76-5.97), disease severity (aOR 2.21, 95% CI 1.52-3.22), and vaccine efficacy (aOR1.99, 95% CI 1.33-2.97). The fact that these factors were significant in our study, which, unlike the others, also included other personal and systemic factors, is meaningful. This suggests that while vaccine safety concern is greater in the incompletely immunized group, negative views about vaccine effectiveness and lack of belief in susceptibility and seriousness of disease are even more prominent, even when other personal and systemic factors are considered. Perhaps this suggests that if parents do not trust in the efficacy of the vaccine and do not believe in the severity and susceptibility of the disease, then any small safety concern may lead them to not have their children vaccinated.

Other Personal Factors

In addition to concern about vaccine safety and other knowledge, attitudes, and beliefs, a number of other personal factors of interest emerged in our study. One of the personal factors found to have a significant association in our multivariate model was having moved to a new residence since the child was born. This finding is consistent with previous research which indicates that having moved since the child's birth was associated with under- immunization (Li & Taylor, 1993; Miller et al., 1994). Such a finding has implications for ensuring appropriate follow-up and tracking of families in the registry. The large number of undeliverable surveys in our sample (274, of which 214 were cases), also suggests that high residential mobility in the years after the birth of a child is a problem, not only for immunization uptake, but also for maintaining accurate records.

Another personal factor that was significantly associated with greater likelihood of completing immunizations in our multivariate model was having a primary caregiver who worked outside the home in the first two years after the child was born, if the child also attended daycare (aOR 0.310, 95% CI 0.144 – 0.671). The association was not significant if the child did not attend daycare. This finding suggests that the primary caregiver's return to work did not in fact act as a barrier to completion of children's immunizations, and/or that attendance at daycare promoted immunization completion. We do not have the data to explain why this occurs, although we hypothesize that parents' perception of risk may be altered once their child leaves the 'safe haven' of their home. Daycare immunization policies were not responsible for this finding, as there is no legislated daycare immunization policy in this region; the majority of parents in our study reported that their child's daycare did not require documentation of immunization for enrollment; and there are no routine immunization delivery programs targeting daycare populations in the region. Conventional wisdom has often been to target children in daycare centres as a means of increasing coverage rates, but if these are the children more likely to get immunized, it may be the children with a stay-at-home parent that need to be targeted with additional programs. Few studies have assessed the impact of return to work and daycare attendance on immunization status. One Canadian study (Boulianne et al., 2003) found that a mother with employment outside the home was a significant predictor of incomplete immunization, but they did not note whether the child was also attending daycare. Two other Canadian studies assessed the impact of daycare on uptake of influenza vaccine, specifically, and found it did not promote uptake (Chobotuk & Kellner, 2006; Grant et al., 2003). This is an issue requiring further exploration, and has potential policy implications for targeted programs to improve coverage.

Sociodemographic Characteristics

The only sociodemographic variable found to have a statistically significant relationship with incomplete immunization in our study was having three or more children, which was only significant in bivariate analysis. Other studies have found an association between having multiple children and under immunization, even in multivariate analysis (Boulianne et al., 2003; Dombkowski, Lantz, & Freed, 2004; Gust et al., 2008; Luman et al., 2005; Miller, Hoffman, Baron, Marine, & Melinkovich, 1994; Zhang et al., 2008), although none included systemic factors in their models. We are unsure of why this association did not hold up in our multivariate model. We hypothesized that this might be due to confounding or interaction between this variable and the general or specific hassles of getting children immunized, but neither were found in analysis. It could also be that the number of children exerts an indirect effect, which is explained by a more direct effect that we could not ascertain, or that our study was underpowered to detect the effect with all other variables included in the model.

We found that immunization status was not associated with any of the other sociodemographic variables tested in the model. Although many studies have found an association between low immunization uptake and certain sociodemographic factors (e.g., younger or older maternal age, low education, single marital status, non-Caucasian race, and income level) (Bobo, Gale, Thapa, & Wassilak, 1993; Boulianne et al., 2003; Cutts, Orenstein, & Bernier, 1992; Guttmann et al., 2006; Humiston et al., 1993; Li & Taylor, 1993; Miller et al., 1994; Prislin, Dyer, Blakely, & Johnson, 1998; Salsberry, Nickel, & Mitch, 1994; Zhang et al., 2008), other studies have found no association between these factors and uptake (Bigham, et al., 2006; Dummer, Cui, Strang, & Parker, 2012; Gust et al., 2004; Lieu et al., 1994).

Systemic Factors

Although some parental experiences with immunizations and the immunization system were significant in bivariate analysis, many did not maintain significance in the multivariate model. Such variables included: experience with side effects to a vaccine (less likely to be UTD), having positive experiences with the immunization provider (more likely to be UTD), having received adequate information on immunizations (more likely to be UTD), having heard negative views about immunizations in media (less likely to be UTD), and having considered not getting immunizations due to needle pain (less likely to be UTD). It is possible that sample size limited the ability of the study to detect differences in multivariate analysis, or these factors may exert an indirect effect on immunization uptake that is being mediated when a more direct effect is entered into the model. Either way, further research with a larger sample which enables multi-level modelling is needed to test these associations.

One highly significant variable in our study was having ever delayed the child’s immunizations because there were too many needles given at one visit, which was strongly associated with being incompletely immunized, both in the bivariate (OR 15.100, 95% CI 6.391 – 35.675) and multivariate models (aOR 7.734, 95% CI 2.598 – 23.025). This is consistent with other studies which have found that parents object to the number of injections (Happe, Lunacsek, Marshall, Lewis, & Spencer, 2007; Madlon-Kay and Haper, 1994; Meyerhoff & Jacobs, 2005; Woodin et al., 1995) and that fewer injections at each visit might improve uptake (Happe et al., 2007; Marshall, 2004). This finding suggests that measures to reduce the number of needles (either number overall in the schedule or number per visit) might have a meaningful impact on parents’ decision to complete immunizations. Unfortunately, such measures are not straight forward and may conversely reduce uptake. Decreasing the total number of needles in the schedule means using more combination vaccines, which in addition to the challenges of developing such vaccines, might antagonize parents who object to combining too many antigens in one vaccine (Gidengil et al., 2012). The other alternative, decreasing the number of needles per visit, then requires more visits, which in itself may decrease likelihood of completing immunizations (Dietz et al., 1994; Luman, Stokley, Daniels, & Klevens, 2001).

Our study sought to determine whether the logistic challenges of accessing immunization services acted as a barrier to completion of immunizations. This was measured using a general question about parents' perception of whether getting immunizations was a "hassle", i.e. was it difficult to do, as well as by asking about the specific challenges/hassles of accessing services. We found that parents who reported that it was a big hassle to get immunizations (measured as being 'quite or very difficult') were more likely to have a child who was incompletely immunized (aOR 14.470, 95% CI 2.206- 34.922). However, none of the *specific* logistical challenges were found to be significant, these being: difficulty travelling to the clinic, the clinic being far from home, having to bring other children or get childcare, having to take time off work or rearrange one's work schedule, or clinic hours/appointment times that were not convenient. Authors of earlier studies have suggested that these factors may play a role in completion of immunizations (Gore et al., 1999; Lannon et al., 1995; Morrow et al., 1998; Orenstein, Atkinson, Mason, & Bernier, 1990; Roberts, Poffenroth, Roos, Bebchuk, & Carter, 1994; Salsberry, Nickel, & Mitch, 1993; Thomas et al., 2004), but few have actually tested the association. One correlational study (Prislin et al., 1998) exploring this issue found that difficulty getting to the clinic (transportation and weather issues) and inconvenient clinic hours were associated with incomplete immunizations. Other than Prislin, previous studies did not test this association, instead making the assumption that such logistic challenges act as barriers to immunization uptake. The fact that our study did not find any significant relationship with uptake suggests that such assumptions may not hold true. Clearly more investigation is required to determine what is contributing to parents' perception of the challenges of immunization.

Our study found that having a regular family doctor or pediatrician was associated with completion of immunizations, with an aOR of 0.219 (95% CI 0.057 – 0.846) in multivariate analysis. Although previous studies have also identified that a relationship with a trusted health care provider positively influenced immunization uptake (Bigham et al., 2006; Gust et al., 2008; Omer et al., 2009), our study was conducted in a setting where childhood immunizations are not provided by physicians, but by public health nurses in community-based clinics. Studies that found this association in a context where physicians are the ones providing the immunizations might have difficulty drawing conclusions about the relationship between having a physician and getting immunizations due to confounding, since one has to go to the doctor to get one's shots, so consequently having a doctor is associated with being immunized. This study is unique in that it completely removes that factor. The finding that having a regular physician influences immunization uptake even when provided by public health nurses could be interpreted in a number of ways; it is possible that family physicians and pediatricians are discussing/promoting immunizations with their patients, even though they are not the ones providing them. Or it may just be that the type of person who has a mainstream healthcare provider, like a family doctor/pediatrician, is also more likely to complete their child’s immunizations.

Study Limitations

There are certain potential limitations to this study that should be considered in interpreting the findings. Although non-coverage error was minimized through use of a sampling frame that included almost the entire cohort of interest, it did exclude Aboriginal children living on reserves and children that moved into the region and made no contact with the public health system. Non-inclusion of these children in the database does not influence the comparability of cases and controls, and thus does not influence the internal validity of the study, but it does limit the generalizability of the findings to these groups.

Measurement error of both exposures and outcome was minimal in this study. Although use of a previously validated questionnaire may have been preferable, in the absence of such an instrument we followed a rigorous questionnaire development process and used validated questions whenever possible. We also anticipate that bias in the response to the primary variable of interest (concern about vaccine safety) was minimal, as participants were not aware that this was the primary exposure of interest in this study, so there should not be any differential responses regarding that particular variable between cases and controls. Misclassification of the outcome (immunization status) was largely avoided in our study, because although parents were asked their child’s immunization status, actual classification was based on the immunization registry, and validated with clinic records as needed.

The possibility of non-response error, both due to item non-response and unit non-response, was also considered. Item non-response in our study was minimal and not associated with immunization status or other characteristics of the participants; only 0.8% of questions were unanswered, and more than half of these were due to survey pages being stuck together (annoying, but not indicative of any pattern of item non-response on the part of the participant).

Our considerable efforts to minimize unit non-response enabled us to achieve a response rate of 43%, close to our anticipated response rate of 50%. This is similar to the levels of response achieved by the National Immunization Survey conducted annually in the U.S., in which response rates in the region of 52% have been reported, with lower rates of response from parents of not UTD children, as compared to UTD children (Gust et al, 2004; Bardenheier et al., 2004). However, this modest response rate does leave open the possibility for non-response bias if the associations determined in the sample differed between respondents and non-respondents.

Non-response bias assessment indicated that a higher proportion of controls (51.7%) in the sample responded to the survey, while only 30.4% of cases responded. It is unclear whether this is due to differential *refusal* on the part of cases, or *non-contacts* (i.e. undeliverable surveys that were not ‘returned to sender’ by the post office). Non-response assessment based on subjects’ designated health centre indicated a higher rate of non-response from some of the lower income neighbourhoods in the region, which may reflect less willingness/ability to respond to the survey due to competing priorities or a higher rate of non-contact due to a highly mobile lifestyle (Li & Taylor, 1993). The possibility that low response is due to higher rate of ‘undiagnosed non-contact’ (i.e. subjects did not receive the questionnaire, but they were not returned to us by the post-office), is supported by the fact that some of the lower income neighbourhoods also had a higher proportion of subjects LTFU. Unfortunately, without the ability to link non-response to variables of interest in this study (e.g. concern about vaccine safety), it is not possible to determine if real bias is present and thus there are no grounds for post-survey adjustment of the data (e.g. by weighting).

Conclusions

Prior to this study, there was limited evidence about the influence of parental concern on uptake of vaccines in a multivariate model including personal and systemic factors. This study contributed the following new knowledge: (1) There is a difference in concern about vaccine safety between parents who did not give any vaccines, those who incompletely immunized (i.e. started, but did not complete immunizations), and those that completed their children’s immunizations; (2) There are other personal and systemic factors that influence immunization completion; (3) Parental concern about vaccine safety is significantly associated with incomplete immunization, even after controlling for other factors; (4) Parental concern about vaccine safety does influence uptake of vaccines in a region without mandatory school immunization policies

In addition to the findings regarding concern about vaccine safety, this study contributes new knowledge and reinforces previous understanding regarding the other influences on immunization uptake. The other factors remaining significant in the multivariate model included:

- Lack of belief in vaccine effectiveness and disease susceptibility and severity (decreased uptake)
- Having moved to a new residence since the child was born (decreased uptake)
- Having a primary caregiver who worked outside the home in the first two years after the child was born, if the child also attended daycare (increased uptake)
- Having ever delayed the child's immunizations because there were too many needles given at one visit (decreased uptake)
- Having a regular family doctor or pediatrician (increased uptake)

The fact that some of the identified issues (e.g. concern about the number of needles) are policy and/or program related issues and that the solutions do not rest in public/parent health education may provide an opportunity. Given the challenge of changing attitudes and beliefs (Rosenstock & Strecher, 1988), these findings suggest additional ways that health providers and program and policy administrators can take measures to improve coverage levels.

There is clearly a need for more research that includes systemic factors alongside knowledge, attitudes, beliefs, other personal factors, and sociodemographic characteristics. Many of these factors will be challenging to assess, requiring multiple data sources (such as immunization registries, other databases, surveys, parent interviews) to enable linkage of reliable immunization data to parents' knowledge, attitudes, beliefs, and experiences with and access to the immunization delivery system. Multifactorial and multi-level studies that simultaneously examine personal and systemic factors are time and labour intensive methods of assessment, requiring large sample sizes and often multi-site collaboration, and necessitating considerable financial and logistic support.

While this study focused on an important population, namely parents who start, but do not complete immunizations, another particular focus for future studies is ‘fence-sitters’, i.e. parents who are concerned about vaccine safety, yet currently still go on to immunize (Opel et al., 2011). As was aptly stated in a recent editorial (Diekema, 2012), “because parents who oppose vaccination on the basis of personal beliefs will probably remain opposed despite the best efforts of clinicians and public health experts, the most effective way to increase vaccine coverage is to improve immunization rates among children whose parents either are open to vaccination but encounter barriers to obtaining vaccines or hesitate because of fears and concerns about safety” (p. 392). Attending to this larger group of parents has the potential to measurably improve immunization uptake, thereby promoting and protecting the health of children and the general public.

It is critical to understand the role of parental concern about vaccine safety in determining vaccine acceptance, as public confidence in the safety of vaccines is essential to maintaining high rates of immunization coverage (Salmon et al., 2005). As such vaccine safety concerns become more prominent in the media and on the Internet, the effects of these concerns will likely increase (Gust et al., 2004). However, it is also important to understand the influence of other personal and systemic factors in parents’ decisions regarding immunizations.

Understanding the factors associated with immunization uptake, and how they influence parents who have immunization safety concern will enable the design of more effective interventions to promote and maintain high levels of immunization coverage.

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Table 5-1: Characteristics of Parents According to Child's Immunization Status (None, Incomplete, Complete)

Variable	Immunization Status No Immunizations (N=17) [a]	 Incompletely Immunized (N=113) [a]	 Completely Immunized (N=331) [a]
Mother's age (mean in years)	33.18	32.81	32.85
Father's age (mean in years)	36.12	34.75	35.16
Mother's place of birth, % (n)			
In Canada	76.5% (13)	81.4% (92)	80.1% (265)
Not in Canada	23.5% (4)	16.8% (19)	19.3% (64)
Father's place of birth, % (n)			
In Canada	88.2% (15)	75.2% (85)	80.1% (265)
Not in Canada	11.8% (2)	22.1% (25)	19.0% (63)
Mother's level of education, % (n)			
Less than high school diploma	0% (0)	6.2% (7)	4.5% (15)
High school graduate	5.9% (1)	11.5% (13)	12.4% (41)
Some college/university	29.4% (5)	17.7% (20)	14.5% (48)
College or Trade certificate/ diploma	29.4% (5)	20.4% (23)	26.6% (88)
University undergraduate degree	17.6% (3)	30.1% (34)	30.2% (100)
Graduate/Post-graduate degree	17.6% (3)	12.4% (14)	10.6% (35)
Father's level of education, % (n)			
Less than high school diploma	0% (0)	4.4% (5)	6.6% (22)
High school graduate	0% (0)	12.4% (14)	13.6% (45)
Some college/university	0% (0)	10.6% (12)	9.1% (30)
College or Trade certificate/ diploma	58.8% (10)	28.3% (32)	39.3% (130)
University undergraduate degree	23.5% (4)	19.5% (22)	16.9% (56)
Graduate/Post-graduate degree	17.6% (3)	20.4% (23)	11.8% (39)
Primary caregiver Aboriginal, % (n)			
No	100.0% (17)	92.9% (105)	93.1% (308)
Yes	0% (0)	4.4% (5)	3.0% (10)
Primary caregiver a single parent, % (n)			
No	94.1% (16)	87.6% (99)	91.8% (303)
Yes	5.9% (1)	12.4% (14)	8.2% (27)
Household income, % (n)			
Less than $40,000	17.6% (3)	9.7% (11)	7.5% (25)
$40,000-59,999	23.5% (4)	9.7% (11)	10.3% (34)
$60,000-79,999	29.4% (5)	10.6% (12)	14.8% (49)
$80,000-99,000	11.8% (2)	15.9% (18)	16.9% (56)
$100,000-119,999	5.9% (1)	12.4% (14)	14.8% (49)
$120,000-139,999	5.9% (1)	6.2% (7)	9.4% (31)
More than $140,000	5.9% (1)	19.5% (22)	13.3% (44)

[a] Frequencies may not add up to total due to item non-response

Table 5-2: Unadjusted and Adjusted Odds Ratios for Association with *Incomplete* Immunization (As Compared To Complete Immunization)*

***** Odds ratios in **bold** lettering indicate statistically significant findings

Variable	Unadjusted OR (95% CI)	Adjusted OR [a] (95% CI)
Mother’s age (in years)	0.999 (0.959 - 1.040)	1.018 (0.937 – 1.106)
Father’s age (in years)	0.987 (0.950 – 1.026)	0.984 (0.910 – 1.064)
Mother’s place of birth		
In Canada	Reference	Reference
Not in Canada	0.856 (0.488 – 1.502)	1.067 (0.421 – 2.702)
Father’s place of birth		
In Canada	Reference	Reference
Not in Canada	1.235 (0.733 – 2.081)	1.798 (0.758 – 4.266)
Mother’s level of education [b,c]		
Less than high school diploma	Reference	Reference
High school graduate	0.679 (0.228 - 2.026)	0.687 (0.158 – 2.979)
Some college/university	0.893 (0.316 – 2.520)	0.609 (0.144 – 2.570)
College or Trade certificate/diploma	0.560 (0.204 – 1.534)	0.302 (0.071 – 1.287)
University undergraduate degree	0.729 (0.274 – 1.937)	0.597 (0.143 – 2.493)
Graduate or Post-graduate degree	0.857 (0.288 – 2.550)	0.777 (0.155 – 3.886)
Primary caregiver Aboriginal		
No	Reference	Reference
Yes	1.472 (0.491 – 4.413)	1.850 (0.377 – 9.069)
Primary caregiver a single parent		
No	Reference	Reference
Yes	1.588 (0.801 – 3.149)	1.655 (0.587 – 4.669)
Household income [b,c]		
Less than $40,000	Reference	Reference
$40,000-59,999	0.735 (0.275 – 1.964)	1.625 (0.416 – 6.346)
$60,000-79,999	0.557 (0.215 - 1.438)	0.809 (0.213 – 3.073)
$80,000-99,000	0.731 (0.301 – 1.772)	1.442 (0.397 – 5.229)
$100,000-119,999	0.649 (0.257 - 1.638)	2.071 (0.507 - 8.464)
$120,000-139,999	0.513 (0.174 – 1.518)	1.467 (0.298 – 7.215)
More than $140,000	1.136 (0.474 – 2.725)	3.770 (0.965 – 14.733)
Number of children in household		
<3	Reference	Reference
≥3 children	**1.643 (1.032 - 2.618)**	1.919 (0.927 – 3.973)
Need more social support [d]	1.044 (0.945 – 1.153)	1.099 (0.950 - 1.271)
Member of household with serious health issue		
No	Reference	Reference
Yes	1.264 (0.674 – 2.371)	1.615 (0.682 – 3.828)
Moved in past two years		
No	Reference	Reference
Yes	**2.471 (1.564 – 3.904)**	**3.908 (2.075 – 7.358)**

Worked & Used childcare in first two years?		
Did not work	Reference	Reference
Worked, but no childcare outside home	0.706 (0.417 – 1.195)	0.525 (0.247 - 1.116)
Worked and used childcare outside home	**0.488 (0.290 – 0.819)**	**0.310 (0.144 - 0.671)**
Concerned about vaccine safety [e]		
No	Reference	Reference
Yes	**7.338 (4.138– 13.012)**	**2.829 (1.151 – 6.957)**
Lack of belief in disease susceptibility & severity, and vaccine effectiveness [f]		
No	Reference	Reference
Yes	**6.001 (3.717 – 9.690)**	**4.629 (2.017 – 10.625)**
Distrust in medical professionals [g]	**1.317 (1.131 – 1.533)**	0.973 (0.750 – 1.262)
Distrust in government [h]	**1.116 (1.046 – 1.306)**	0.972 (0.813 – 1.162)
Knew someone with a vaccine-preventable disease		
No	Reference	Reference
Yes	0.810 (0.496 – 1.324)	0.813 (0.408 – 1.619)
Bad immunization experience with older child		
No	Reference	Reference
Yes	1.532 (0.806 – 2.915)	0.732 (0.285 – 1.881)
Experience with side effect(s)		
No	Reference	Reference
Yes	**2.688 (1.714 - 4.216)**	1.657 (0.869 – 3.160)
Positive experience with immunization provider [i]	**0.849 (0.789 – 0.912)**	0.993 (0.882 – 1.117)
Received adequate information on immunizations		
No	Reference	Reference
Yes	**0.320 (0.196 – 0.520)**	1.220 (0.535 – 2.780)
Heard negative views about immunizations in the media		
No	Reference	Reference
Yes	**1.789 (1.020 – 3.135)**	1.768 (0.783 – 3.996)
Ever delayed immunizations because too many needles at once?		
No	Reference	Reference
Yes	**15.100 (6.391–35.675)**	**7.734 (2.598 – 23.025)**
Consider not getting immunizations because so painful for child?		
No	Reference	Reference
Yes	**2.632 (1.399 – 4.953)**	0.818 (0.293 – 2.248)
Child has a regular family doctor/pediatrician		
No	Reference	Reference
Yes	**0.182 (0.070 – 0.474)**	**0.219 (0.057 – 0.846)**

Getting immunizations was a hassle/difficult [b,c]		
Not difficult	Reference	Reference
Slightly difficult	0.506 (0.061 – 4.191)	1.389 (0.676 - 2.852)
Somewhat difficult	1.372 (0.830 – 2.268)	1.089 (0.373 - 3.177)
Quite or Very difficult	1.983 (0.972 – 4.047)	**14.470 (2.206- 34.922)**
Specific hassles:		
Difficult to travel to clinic? [j]		
No	Reference	Reference
Yes	1.087 (0.637 – 1.854)	0.581 (0.242 – 1.396)
Clinic far from home? [k]		
No	Reference	Reference
Yes	1.243 (0.731 – 2.115)	1.089 (0.517 – 2.294)
Wait time in clinic unreasonable		
No	Reference	Reference
Yes	1.163 (0.627 – 2.158)	(0.653 (0.256 – 1.667)
Had to bring other children or get childcare		
No	Reference	Reference
Yes	1.111 (0.714 – 1.730)	1.047 (0.533 – 2.056)
Had to take time off/rearrange work schedule		
No	Reference	Reference
Yes	1.278 (0.827 – 1.975)	1.559 (0.808 – 3.007)
Clinic hours/appointment time convenient [l]	0.882 (0.777 – 1.001)	0.945 (0.774 – 1.153)

[a] Adjusted for all other variables in the model/table

[b] Variable non-significant overall in multivariate analysis

[c] Categories for Don’t know and/or Missing not shown and not significant

[d] Measured on a scale from 2 to10, based on previously validated measure (Seeman & Berkman, 1988)

[e] Measured on a scale from 5-25; Composite score of 5 variables (each on 5-point Likert scale) measuring vaccine safety. Dichotomized at natural breakpoint; No= scored ≤12; Yes= scored >12

[f] Measured on a scale from 9-45; Composite score of 9 variables (each on 5-point Likert scale) measuring belief in susceptibility to and severity of disease, and effectiveness of vaccines. Dichotomized at natural breakpoint; No= scored ≤ 33; Yes= scored >33

[g] Measured on a scale from 2 to 10; Composite score of 2 variables (each on 5-point Likert scale) measuring distrust in nurses and physicians

[h] Measured on a scale from 2 to 10; Composite score of 2 variables (each on 5-point Likert scale) measuring distrust in provincial and federal governments

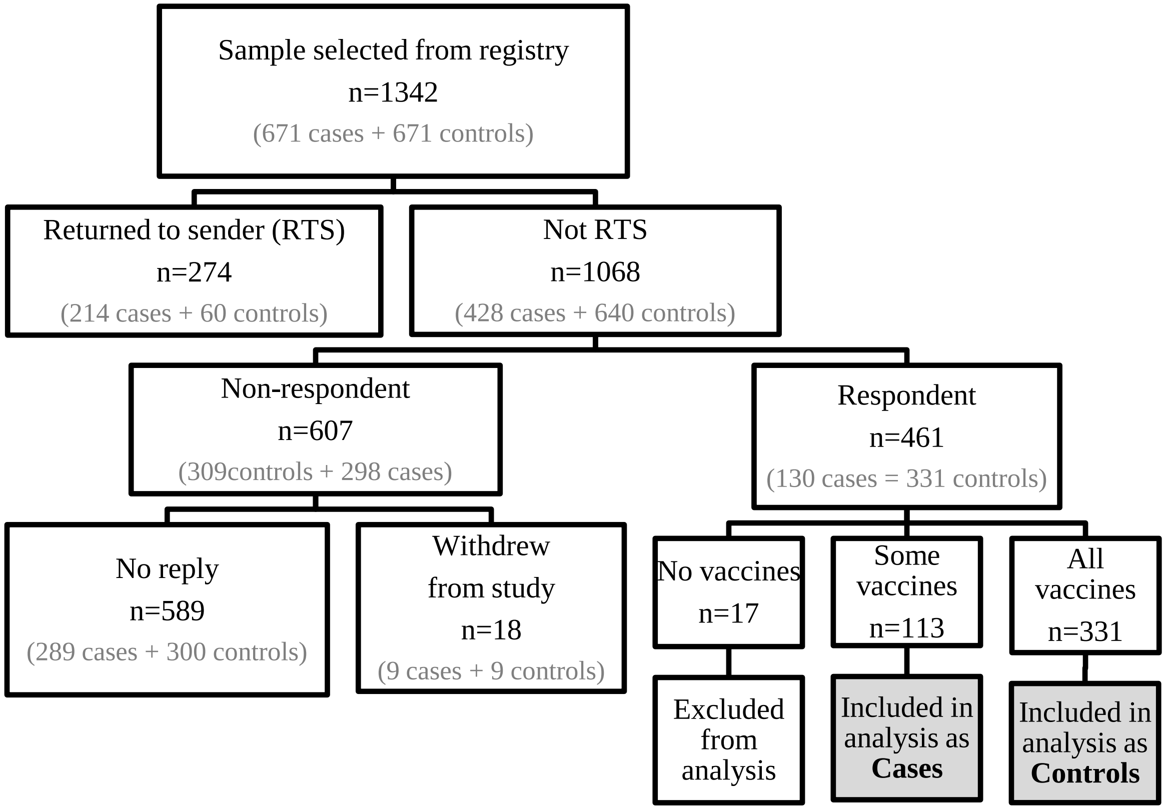
[i] Measured on a scale from 5-25; Composite score of 5 variables (each on 5-point Likert scale) measuring quality of previous experience (trust and positive interactions) with immunization providers (nurses and clinic staff).

[j] Measured on 5-point Likert scale. Dichotomized: No=Not difficult at all, Yes= slightly difficult to very difficult

[k] Measured on 5-point Likert scale. Dichotomized: No= Very or quite close, Yes=Quite or very far

[l] Measured on a scale from 2 to 10; Composite score of 2 variables (each on 5-point Likert scale) measuring convenience of clinic hours and appointment time

Figure 5-1: Sample Included in Analysis



Chapter 6: Conclusion

This final chapter presents a summary of the main findings of the four papers that comprise the thesis, the implications and contributions of the study to nursing and public health, the limitations of the study, and an outline of the next steps in my program of research.

Summary of Thesis Papers

The first two papers of this thesis (Chapters 2 and 3) provided important context and background for the thesis study. Chapter 2 presented a detailed description of the framework utilized in the conduct of the thesis study. This paper described the population health framework and highlighted the value of this approach for nurse researchers seeking to better understand multi-level influences on health behaviours. Chapter 3 identified the merits of using postal surveys for research in certain settings and populations, such as in this thesis study. This paper also outlined the potential pitfalls and recommended actions to consider in utilizing this research method.

The final two papers (Chapters 4 and 5) presented the findings of the research study itself. Chapter 4 described the assessment of database accuracy for classifying immunization status in the study. This was a critical step in assuring the validity of the study findings, as misclassification of this outcome measure would call into question all further analysis of associations. This paper reported that database misclassification was significantly less common than misclassification by parent report, but that it is still a consideration when using this data source. This confirmatory process ensured that the classification of immunization status used in our data analysis was correct. This study also made a contribution of new knowledge to the literature, which thus far has not focused on the accuracy of database classification, despite the fact that registries are being promoted as the new best source of immunization coverage data (PHAC, 2004a).

Chapter 5 presented the main findings of the thesis study, namely a bivariate and multivariate analysis of the factors potentially influencing immunization completion. The study found that while concern about vaccine safety was an important predictor of immunization completion, other factors mediated this relationship and played an important role in predicting completion of immunizations. Specifically, this study determined that:

1) Parental concern about vaccine safety was significantly associated with incomplete immunization of pre-school children, i.e. children that start, but do not complete immunizations (as distinct from those that refuse all vaccines), as compared to those that complete immunizations.
2) There are other personal and systemic factors that influenced immunization completion and that mediated the influence of parental concern about vaccine safety. Factors that decreased uptake included: (a) Lack of belief in vaccine effectiveness and disease susceptibility and severity; (b) Having moved to a new residence since the child was born; and (c) Having ever delayed the child’s immunizations because there were too many needles given at one visit. Factors that increased uptake included: (a) Having a primary caregiver who worked outside the home in the first two years after the child was born, if the

child also attended daycare; and (b) Having a regular family doctor or pediatrician.

3) The association between immunization uptake and parental concern about vaccine safety remained even after other personal and systemic factors, and sociodemographic covariates were added to the model.
4) Parental concern about vaccine safety influenced uptake of vaccines even in a region without mandatory school immunization policies.

The specific implications of these findings and the recommendations arising from them were discussed in Chapter 5. The following section will describe some of the overall implications and contributions that this study makes to nursing and to public health.

Implications and Contributions of the Study

There are a number of significant implications for nursing and public health arising from this study. This study has made an important contribution to new knowledge and reinforced previous knowledge from studies in other settings. The extent of immunization program research conducted in Canada is limited as compared to other regions of the world, most notably the U.S. and Australia. Differences in immunization administration and surveillance systems in those countries make it critical that Canadian immunization programs and providers are guided by data that is relevant to their context and needs. This study has addressed a significant gap in knowledge regarding the influences on immunization uptake in Canada and makes unique contributions to nursing knowledge and practice and to the public health system.

Implications for and Contributions to Nursing Knowledge and Practice

The results of this study are of key relevance to nurses, both those practicing in public health as well as those in other clinical/research areas. Provision of immunization against vaccine-preventable disease is a health service of primary importance to nurses, as well as to the public health system as a whole. Administration of immunizations is within the scope of practice of registered nurses across Canada and is a core competency of public health nurses (Canadian Nurses Association [CNA], 2001). In some provinces, such as Alberta, public health nurses are the sole provider of routine childhood immunizations, while other provinces/territories use a combination of nurse and physician delivery (CNA, 2001).

The role of nurses in immunization administration includes not only the safe and effective administration of the injection but also awareness of the facilitators/barriers to uptake and assessment and management of the concerns and needs of clients and their families. In order to administer immunizations safely and competently, registered nurses must possess knowledge, skills, and judgment related to the specific vaccines to be administered, and they must be prepared to address the concerns of clients related to the need for vaccines, vaccine safety, and vaccine effectiveness. The Immunization Competencies for Health Professionals document published by the Public Health Agency of Canada (PHAC) in 2008 (PHAC, 2008) stipulates that immunization providers are required to:

- “Apply relevant principles of population health for improving immunization coverage rates” (p. 13), including identifying barriers (economic, educational, system-based, and social factors) that may prevent uptake of immunizations; considering environmental factors, such as the clinic setting, appointment timing, and attitudes of staff to immunization, that impact on uptake; and developing strategies to overcome barriers and improve immunization services.
- “Communicate effectively about immunization” (p. 17), including understanding the importance of risk perception for immunization decision making; and assessing and responding appropriately to client knowledge, attitudes, and beliefs regarding immunization.
- “Address immunization issues using an evidence-based approach” (p. 26), including recognizing factors that lead to doubts, by both health professionals and the general public, regarding immunization; understanding the impact that misperceptions regarding vaccines have on the effectiveness of immunization programs; addressing these misperceptions using an evidence-based approach, such as knowing how to locate evidence-based sources of information; and using evidence-based scientific knowledge to develop clear, concise, and accurate messaging regarding vaccines.

All of these core competencies are supported by the findings of this thesis study. Clearly, understanding of the barriers and facilitators to immunization uptake is critical to practice effectively in this field (PHAC, 2008). The finding that many parents, regardless of their views on vaccine safety, do not see vaccine-preventable diseases as a serious threat to their child's health has significant implications for how nurses educate their clients. Strategies to improve accurate risk perception (including accurate knowledge about susceptibility and severity) by parents might involve individual-level educational programs for parents during one-on-one clinical care, as well as collective population-level programs through targeted public health interventions, public service announcements, and strategic use of the media. Such strategies emphasize the value of a 'population health' approach, not only for assessment of factors influencing health, but for development of multi-level interventions to improve health outcomes.

In addition to nurses whose designated role it is to administer immunizations, nurses practicing in all clinical areas have a responsibility to assess the immunization status of their clients as part of their role in promoting and protecting health (Alberta Health, 2007; CNA, 2001; Nies & Swanson, 1997). Nurses also play a role in passive surveillance[3] and active surveillance[4] of notifiable diseases and adverse events following immunizations (PHAC, 2008).

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[3] **Passive surveillance:** A system of surveillance relying on mandatory reporting by front-line healthcare providers. Examples include the Canadian Notifiable Diseases Surveillance System (PHAC, 2005) and the Canadian Adverse Events Following Immunization Surveillance System (CAEFISS) (PHAC, 2012).

[4] **Active surveillance:** Active case-finding, such as through regular review of hospital admission records. One such example is Canada's pediatric active surveillance system for identifying serious adverse events following immunization, vaccination failures, and selected infectious diseases, known as Immunization Monitoring Program – Active (IMPACT) (Canadian Pediatrics Society [CPS], 2012).

This study supports nursing knowledge and practice through provision of evidence-based knowledge of the specific barriers and facilitators to vaccine uptake, improved understanding by nurses of the role of personal and systemic barriers, and awareness by nurses of the role that they can play in improving uptake. Improved knowledge of the factors influencing uptake of immunizations is imperative to improving the provision of nursing care, and ultimately the protection of the public's health. This study serves as an example of how nursing research can be effectively guided by the population health framework, as described in Chapter 2. This study also provides new evidence regarding program and policy level issues in the public health system that can lead to improvements in immunization delivery systems, thereby improving the context for nursing practice and promoting the quality of nursing care.

Implications for and Contributions to the Public Health System

Improved knowledge of the systemic factors influencing immunization uptake has important implications and the potential to make contributions that impact public health programs and policy. The Canadian Immunization Guide and Canada's National Immunization Strategy both identify the need to monitor the quality of immunization services and to implement processes aimed at improving the effectiveness and efficiency of immunization programs in Canada (PHAC, 2006 & 2008). An important aspect of this monitoring process includes assessment of the factors influencing uptake of immunizations and potential barriers or facilitators to use of and access to immunization services.

This study has identified a number of factors which are best addressed through program or policy approaches. The fact that the solution to some of the issues identified in this study (e.g. number of needles, influence of daycare attendance) does not rest in public health education provides an opportunity to make system improvements that can target populations, rather than solely relying upon one-on-one interventions with individuals. For example, the fact that children attending daycare had higher rates of vaccine uptake suggests the need for programs that target children do not receive child care outside the home. The strong association between vaccine uptake and objections to multiple needles at one visit suggests the need to develop more combination vaccines, or reschedule the administration timeline of current vaccines, although there are limitations to these approaches, as outlined in Chapter 5.

Through dissemination of these study findings to program and policy makers in the Edmonton region and beyond, I hope to make an impact on immunization policy, programs, and clinical practice. The existing collaborative relationships that I developed with regional health administrators (e.g. Director of Communicable Disease Control and Manager of Immunization programs for AHS) should facilitate this process.

Although this study was conducted in the Edmonton region, these findings will be of relevance for the rest of Alberta, which shares the same immunization delivery programs, as well as Canada-wide, although system level differences in provincial/territorial immunization programs may limit the generalizability of some of the findings. In addition to the direct contributions of our findings, this study can also make contributions to future program, policy, and practice improvements in other regions through use of our study protocols in different settings and populations. The questionnaire that was rigorously developed for this survey incorporated knowledge from a vast array of valuable sources, and tailored the most valid questions for a Canadian context. This instrument could undergo additional testing for validity and reliability and be adopted or modified to enable production of comparable and context specific knowledge in other regions of Canada.

Potential Limitations of the Study

There are a number of potential limitations of this study, particularly in light of the issues discussed in Chapters 2 and 3 of this thesis. These chapters presented the ideal approach in terms of applying a conceptual framework and postal survey methodology in research. However, it is always necessary to balance the ideal with the possible in study design and implementation (McColl et al., 2001).

Limitations Related to Conceptual Framework

In Chapter 2, the value of the population health framework for nursing research was described, including the need to consider intermediate processes that connect population and individual-level factors, and the need to apply multi-level theory and methods as appropriate. This thesis study did apply the population health framework and adopted Milio's Ecological Theory of Prevention in describing how individual's health choices and decisions are limited by the constraints imposed by more distal factors. My study did not, however, focus a great deal on the most distal population-level factors (e.g. political and policy-level factors), instead focusing more on the intermediate processes (e.g. access to services, social support, trust in government), in addition to individual-level factors.

In Chapter 2 we also discussed the value of multi-level analytic methods in research guided by the population health framework. However, while multi-level *theory* is essential to conceptualizing the relationships between multi-level factors, multi-level *methods* are not always necessary or even useful (Diez-Roux, 2000). Our study did not utilize multi-level statistical analysis as we did not have adequate sample size to analyse hierarchical data involving individual-level factors nested within population-level contexts (Diez-Roux 2002). However, a strength of this study was the inclusion of both personal and systemic variables in one model. This is the first step in developing causal hypotheses that will be useful for future directions of inquiry using multi-level methods, such as hierarchical linear modeling, as well as models of direct and indirect effects, such as through structural equation modeling.

Limitations Related to Survey Error

The potential for *survey error,* as described in Chapter 3, must always be considered a potential limitation in the conduct of a postal survey study. A particular strength of this study was the sampling method, which minimized *selection bias* through random selection of both cases and controls from a common well-defined, pre-existing sampling frame of the target population (i.e. the immunization database). This ensured comparability of cases and controls by eliminating the problems that ensue when controls are selected from a different and potentially non-comparable source than cases. There are, however, limitations to the database that might lead to *non-coverage error* (also called sampling frame error); namely, there is an undefined, but likely small, number of children missing from the database. These include Aboriginal children living on reserves, who receive their immunizations through Health Canada, and new arrivals to Alberta who have not yet had contact with the public health system. Non-inclusion of these children in the database did not influence the comparability of cases and controls, and thus did not affect the internal validity of the study, but it will influence the generalizability of the findings to these specific groups. In addition, children who had left the region without informing the health region would still be listed in the database, and thus might influence the determination of coverage rates by increasing the denominator in the coverage equation, and potentially falsely elevating the number of incompletely immunized children (if they left the region before immunizations were completed). Given that the database was the most comprehensive cohort available for the purposes of this study, and was superior to sources used in other Canadian studies of the issue, this limitation is accepted and addressed by ensuring that study findings are not generalized to groups excluded from the sampling frame.

The potential for *information bias* was minimized in this study through measures limiting *measurement error*. *Outcome identification* bias due to misclassification of immunization status was minimal, as the determination of immunization status was based on an algorithm with clear criteria, determined using a pre-existing database, and confirmed by parental report, and the original immunization records as needed. *Observer bias* was not a concern in ascertainment of *exposure identification*, due to objective discernment of exposure information from a database and a questionnaire which was self-administered by participants. There is the potential for *reporting bias* due to intentional recall errors to occur in this study if cases and controls differed in their willingness to provide complete and accurate responses to sensitive questions. For example, participants might resist admitting that they used alternative health practices if they feared that they would be judged for doing so. However, this would only create bias if the cases were more likely to respond falsely than the controls, which seems unlikely. This potential was also minimized by assuring all participants in the cover letter that they were free to respond honestly without consequence. Participants were also not aware of the primary exposure of interest hypothesized in this study (i.e. concern about vaccine safety), so it is unlikely that there were any differential responses regarding that critical variable. *Recall bias* due to errors in memory are a possibility. Although socio-demographic factors and knowledge, attitudes, and beliefs are less dependent on memory, there is some risk of recall bias of systemic factors, as these were dependent on recall of previous experiences with immunizations. However, parents were being asked to recall information from the recent past, so errors in recall were minimized.

The potential for *non-response error* deserves considerable attention in light of the issues discussed in Chapter 3. *Item non-response* (i.e. specific questions being left blank on completed surveys) was discussed in Chapter 5, and not found to be a cause for concern in this study. *Unit non-response* (i.e. surveys not being returned by participants) is always an important consideration in postal survey research. This study undertook considerable measures to promote a high response rate, as described in Chapter 5. However, our response rate (43%) fell slightly below our goal of 50%, and leaves the possibility that unit non-response was an issue. As described in Chapter 3, there are a number of possible implications of survey non-response. A lower than anticipated response rate reduces the absolute sample size in a study, thereby (a) decreasing the statistical power of the study and increasing the likelihood for Type II error (not detecting a real effect that existed); and (b) increases the random error around the measurements, thereby increasing the standard error of the estimate, both of which increase the confidence intervals around the values and decrease the precision of the measurements (MacDonald, Newburn-Cook, Schopflocher, & Richter, 2009).

Our response rates also leave the potential for *non-response bias.* Because non-response bias is "a function of both the non-response rate and the magnitude of the difference between respondents and non-respondents on a key variable of interest in the study" (MacDonald et al., 2009, p. 98), we cannot presume that our modest response rate necessarily led to non-response bias. Non-response bias assessment is required to definitively determine this, the first step of which is to identify the reasons for non-response (typically non-contact and refusals) (Singer, 2006). The fact that we also had a high number of undeliverable surveys returned by the post office (20.4% were returned with no forwarding address) indicates that our database suffered from outdated address listings. This leaves the possibility that additional surveys that were not ‘returned to sender’ may not have been received by participants (i.e. actually non-contact, rather than refusal), which would have falsely elevated our rate of non-response. However, since we can only speculate on this matter, we must presume that those surveys that were not returned to sender were in fact refusals, thus requiring assessment for non-response bias.

Assessment for bias requires having auxiliary data available on the respondents and some or all of the non-respondents in order to identify the presence and magnitude of bias, and to carry out statistical adjustment as needed (MacDonald et al., 2009). In our study, we anticipated using the variables available in the Caseworks immunization registry (see Appendix A) and additional variables available through linkage with Babyworks, another database of the cohort maintained by AHS-Edmonton (see Appendix I) (Zhang et al., 2008). These represented a *rich sampling* frame and a *benchmark comparison*, respectively, as described in Chapter 3. Unfortunately, the high number of missing values (both individual items and entire subjects) in the Babyworks database precluded this planned benchmark comparison. Due to privacy concerns, we were not permitted to access participants’ phone numbers to conduct *double sampling*, which would have enabled us to assess responses from a sample of non-respondents, in order to estimate the measure of the key variables in the target population (MacDonald et al., 2009). We also considered using participants’ postal codes to link to sociodemographic characteristics available in Canada census data. However Canadian census data does not have a comparable reference group to our target population, i.e. families with young children, and does not provide information on the key variables of interest, i.e. vaccine safety concern and other personal and systemic variables. As previously stated in Chapter 3, often the choice of strategy for non-response bias assessment is dependent on the availability of data and time/financial constraints.

Assessment for non-response bias was therefore based on the relevant variables available in the Caseworks immunization registry, namely immunization status and local public health centre (as determined from participants' postal codes). Analysis indicated that 51.7% (331/640) of controls in the sample responded to the survey, while only 30.4% (130/428) of cases responded. This level of response and differential response rate for cases and controls is not uncommon in comparable surveys (Gust et al., 2004; Bardenheier et al., 2004; Salmon et al., 2005). It is unclear in our study whether this difference is due to differential *refusal* on the part of cases, or non-contacts (i.e. undeliverable surveys that were not 'returned to sender' by the post office). The latter is a distinct possibility, given the differentially large number of case surveys that were returned to sender (214 cases versus 60 controls).

The differential response rates based on subjects' designated health centres are seen in Figure 6-1 and the location of the health centres are seen in Figure 6-2. While Bonnie Doon, St. Albert, and Woodcroft had fairly equal numbers of respondents and non-respondents, the more rural regions of Strathcona County, Sturgeon County, and Westview (Stony Plain) had more respondents than non-respondents, although the differences were not statistically significant. There was a tendency for a higher rate of non-response from some of the lower income neighbourhoods in the region, with statistically significant differences in response rates from Eastwood and North-Central. Unfortunately, the reasons for these differentials cannot be clearly explained based on the data available. I speculate that these lower income regions may have more non-response due to the same systemic barriers that influence access to immunization services, but it might be that more residential mobility in these regions resulted in non-delivery of surveys, rather than actual refusal to participate (this is borne out by the data presented in Chapter 5 regarding more surveys being returned to sender in low income neighbourhoods).

Although interesting, differences or similarities in demographic characteristics often do not translate into analogous differences/similarities on study endpoints of interest (Jenkins et al., 2004). Unfortunately, none of the auxiliary data we had available provided data on the primary exposure of interest, namely concern about vaccine safety, or many of the other key exposure variables. So, although we identified some differences in response rates for parents from different public health centres, there is no necessary relationship with differences in measures of exposures, i.e. there is no reason to believe that respondents and non-respondents differed in how they would respond to the survey questionnaire.

The limitations in non-response bias assessment due to limited availability of auxiliary data precluded the possibility of conducting post-survey adjustment of the data. Although these measures are ideal in many circumstances (see Chapter 3), there are assumptions that must be met in order for these techniques to avoid compounding the bias in measurement. In particular, the assumption that respondents and non-respondents with similar measurable characteristics (in our case, immunization status and designated public health centre) are also similar on key survey variables (e.g., concern about vaccine safety) was not met, making post-survey adjustment inadvisable.

Additional Limitations

The choice of a case-control study design precluded the ability of our study to estimate prevalence for the variables of interest (e.g., how common is incomplete immunization, how many parents in the general population are concerned about vaccine safety), because participants were not a randomly selected representation of the target population, instead being chosen on the basis of outcome (i.e. immunization status). The decision to use the case control study design did, however, enable us to obtain a large enough number of cases (incompletely immunized children) in the sample. This would likely have been a challenge for a cohort design, given the relative infrequency of the outcome in the population. It also avoided the long timeline of following children from exposure to outcome (a period of up to three years), as would occur in a prospective cohort study.

It is recognized that non-English speaking parents were unlikely to respond to this survey. However, we had no way of identifying these individuals in advance, in order to offer assistance. Such participants were free to enlist help with the completion of the questionnaire on their own behalf, but realistically, I believe that they were unlikely to participate. However, according to Canadian census data consulted at study initiation, 98.5% of the population in the Edmonton area are English-speaking (Statistics Canada, 2007). Even in census tracts thought to have a higher population of immigrants, the proportion of English-speakers is 96-97%. Exclusion of this small number of non-English-speakers from this study is unlikely to have substantially biased the results, and did not warrant the substantial expenditure of resources required to identify and assess them.

Certain exposures of interest could not be measured in this study, which may limit generalizability to other regions. For instance, the influence of type of vaccine provider and cost of vaccines are factors explored in previous American studies, but could not be assessed in this study given the immunization delivery policies and programs in Alberta (i.e. single provider and no cost for relevant vaccines). This will not affect applicability of this study to Alberta's population, but will need to be considered in attempting to generalize these findings to other countries (or other provinces that have multiple provider systems). This study was also unable to assess the influence of remote rural residence, as the majority of the Edmonton health region falls within the urban municipality of Edmonton and relatively close rural counties.

Next Steps

The next steps following completion of this thesis include: (a) further analysis of data from the study, (b) dissemination of study findings, and (c) establishing my future program of research.

Further Analysis of Thesis Study Data

This study collected data on a large number of variables (as seen in the questionnaire in Appendix E), some of which were not analyzed in the main multivariate model presented in Chapter 5. I intend to conduct further analyses of these data. Specific issues to be explored in future analysis include:

1) Comparison of the knowledge, attitude, and belief (KAB) responses of the three groups of parents, namely those of completely, incompletely, and unimmunized children. The unimmunized group were not included in the multivariate model described in Chapter 5, so this data are as yet unexplored. In addition, the 17 KAB questions in the survey underwent factor analysis to create two main KAB variables for this model; one that measured concern about vaccine safety and one that measured belief in vaccine effectiveness and disease susceptibility and severity. Although this was a useful process to operationalize those specific factors and to reduce the number of variables included in the multivariate model, the specific responses of parents to each of the 17 KAB questions are of further interest and may provide a better understanding of the specific beliefs about diseases and vaccines held by parents in the three groups.
2) Further exploration of why working outside the home and use of childcare increases the likelihood of immunization. This will involve more detailed analysis treating daycare attendance as a dependent variable in a model with various other independent variables from the study (e.g. income).

3) Analysis of the narrative responses and comments parents reported on the questionnaire. This analysis will enhance the richness of the quantitative study findings and may provide additional knowledge or hypotheses worthy of future exploration.

Plan for Dissemination

Dissemination of the findings and recommendations from this study will involve various strategies that depend upon the different target audiences. This process will be facilitated by the collaborative relationships with AHS immunization program administrators and public health nurses that were established during the planning and conduct of this research. I have also more recently developed relationships with key personnel in immunization policy advisory roles at Alberta Health while planning for my post-doctoral studies. These include the Assistant Deputy Minister of Health, the Senior Provincial Medical Officer of Health, the Director of Population Health Surveillance, the Manager of Infectious Disease Surveillance, the Executive Director of the Surveillance and Assessment Branch for Community and Population Health, and the Executive Director of Immunization Programs. Notably, the latter two of this group are nurses. These relationships will be key to effective knowledge translation strategies. Specific plans for dissemination of study findings include:

1) Publication of study findings in peer-reviewed journals.
2) Presentation at relevant conferences and research meetings attended by immunization researchers and providers. Presentations have already taken

place at the Canadian Immunization Conference and a meeting of the Alberta-Wide Association of Epidemiologists and Biostatisticians (A-WEB).

3) Presentation of the study findings to program administrators at AHS, including the Alberta Director of Communicable Disease Control and the Manager of Immunization Programs, both of whom are nurses and were involved in the study since its inception. It is anticipated that these individuals will identify a core group of interested personnel to attend a presentation of findings.
4) Presentation and interactive discussion of study findings with Communicable Disease Control Clinical Development Nurses at AHS. These nurses are based at each of the public health centres in the region and perform clinical, advisory, and coordinating roles in maintaining best practice standards for the delivery and monitoring of immunization programs (AHS, 2012). During the data collection phase of the study, I met with these nurses to inform them about the study and to enlist their assistance in confirming immunization status from clinic charts when necessary. This group was extremely supportive, recognized the value of the study, and asked for a presentation of the findings of the study upon completion. These individuals can play an integral role in dissemination and implementation of the study findings and recommendations.
5) Study findings and recommendations may also be prepared in written report format for dissemination to various target audiences, including:
    a. Program planners and administrators at AHS

b. Policy makers and advisors at the Alberta Ministry of Health.
c. Public health nurses responsible for administration of immunizations at public health centres
d. Parents of pre-school aged children

Future Program of Research

Canada is facing a resurgence of vaccine-preventable disease outbreaks, leading to concerns regarding current and future immunization programs. However, Canada's National Immunization Strategy has highlighted a shortfall in immunization research capacity in Canada, identifying the need for timely and reliable evidence to support informed decision-making on program implementation and monitoring of vaccines (PHAC, 2004b). In September 2012 Alberta Health also identified the need to improve evidence in this area. My future program of research will support evidence-based immunization practice, programs, and policy through disease and immunization coverage surveillance, and identification of high risk populations and factors influencing immunization uptake. My long-term career goal is to obtain an academic research position with collaborations in public health clinical, program, and policy settings. My desire is for my research to be a direct product of issues that arise in the 'real world', and to feed back into real improvements in clinical, program, and policy decisions.

In addition to the knowledge and skills acquired in my research career to date, there are additional skills that I wish to obtain before seeking a faculty position. Through my exploration of the population health framework, I grew to appreciate the value and need for nurse researchers to utilize multi-level methods when appropriate. Given the evidence produced in my thesis study, the next step is to develop theoretical conceptualizations of how variables in the model are related and test this using a larger sample size and more advanced statistical methods to determine direct and indirect causes of immunization uptake and the relationship between variables at different levels. This will likely require a multi-site study in collaboration with other researchers to achieve the necessary sample size. While this will be a more long term goal, I intend to further my education in the use of structural equation modelling and hierarchical linear modelling.

During my PhD research, I also came to recognize some of the strengths and limitations of using administrative databases for research purposes. This has motivated me to expand my training in the use of administrative and surveillance data for population-based research. I will be pursuing post-doctoral studies to build on both the content and methods of my PhD work. My primary post-doctoral study will address one issue that arose in my PhD study, namely the benefits and disadvantages of reducing the number of needles children receive thorough the introduction of more combination vaccines. The specific objectives being addressed in the study are: (a) To measure the impact on vaccine uptake and disease incidence of introducing a combination measles, mumps, rubella, and varicell (MMR-V) vaccine, and (b) To determine if current surveillance systems are adequate to track coverage and enable timely follow-up of under-immunized children; Currently immunization uptake is assessed at 24 months of age, a full year after the first dose of the MMR-V vaccine is due at 12 months (booster is not due until 4-6 years), which may not facilitate timely follow-up of unimmunized children during a period of high risk for infection.

This fellowship will enable me to develop skills in the use and linkage of administrative databases for research and surveillance purposes. It will also allow me to develop working relationships with immunization program and policy administrators and advisors at Alberta Health, enabling a better understanding of the procedures and complexities of policy decisions and their implementation. This process will develop expertise for my future program of research and broaden my repertoire of research skills to include population-based studies using administrative data, thus enabling me to address more complex research questions. My proposed training will build on my existing strengths and prepare me to address policy-relevant questions with clear knowledge translation potential. This will position me to fill a unique need in the immunization research field and prepare me to provide evidence-based support for the development and implementation of future programs and policy.

Conclusion

In order to ensure that the Canadian public are protected from potential illness or death due to preventable disease it is critical to understand the influence of personal and systemic factors, and specifically the role of parental concern about vaccine safety, in determining immunization coverage. This PhD thesis describes the conceptual framework, methods, results, and contributions of a study of the factors influencing immunization uptake in a population of pre-school children. Through appropriate dissemination and interventions, the findings of this study can positively influence childhood immunization coverage rates in Alberta and beyond. Future research is needed to better understand the direct and indirect influences of the various factors, including development of a model of the influences on immunization uptake. My future program of research will encompass this issue, as well as the use of infectious disease and immunization surveillance systems to assess the need for improvements in health system delivery and nursing practice that will promote optimal protection of the public from vaccine-preventable infectious disease.

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Figure 6-1: Comparison of Non-Response by Subjects' Designated Public Health Centre

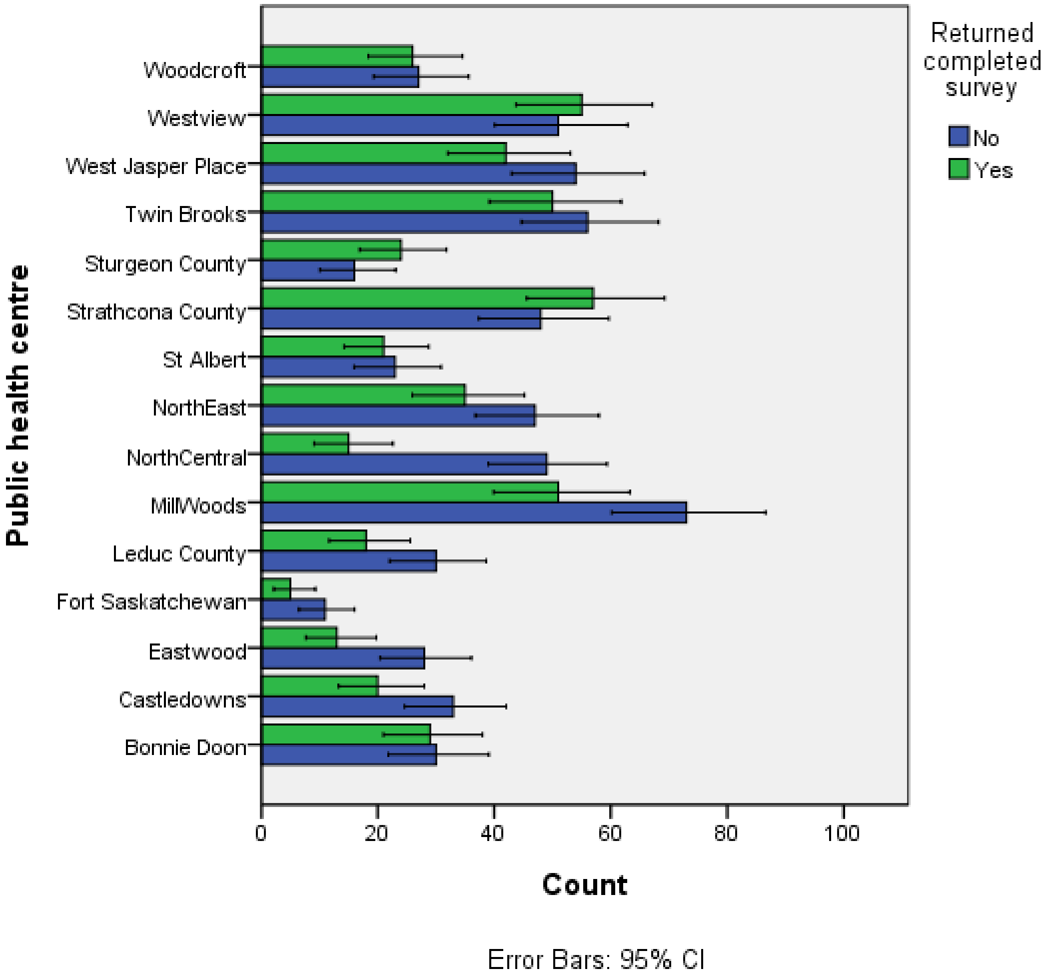
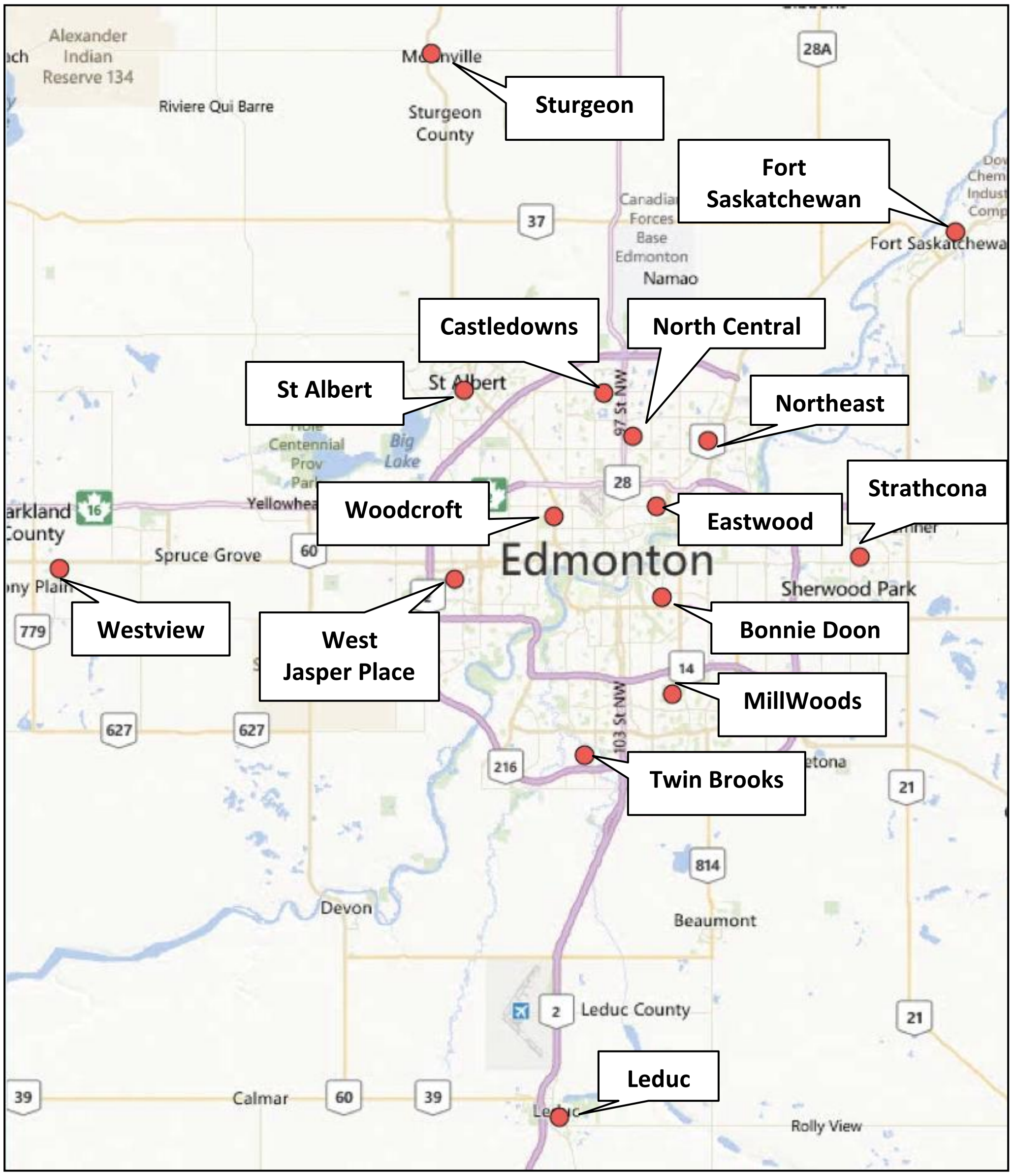


Figure 6-2: Map of Public Health Centres in Edmonton Zone



Appendices

Appendix A: Variables in Caseworks Immunization Database

Variables
File number
Date of birth[a]
Personal health number[a]
Address, including postal code[b]
Vital status
Gender
Health centre, based on current address
Immunization date for each of the recommended vaccine doses

[a] Not available to the researcher for privacy reasons
[b] Only postal code available to researcher

Appendix B: Alberta Immunization Schedule [a]

Age	Vaccine
2 months	• DTaP-IPV-Hib (diphtheria, tetanus, acellular pertussis, polio, haemophilus influenza type B) • PCV7 (pneumococcal conjugate 7-valent) • Men C (meningococcal conjugate)
4 months	• DTaP-IPV-Hib • PCV7 • Men C
6 months	• DTaP-IPV-Hib • PCV7
12 months	• MMR (measles, mumps, rubella) • Varicella • PCV7 • Men C
18 months	• DTaP-IPV-Hib

[a] At the time of the study (April 2009)

Appendix C: Advance Notice Letter

** Format differs from actual letter*

Advance Notice:
Study of Parents' Views and Experience with Immunization

Dear Parent or Guardian:

As the parent or guardian of a pre-school child in the Edmonton area, we are contacting you to ask for your help with a research study. The goal of this study is to better understand parents' needs and to improve the care of children in Alberta. This letter has been mailed to you by Alberta Health Services. Your name and address have not been given to us, the researchers.

The title of this research study is: **Determining the factors influencing immunization of Alberta pre-school children**. The purpose of this study is to find out what influences parents' decision of whether to immunize their children. We are interested in both the views of parents who have immunized their children and parents who have not. Feedback from both groups of parents is important for us to understand the reasons behind parents' choices.

A week from now, we will send you a survey asking about your views and experience with immunization. It should take about 20 minutes to complete the survey. A stamped envelope will be included, so that you can mail the survey back to us. Any information we collect during this study will not identify you by name. We will never see your name, address, or health care number.

Your participation in this study is completely voluntary and you can withdraw from the study at any time. This will not affect your or your child's health care in any way. If you do not want to take part in the study, please leave a message at: (780) XXX-XXX, stating the ID number located at the bottom of this page.

We hope that you will agree to help us in this important study. We believe that it will help us to better understand parents' needs and to improve the care of children and families in Alberta.

Sincerely,

Shannon MacDonald, RN, MN

On behalf of the research team:

Principal Investigators:	Dr. Christine Newburn-Cook RN, PhD, Professor, University of Alberta Faculty of Nursing Shannon MacDonald RN, MN (PhD student), Faculty of Nursing
Co-Investigators:	Dr. Linda Reutter RN, PhD, Professor, Faculty of Nursing Dr. Don Schopflocher PhD, Associate Professor, Faculty of Nursing Dr. Wendy Vaudry MD, Associate Professor, Faculty of Medicine

If you have any questions, please contact Shannon MacDonald at (780) XXX_XXXX or shannon.macdonald@ualberta.ca, or Christine Newburn-Cook at (780) XXX-XXXX or christine.newburn-cook@ualberta.ca. If you have any concerns about this study, you may contact Alberta Health Services Patient Relations Office (780) 482-8080.

ID# ______ This number helps us track your letter. It does not enable the researchers to identify who you are.

Appendix D: Information Letter

** Format differs from actual letter*

Information Letter: Study of Parents' Views and Experience with Immunization

Dear Parent or Guardian:

As the parent or guardian of a pre-school child in the Edmonton area, we are contacting you to ask for your help with a research study. The goal of this study is to better understand parents' needs and to improve the care of children in Alberta. This letter has been mailed to you by Alberta Health Services. Your name and address have not been given to us, the researchers.

Title of Research Study:	Determining the factors influencing immunization of Alberta pre-school children
Principal Investigators:	Dr. Christine Newburn-Cook RN, PhD, Professor, University of Alberta Faculty of Nursing Shannon MacDonald RN, MN (PhD student), Faculty of Nursing
Co-Investigators:	Dr. Linda Reutter RN, PhD, Professor, Faculty of Nursing Dr. Don Schopflocher PhD, Associate Professor, Faculty of Nursing Dr. Wendy Vaudry MD, Associate Professor, Faculty of Medicine

What is this study about? The purpose of this study is to find out what influences parents' decision of whether to immunize their children. We are interested in both the views of parents who have immunized their children and parents who have not. Feedback from both groups of parents is important for us to understand the reasons behind parents' choices.

What are we asking you to do? Included with this letter is a survey asking about your views and experience with immunization. We would like you to complete the survey for the child whose name is on the envelope (TO THE PARENT/GUARDIAN OF _________). It should take about 20 minutes to complete the survey. A stamped envelope is included, so that you can mail the survey back to us. By returning the survey, you are giving your consent to participate in the study. Your participation in this study is completely voluntary and you can withdraw from the study at any time. This will not affect your or your child's health care in any way. If you do not want to take part in the study, please leave a message at: (780) XXX-XXXX, stating the ID number located on the back page of the survey.

What will we do with the survey? When we receive your completed survey, we will link it to your child's immunization record, which will be anonymized (all identifying information removed) by Alberta Health Services. We will never see your name, address, or health care number. Your survey will be kept in locked storage at the University of Alberta Faculty of Nursing for 7 years (as required by university regulations), at which point it will be destroyed.

What are the benefits and risks of the study? You will not receive any direct benefit from taking part in this study, but your participation will help us to better understand parents' needs and to improve the care of children and families in Alberta. There are no risks to taking part in this study.

We hope that you will agree to help us in this important study.

Sincerely,

Shannon MacDonald, RN, MN

If you have any questions, please contact Shannon MacDonald at (780) XXX-XXXX or shannon.macdonald@ualberta.ca, or Christine Newburn-Cook at (780) XXX-XXXX or christine.newburn-cook@ualberta.ca. If you have any concerns about this study, you may contact Alberta Health Services Patient Relations Office (780) 482-8080.

Appendix E: Questionnaire

** Format differs from actual survey*

Parents' Views and Experience with Immunization

♦♦♦♦♦♦♦♦♦♦♦♦♦♦♦♦♦♦♦♦♦♦♦♦♦♦

- ♦ We are very interested in both the views of parents who have immunized their children and those who have not.
- ♦ The best person to complete this survey is the person who makes immunization decisions for your child or takes him/her for immunizations.
- ♦ Please answer the questions with reference to your child who is identified on the envelope (To the parent or guardian of …)
- ♦ It should take about 20 minutes to complete the survey. Most questions are simple check-boxes.
- ♦ Note that the word "immunization" means the same thing as "vaccination" and "shot".
- ♦ The "childhood immunizations" that we refer to in this survey are the immunizations usually offered at 2, 4, 6, 12, & 18 months of age. These include Diphtheria, Tetanus, Whooping cough (Pertussis), Polio, Haemophilus influenzae type b (Hib), Measles, Mumps, German measles (Rubella), Chickenpox (Varicella), Pneumococcal, & Meningococcal vaccines. We are *not* referring to influenza (flu shot), HPV (Gardasil), or Hepatitis B vaccines.

Start here

0) Who makes the immunization decisions for your child?

☐ Myself
☐ Myself and someone else. Who? ______________________
☐ Someone else. Who? _______________________

VIEWS ABOUT DISEASES AND IMMUNIZATIONS

We are interested in the different views that parents have about immunization. There are no “right” or “wrong” answers to these questions.

1) These are some of the beliefs that parents may have about immunizations and the diseases they are given for. How much do you agree or disagree with these beliefs?

	Strongly Disagree	**Disagree**	**Neither Agree Nor Disagree**	**Agree**	**Strongly Agree**	**Don’t Know**
a) It is possible that my child will get these diseases if he/she is not immunized	☐	☐	☐	☐	☐	☐
b) These diseases can lead to serious illness or sometimes death	☐	☐	☐	☐	☐	☐
c) I am scared of the possible long-term side-effects of vaccines	☐	☐	☐	☐	☐	☐
d) I am scared of the possible short-term side-effects of vaccines	☐	☐	☐	☐	☐	☐
e) My child should be immunized at the recommended age	☐	☐	☐	☐	☐	☐
f) Immunizations are so painful for my child that I consider not getting them	☐	☐	☐	☐	☐	☐
g) Vaccines are safe for children	☐	☐	☐	☐	☐	☐
h) My child could get the disease from the vaccine	☐	☐	☐	☐	☐	☐
i) Immunization will help protect my child against these diseases	☐	☐	☐	☐	☐	☐
j) My child’s immune system could be weakened as a result of too many immunizations	☐	☐	☐	☐	☐	☐
k) My child should receive all the doses of recommended vaccines	☐	☐	☐	☐	☐	☐
l) The use of alternative practices, such as homeopathy, can eliminate the need for immunization	☐	☐	☐	☐	☐	☐

	Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree	Don’t Know
m) If my child has a cold or stomach flu he/she can still be immunized	☐	☐	☐	☐	☐	☐
n) The additives and preservatives in vaccines are safe	☐	☐	☐	☐	☐	☐
o) Vaccines are more dangerous than the diseases they are meant to protect against	☐	☐	☐	☐	☐	☐
p) People might criticize me if I don’t immunize my child	☐	☐	☐	☐	☐	☐
q) My child doesn’t need to be immunized, because he/she is protected from disease by all the other immunized children around them	☐	☐	☐	☐	☐	☐
r) I myself am scared of getting needles	☐	☐	☐	☐	☐	☐
s) Combining vaccines into one shot is safe (e.g. Measles-Mumps-Rubella)	☐	☐	☐	☐	☐	☐

2) Do you feel that Alberta should have a law requiring immunizations for entry to school (unless there is a medical reason why the child can’t be immunized)? *(Choose only one)*

☐ No
☐ Yes, but only if people can opt out for religious or personal reasons
☐ Yes, absolutely
☐ Don’t know

3) How much do you trust each of these people or organizations (we mean in general, not specifically related to immunizations)?

	No Trust	Very Little Trust	Some Trust	Moderate Amount of Trust	A Lot of Trust	Don't Know
Medical doctors	☐	☐	☐	☐	☐	☐
Registered nurses	☐	☐	☐	☐	☐	☐
Alberta provincial government	☐	☐	☐	☐	☐	☐
Government of Canada	☐	☐	☐	☐	☐	☐

4) Are you worried about side effects or reactions from each of these vaccines?

	Not at all Worried	Slightly Worried	Somewhat Worried	Quite Worried	Extremely Worried	Don't Know
DTaP-IPV-Hib vaccine (sometimes called Pentacel or Pediacel) which includes Diphtheria, Tetanus, Polio, Whooping cough (Pertussis), & Haemophilus influenzae type b	☐	☐	☐	☐	☐	☐
MMR vaccine which includes Measles, Mumps, & German measles (Rubella)	☐	☐	☐	☐	☐	☐
Chickenpox (Varicella) vaccine	☐	☐	☐	☐	☐	☐
Pneumococcal vaccine	☐	☐	☐	☐	☐	☐
Meningococcal vaccine	☐	☐	☐	☐	☐	☐

5) If you have concerns about the safety of specific vaccines, please tell us which vaccine, or which part of the vaccine, and the reason for each.

____

____

____

____

6) Have you or anyone you have known personally ever had any of the diseases mentioned in Question 5?

☐ No

☐ Yes. If yes, which one(s)? ______________________________

☐ Don't know

7) Does your religion or culture influence your decision about childhood immunization?

☐ No
☐ Yes
☐ Don't know

a) If yes, which religion or culture is it? ___________________________

SOURCE OF HEALTH CARE

8) Who is your child's regular health-care provider (the person you take your child to for check-ups or when they are sick)**?** *(Choose only one)*

☐ My child doesn't have a regular health-care provider
☐ Family Doctor or Pediatrician
☐ Nurse
☐ Chiropractor
☐ Homeopathic doctor
☐ Naturopathic doctor
☐ Spiritual/Folk healer
☐ Acupuncturist
☐ Other. Please specify: _________________________

9) Here is a list of health care providers. Please tell us whether each of these providers has encouraged or discouraged you to immunize your child. If you have never visited or received immunization advice from this type of provider, choose "Never visited *or* Didn't get advice"

	Strongly Discouraged	**Discouraged**	**Neither Encouraged Nor Discouraged**	**Encouraged**	**Strongly Encouraged**	**Never visited *or* Didn't get advice**
Doctor	☐	☐	☐	☐	☐	☐
Nurse	☐	☐	☐	☐	☐	☐
Chiropractor	☐	☐	☐	☐	☐	☐
Homeopathic doctor	☐	☐	☐	☐	☐	☐
Naturopathic doctor	☐	☐	☐	☐	☐	☐
Spiritual/Folk healer	☐	☐	☐	☐	☐	☐
Acupuncturist	☐	☐	☐	☐	☐	☐

IMMUNIZATION STATUS

Please remember to answer these questions in reference to the child identified on the envelope (To the parent or guardian of …). You can look at your child’s immunization card if you wish, but it is not necessary.

10) Please choose the statement below which is most true for you.

☐ My child has not received any immunizations.

Please explain the reason(s) ____

☐ My child has received some, but not all, the immunizations for their age.

Please explain the reason(s)____

☐ My child has received all the immunizations for their age.

☐ I don’t know if my child has received all the immunizations for their age.

11) Do you plan to continue getting your child’s recommended immunizations?

☐ No
☐ Yes
☐ Don’t know

12) Does your child have an allergy or other medical reason why he/she can not be immunized?

☐ No
☐ Yes. Please explain, being as specific as possible ______________________________
☐ Don’t know

PREVIOUS EXPERIENCE WITH IMMUNIZATIONS

We are interested in your previous experiences with immunizations. Please think back to when your child was getting his/her immunizations.

If your child has never been immunized, please skip to question #27

13) In general, how difficult (how much hassle) was it to get your child immunized?

☐ Not difficult at all
☐ Slightly difficult
☐ Somewhat difficult
☐ Quite difficult
☐ Very difficult

14) How difficult is it for you to get to and from the clinic for your child's immunizations?

☐ Not difficult at all
☐ Slightly difficult
☐ Somewhat difficult
☐ Quite difficult
☐ Very difficult

15) How close is the clinic to your home?

☐ Very close
☐ Quite close
☐ Neither close nor far
☐ Quite far away
☐ Very far away

16) Once you arrive at the clinic, how long do you usually have to wait past your scheduled appointment time?

☐ No wait
☐ Less than 15 minutes
☐ 15 to 30 minutes
☐ More than 30 minutes

a) Do you think this is a reasonable amount of time?

☐ No
☐ Yes
☐ Don't know

17) Have you ever had to bring other children with you, or get a baby-sitter for your other children, when your child had to go for his/her immunizations?

☐ I don’t have other children
☐ No
☐ Yes

a) If yes, how difficult did this make it for you to take your child for his/her immunizations?

☐ Not difficult at all
☐ Slightly difficult
☐ Somewhat difficult
☐ Quite difficult
☐ Very difficult

18) Did you ever have to take time off work, or re-arrange your work schedule, to take your child for his/her immunizations?

☐ I don’t work outside the home
☐ No
☐ Yes

a) If yes, how difficult did this make it for you to take your child for his/her immunizations?

☐ Not difficult at all
☐ Slightly difficult
☐ Somewhat difficult
☐ Quite difficult
☐ Very difficult

19) Have you ever missed or delayed your child’s immunizations because:

	No	**Yes**	**Don’t Remember**
a) You forgot?	☐	☐	☐
b) You were too busy?	☐	☐	☐
c) It was just too much hassle?	☐	☐	☐
d) Your child was sick with a cold or stomach flu?	☐	☐	☐
e) You didn’t want him/her to get too many needles in one visit?	☐	☐	☐

20) These questions are about the clinic hours and appointment times.

Please tell us how much you agree or disagree with the following statements.

	Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree	Don't Know
a) The hours when the immunization clinic is open generally suit me	☐	☐	☐	☐	☐	☐
b) The clinic usually has an appointment available near the date when my child's immunization is due	☐	☐	☐	☐	☐	☐

21) These questions are about your previous experience with immunization providers.

Please tell us whether you agree or disagree with the following statements.

	Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree	Don't Remember
a) The front desk staff at the clinic treated me well	☐	☐	☐	☐	☐	☐
b) The nurses at the clinic treated me well	☐	☐	☐	☐	☐	☐
c) I trusted the advice of the nurses at the clinic	☐	☐	☐	☐	☐	☐
d) The nurse gave me the information that I wanted to know about immunizations	☐	☐	☐	☐	☐	☐
e) The nurse acted like my questions and concerns were important	☐	☐	☐	☐	☐	☐

22) When you have gone to the clinic for your child's immunizations, did the nurse ever refuse/delay immunizing your child because of the following reasons?

	No	Yes
a) My child was too young	☐	☐
b) The clinic did not have the vaccine	☐	☐
c) The nurse didn't want to give so many needles at one visit	☐	☐

23) Has your child ever gone to get immunized when he/she had a cold or stomach flu?

☐ No
☐ Yes ↳ **If yes, did the nurse ever refuse/delay immunizing your child for this reason?**
  ☐ No
  ☐ Yes

24) Has your child ever gone to get immunized when he/she was taking antibiotics?

☐ No
☐ Yes ↳ **If yes, did the nurse ever refuse/delay immunizing your child for this reason?**
  ☐ No
  ☐ Yes

25) Has your child ever arrived at the clinic late for his/her immunization appointment?

☐ No
☐ Yes ↳ **If yes, did the nurse ever refuse/delay immunizing your child for this reason?**
  ☐ No
  ☐ Yes

EVERYONE SHOULD ANSWER THE QUESTIONS FROM HERE ON:

26) Have you ever had a bad experience with one of your older children when he/she was receiving their immunizations? *(Choose one)*

☐ I don’t have any older children
☐ I did not immunize my older children
☐ No
☐ Yes. Please explain ____
☐ Don’t remember

27) Have you or anyone you have known personally ever had a side effect or serious reaction following an immunization?

☐ No
☐ Yes
☐ Don't know *or* Don't remember

a) If yes, what was it? ______________________
____

SOURCES OF INFORMATION

28) Who or what has been your most trusted source of information about immunization? ____
____

29) Do you feel that you received enough information about immunization?

☐ No
☐ Yes
☐ Don't know *or* Don't remember

30) Have you heard from the media (e.g. magazines, newspapers, TV, internet) opinions that do not support immunization?

☐ No
☐ Yes

a) If yes, have they influenced your opinion about immunizations?

☐ No, not at all
☐ Yes, but I haven't stopped immunizing my child
☐ Yes, I stopped immunizing my child
☐ Other. Please specify:______________________________________

DEMOGRAPHIC INFORMATION

This last set of questions will help us describe the group of parents who participated in the survey. No individual can be identified from this information.

31) How are you related to the child?

☐ Mother (including step, foster, adoptive) or female guardian
☐ Father (including step, foster, adoptive) or male guardian
☐ Other (Please specify your relationship with the child) ________________________

32) How many people live in your household (including yourself)? _______

33) How many children under 18 years of age are you responsible for? _______

a) Please list their age(s) (Use age on last birthday)___________ , ___________ ,
___________ , ___________ , ___________ , ___________ ,
___________ , ___________ , ___________ , ___________ ,
___________ , ___________ .

34) Are you a single-parent?
☐ No
☐ Yes

35) How old is the child's mother? Give age on last birthday: ________

a) If you don't know, or prefer not to give the exact age, is the child's mother:
☐ Less than 20 years
☐ 20-29 years
☐ 30-39 years
☐ 40 years or more
☐ Don't know__________

36) What is the highest level of education completed by the child's mother?
☐ Grade 9 or less
☐ Some high school
☐ High school graduate
☐ Some college/university
☐ College/Non-university /Trade certificate or diploma
☐ University undergraduate degree
☐ Graduate or post-graduate degree (Masters, PhD, Post-Doctorate)
☐ Other. Please specify _________________________
☐ Don't know

37) How old is the child's father Give age on last birthday: ________

a) If you don't know, or prefer not to give the exact age, is the child's father:
☐ Less than 20 years
☐ 20-29 years
☐ 30-39 years
☐ 40 years or more
☐ Don't know__________

38) What is the highest level of education completed by the child's father?

☐ Grade 9 or less
☐ Some high school
☐ High school graduate
☐ Some college/university
☐ College/Non-university /Trade certificate or diploma
☐ University undergraduate degree
☐ Graduate or post-graduate degree (Masters, PhD, Post-Doctorate)
☐ Other. Please specify ________________________
☐ Don't know

39) This question relates to the amount of support that you receive in your daily life. **Please tell us whether you agree or disagree with the following statements.**

	Strongly Disagree (don't need any help)	**Disagree** (don't need much more help)	**Neither Agree Nor Disagree**	**Agree** (need more help)	**Strongly Agree** (need much more help)	**Don't Know**
a) I could use more help with daily tasks than I currently receive	☐	☐	☐	☐	☐	☐
b) I could use more emotional support than I currently receive	☐	☐	☐	☐	☐	☐

40) Does anyone in your household have a serious health issue that requires extra time and attention?

☐ No
☐ Yes
☐ Don't know

41) Please estimate the total income from all sources for all members of your household combined (before taxes and deductions) in 2008. Please be assured that, like all your survey answers, this information will be kept confidential. *(Choose one)*

☐ Under $20,000
☐ $20,000 – 39,999
☐ $40,000 – 59,999
☐ $60,000 – 79,999
☐ $80,000 – 99,999
☐ $100,000 – 119,999
☐ $120,000 – 140,000
☐ Over $140,000
☐ Prefer not to answer *or* Don't know

42) Do you consider yourself to be of Aboriginal origin?
☐ No
☐ Yes
☐ Prefer not to answer *or* Don’t know

43) Where was your child born?
☐ In Canada
☐ In another country. Please specify ______________________________

44) Where was the child’s mother born?
☐ In Canada
☐ In another country
What country? _____________________________
How long ago did she move to Canada? ________

45) Where was the child’s father born?
☐ In Canada
☐ In another country
What country? _____________________________
How long ago did he move to Canada? ________

46) Did you work outside the home or attend school (or other training or educational program) at any time within the first 2 years after your child was born?
☐ No
☐ Yes
a) If yes, how old was he/she when you began work/school?
Age in months when you began _______

47) Did your child receive regular child-care outside the home during the first 2 years of life?
☐ No
☐ Yes
a) If yes, did any of these care-providers ask for proof that your child had received his/her immunizations?
☐ No
☐ Yes

48) Have you moved in the last two years?
☐ No
☐ Yes

We are very interested in your views. Please feel free to provide additional comments about your views or experience with immunizations, or any comments about this study or questionnaire.

We welcome any additional comments:

Thank you for taking the time to complete this survey. Your participation will help us respond better to the needs and problems that you have identified.

People to contact for information:
If you have any questions or comments about this study, please contact:
Shannon MacDonald at (780) XXX-XXXX or shannon.macdonald@ualberta.ca *or*
Christine Newburn-Cook at (780) XXX-XXXX or christine.newburn-cook@ualberta.ca.
Mailing address: Nursing Research Office, Faculty of Nursing, 4-103 Clinical Sciences Building, University of Alberta, Edmonton, AB T6G 2G3, Attention: Shannon MacDonald

ID# ______ This number helps us track your survey. It does not enable the researchers to identify who you are.

Please return this survey in the stamped, pre-addressed envelope

Appendix F: Postcard Reminder

** Format differs from actual postcard*

A survey asking about your views and experience with childhood immunization was recently mailed to you. If you have already completed and returned the survey, please accept our sincere thanks. If you have not yet had an opportunity to complete the survey, we are hoping that you will do so today.

We are interested in both the views of parents who have immunized their children and parents who have not. Your input is valuable to us, as it will help us to better understand parents' needs and to improve the care of children and families in Alberta.

If you did not receive a survey, or if it was misplaced, please call us at (780) XXX-XXX and we will send you another one right away.

Sincerely,

Shannon MacDonald, RN, PhD Student & Christine Newburn-Cook, RN, PhD

Appendix G: Final Notification Letter

** Format differs from actual letter*

Final Request:
Study of Parents' Views and Experience with Immunization

Dear Parent or Guardian:

We are making one final appeal for your help. A survey asking about **Parents' Views and Experience with Immunization** was recently mailed to you. To the best of our knowledge, we have not yet received your reply. If you have already completed and returned the survey, please accept our sincere thanks.

The responses from parents who have completed the survey so far include both positive and negative views and experiences with immunizations. All of this information is important in helping us to better understand parents' needs and to improve the care of children and families in Alberta.

We are contacting you again because of the importance of your input. Although we have had a good response to the survey so far, it is important that we hear back from as many parents as possible, in order to get a more complete picture of parents' views.

I want to reassure you of the confidentiality of your responses. Some parents have wondered if they need to include their child's name on the cover of the survey. This is not necessary, and for parents who have written their child's name on the survey, we blacken it out to maintain their confidentiality.

We hope that you will fill out and send back the survey, but if you prefer not to, please let us know by mailing a note or blank survey back to us in the enclosed stamped envelope, or by phoning to leave a message at (780) XXX-XXXX. Please include the ID number located on the back page of the survey.

If you have any questions, please feel free to call me at (780) XXX-XXXX.

Sincerely,

Shannon MacDonald, RN, MN, PhD Student
& Christine Newburn-Cook, RN, PhD
University of Alberta Faculty of Nursing

Appendix H: Health Research Ethics Board Approval

APPROVAL FORM

Date: March 4, 2009
Principal Investigator:Christine Newburn-Cook
Study ID:Pro00004392
StudyTitle:
Sponsor:12/16/0812/16/08ID00000145Izaak Walton Killam Doctoral Award (research allowance)
12/16/0812/16/08ID00000144Alberta Heritage Foundation for Medical Research Health Research Studentship (research allowance)

Thank you for submitting the above study to the Health Research Ethics Board (Health Panel). Your application has been reviewed and approved on behalf of the committee.

The ethics approval is valid until March 3, 2010. A renewal report must be submitted next year prior to the expiry of this approval if your study still requires ethics approval. If you do not renew on or before the renewal expiry date, you will have to re-submit an ethics application.

Approval by the Health Research Ethics Board does not encompass authorization to access the patients, staff or resources of Capital Health or other local health care institutions for the purposes of the research.

Enquiries regarding Capital Health administrative approval, and operational approval for areas impacted by the research, should be directed to the Capital Health Regional Research Administration office, #1800 College Plaza, phone (780) 407-1372.

Sincerely,

Glenn Griener, Ph.D.
Chair, Health Research Ethics Board (Health Panel)

Note: This correspondence includes an electronic signature (validation and approval via an online system).

Appendix I: Variables in Babyworks Database

Variables
File number
Date of birth[a]
Personal health number[a]
Address, including postal code[b]
Gender
Birth weight
Age of mother at time of delivery
First language of mother
Mother's marital status at time of delivery
Breastfed/Formula fed/Feeding method unknown
Birth location: Hospital versus home birth
Hospital where delivery occurred
Delivery by midwife

[a] Not available to the researcher for privacy reasons

[b] Only postal code available to researcher