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Protocol for Establishing an Infant Feeding Database to Conduct Population-Based Research on Breastfeeding Practices

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ABSTRACT

Introduction

Breastfeeding is associated with many health benefits for mothers and infants. But despite extensive public health efforts to promote breastfeeding, many mothers do not achieve their own breastfeeding goals; and, inequities in breastfeeding rates persist between high- and low-income mother-infant dyads. Developing targeted programs to support breastfeeding dyads and reduce inequities between mothers of different socioeconomic status are a priority for public health practitioners and health policy decision makers; however, many jurisdictions lack the timely and comprehensive population-level data on infant feeding practices required to monitor trends in breastfeeding initiation and duration. This protocol describes the establishment of a population-based infant feeding database in the Canadian province of Manitoba, providing opportunities to develop and evaluate breastfeeding support programs.

Methods and Analysis

Routinely collected administrative health data on mothers' infant feeding practices will be captured during regular vaccination visits using the Teleform fax tool, which converts hand-written information to an electronic format. The infant feeding data will be linked to the Manitoba Population Research Data Repository, a comprehensive collection of population-based information spanning health, education, and social services domains. The linkage will allow us to answer research questions about infant feeding practices and to evaluate how effective current initiatives promoting breastfeeding are.

Ethics and Dissemination

Approvals have been granted by the Health Research Ethics Board at the University of Manitoba. Our integrative knowledge translation approach will involve disseminating findings

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through government and community briefings, presenting at academic conferences, and publishing in scientific journals.

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Strengths and Limitations

- This study is among the first to establish a mechanism for collecting infant feeding data at a population level in Canada. Using linked whole-population data has several advantages over survey data, including not being subject to loss-to-follow-up, and allowing us to study how individuals whose data are captured differ from those who are missing from the database.
- Our ability to link the infant feeding database with a large repository of administrative data spanning several domains increases the number of confounding characteristics we can adjust for in our analyses.
- Collecting longitudinal data provides an opportunity to study the impact of policy, programs and services on infant feeding practices.
- The infant feeding data collection system uses vaccination visits as the point of contact, and although more than 90% of infants receive the recommended vaccinations at 2 months of age, those who are not vaccinated will not be captured in the database. Collecting data on infant feeding also routinely relies on maternal report, which can be subject to social desirability bias.

Introduction

Breastfeeding is associated with numerous health benefits for mothers and their infants.[1–7] The World Health Organization, UNICEF, and other health authorities recommend exclusive breastfeeding for the first six months of life, followed by continued feeding of breastmilk along with complementary foods for two years and beyond.[8–12] However, in spite of extensive public health efforts to support breastfeeding, two challenges remain: (1) many mothers do not achieve their own breastfeeding goals; and (2) inequities in breastfeeding outcomes persist between mother-baby dyads living in marginalized circumstances and their more advantaged counterparts.[13–15] Findings from the Canadian Maternity Experiences Survey showed that although breastfeeding initiation rates were relatively high in Canada, exclusive breastfeeding duration fell short of globally recommended standards, with only 14.4% of mother-baby dyads breastfeeding exclusively at 6 months after birth.[16] Based on these figures, developing targeted programs and interventions to support breastfeeding dyads and reduce breastfeeding inequities have become a priority for public health practitioners and health policy decision makers.[17,18] However, many jurisdictions lack the timely and comprehensive population-level data on infant feeding practices required to monitor trends in breastfeeding initiation and duration.

Current State of Infant Feeding Surveillance

In North America, much of the data on infant feeding practices are collected through primary data collection methods such as cross-sectional surveys and cohort studies. Most global surveillance of longitudinal infant feeding is accomplished through periodic surveys of populations, often at the time of hospital discharge or in the postpartum period.[19–22] These methods of epidemiological surveillance have some important limitations:[23–27]

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3 1. Significant resources are required to design and implement novel high-quality cohort
4 studies;
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8 2. Families living in disadvantaged social and economic circumstances – such as low-income
9 households and families with high residential mobility – may be under-represented in survey
10 research;
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- 13 3. Lack of whole-population data makes generalizability challenging and limits planners’
14 ability to conduct small area-level analyses;
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16
- 17 4. Relying on survey data collected for a single purpose makes it difficult to track outcomes
18 across the life span.
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25 In light of these and other limitations, researchers are turning to routinely collected
26 administrative health data to conduct a wide variety of epidemiological research studies.[27]
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29 30 *How Can Administrative Health and Social Data Help Address Evidence Gaps?* 31

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33 Contacts with the health and social services systems generate data in the form of
34 administrative records. Linking these routinely collected records across sectors is a powerful tool
35 for conducting large-scale, longitudinal epidemiological research.[23,25–28] For example,
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37 researchers in Europe and Australia have been using linked administrative health data to monitor
38 breastfeeding initiation and duration rates for the last two decades.[29–32] In Canada, studies
39 have used breastfeeding initiation data obtained from the birth hospital discharge abstracts to
40 track trends and inequities in breastfeeding initiation, and examine outcomes associated with
41 initiating breastfeeding during the first days of life.[13,33] Although providers routinely ask
42 questions about infant feeding practices during well-baby visits throughout the first year of life,
43 including questions about breastfeeding duration, this information is seldom integrated into a
44 centralized database. Thus, researchers and program planners lack comprehensive data on infant
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3 feeding practices once the mother-baby dyad is discharged from the birth hospital stay.

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5 Therefore, there is a critical need to identify a mechanism whereby infant feeding information
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8 that is routinely collected during well-baby visits can be consolidated in a whole-population
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11 database.

12 13 **Research Objective**

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15 The objective of this work is to establish a mechanism for collecting infant feeding
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17 information during routine contacts with the healthcare system, which can then be linked with a
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19 centralized data repository of administrative health data. Specifically, it will evaluate whether a
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21 Teleform fax system is a viable mechanism for (a) collecting infant feeding data when infants
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23 receive their 2-, 4-, and 6-month vaccinations, and (b) automatically depositing that information
24
25 into the new Manitoba Infant Feeding Database (MIFD), and linking it at the individual level
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27 with the Manitoba Population Research Data Repository, an established repository of
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29 administrative health and social data.
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35 We will address the following research questions:

- 36
37 1. What percent of data collected using the Teleform have transcription errors when
38
39 automatically read into an electronic format, requiring manual verification and edits?
- 40
41 2. What are the patterns of missing data in the Manitoba Infant Feeding Database?
- 42
43 3. What percent of infants are captured at the 2-, 4-, and 6-month vaccination visits?
- 44
45 4. Do data capture rates differ by rural/urban status of the study sites?
- 46
47 5. What maternal characteristics (maternal age, income, residential mobility) and infant
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49 characteristics (sex, small for gestational age, large for gestational age, Apgar score) are
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51 associated with data captured at the 2-, 4-, and 6-month vaccination visits?
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Methods and Analysis

Setting

The study funding period began in October 2014 and ends in August 2018. The study takes place in Manitoba, a central Canadian province with approximately 1.3 million residents. For the past four years, the annual number of births in the province has ranged between 15,000 and 17,000 births. Just over 80% of mother-infant dyads initiate breastfeeding during the birth hospital stay; however, initiation rates follow a socioeconomic gradient where low-income dyads are less likely to initiate breastfeeding compared with their higher-income counterparts.[13–15]

A unique and advantageous feature of establishing an infant feeding database in Manitoba is our ability to link the new Manitoba Infant Feeding Database to the established Manitoba Population Research Data Repository.[34,35] The Repository contains more than 30 years of population-based, individual-level information on all Manitobans who are registered with the province of Manitoba's universal health insurance program. Each time a Manitoba resident is in contact with the healthcare system, the information from that contact is recorded and held in the Repository. The Repository data are de-identified using strict protocols to preserve residents' anonymity, but can be linked longitudinally and across sectors using a scrambled personal identification number.[23,25,27] Besides health information, the Repository includes administrative records from social services and government programs, children's education records, and contacts with the criminal justice system (Figure 1).[23,25] The Repository data have been validated and used extensively for maternal and child health research studies.[36–40]

Identifying Opportunities for Data Collection at Routine Vaccination Visits

We began by identifying infant vaccination visits as a consistent and opportune routine point of contact with the healthcare system whereby population-based information on infant

feeding could be collected. In Manitoba, more than 90% of infants complete their 2-month vaccination schedules and 78% complete their 1-year vaccination schedules.[41] Thus, using this point of contact, infant feeding information could be collected from nearly every mother-baby dyad in the province. With consideration for the funding timeline, we selected the 2-, 4-, and 6-month vaccination visits as infant feeding data collection time points.

Optimizing the Teleform Fax Tool for Data Collection

In order to place a minimum burden on mothers and healthcare workers, ensure that the questions could be answered quickly and easily, and maximize the possibility that such a system could be routinely implemented across the province, we conducted a literature search to identify a short set of questions that would yield rich data on infant feeding practices post-hospital discharge.[42] During the summer of 2015, we piloted a draft version of the questions (Box 1) by conducting three focus groups with new mothers: one urban group comprising 8 mothers, one group of 9 mothers in a rural agricultural community, and one group of 12 mothers from a remote rural community.

Box 1. Infant Feeding Questions Pilot Tested with Manitoba Mothers

1. What has your baby been fed since birth?
 - a. Only Breastmilk. (End of questions)
 - b. Only formula/other food. (End of questions)
 - c. Breastmilk and formula/other food. (Go to question 2)
2. During the past week, what did you feed your baby?
 - a. Breastmilk only. (Go to question 3)
 - b. Breastmilk and formula/other food. (Go to question 4)
 - c. Only formula/other food. (Go to question 5)
3. Was your baby only supplemented in the hospital?
 - a. Yes, my baby was only supplemented in the hospital. Otherwise I have only breastfed (End of questions)
 - b. No, my baby was supplemented in the hospital and at home. (Go to question 4)
4. How many weeks old was your baby when you first fed formula/other food?
5. How many weeks old was your baby when you completely stopped breastfeeding?

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4 During the focus groups, the mothers each answered the questions on infant feeding
5 practices and then discussed as a group how they interpreted each question. They provided
6 feedback on question structure and order to improve the clarity of questions and reduce response
7 burden. The final set of questions for the Teleform were selected based on the focus group
8 feedback. The Teleform also collects data for linkage purposes, including (1) the mother's and
9 infant's Personal Health Identification Numbers (PHINs; unique, person-level identifiers held in
10 the Repository), (2) the infant's birth date, (3) the infant's sex, and (4) the mother's postal code.
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12 The final version of the Teleform is presented as a supplemental file.
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23 ***Recruitment and Data Collection***

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25 Recruitment and data collection began in September 2015 and will continue until
26 December 2017. Six study sites are enrolled: one urban clinic where 75% of all urban-dwelling
27 children in Manitoba receive their vaccinations, two rural public health offices located in
28 agricultural communities, and three rural public health offices located in rural remote settings.
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30 Over the past three years, the annual number of children vaccinated across all six sites ranged
31 between 1500 and 2000 children.
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40 Mothers who bring their infants to study site clinics for vaccination visits are asked by
41 clinic staff members to participate in the study. Clinic staff provide them with documents
42 describing the study and its purpose, along with informed consent documentation. Mothers who
43 review the documents and give written informed consent are enrolled in the study. Study
44 participants are asked to complete the Teleform at their infants' 2-, 4-, and 6-month vaccination
45 visits. Mothers fill out the Teleform during the visit, and then return it to staff before leaving the
46 clinic. Data collected with the Teleform are faxed by the clinic staff to the research study office
47 located within a government agency. There, the data are automatically extracted from the faxed
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3 form and an image of the form is placed on a password-protected network in a secure data
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5 environment with restricted card access. Data quality checks are run manually to identify
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7 transcription errors and missing data. For each data field, we are documenting the percentage
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9 with transcription errors, requiring manual verification, and needing manual edits to address
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11 research question 1.
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15 Table 1 presents preliminary summary enrollment figures and vaccination rates of infants
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17 at each study site (September 2015 to December 2016). During this period, approximately 75%
18
19 of mothers consented to provide feeding data for the study. At the end of the data collection
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21 phase, we will conduct descriptive summary statistics to identify patterns of transcription errors
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23 and missing data to answer our first two research questions.
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28 ***Linking Infant Feeding Data with the Manitoba Population Research Data Repository***

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30 The Manitoba Infant Feeding Database is composed of two datasets: (1) the Infant
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32 Feeding Dataset consisting of infant feeding data and individuals' unique study ID; and (2) the
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34 Identifying Dataset comprising mothers' and infants' PHINs, infant's date of birth, infant's sex,
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36 mother's postal code, and infant's unique study ID. Box 2 depicts the information held in the two
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38 datasets. Figure 2 shows the data flow process from point of data collection to acquisition into
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40 the Manitoba Population Research Data Repository for data analyses.
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45 The Manitoba Infant Feeding Database will be held in and linked to the Manitoba
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47 Population Research Data Repository. Figure 1 shows a graphical summary of the Repository, a
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49 collection of over 70 databases containing information on health, education, receipt of social
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51 services, and interactions with the justice system. The Manitoba Health Insurance Registry
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53 includes individuals' unique scrambled PHINs and a Family Registration Number, which allows
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55 linkages between mothers and their infants. Using scrambled PHINs and crosswalk files
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3 generated by Manitoba Health, individual-level data can be linked across all datasets held in the
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5 Repository in a de-identified way.
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8 9 *Study Cohort Development*

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11 We will construct the study cohort using the whole-population data held in the
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13 Repository. The crosswalk file generated by Manitoba Health will be used to link mothers and
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15 infants, and to link infants' feeding data with their health records in the Repository. Specifically,
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17 infant feeding data will be linked with the following administrative health data: (1) the dyad's
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19 birth hospital discharge data, (2) the infant's vaccination records held in the Manitoba
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21 Immunization Monitoring System, (3) medical billing records associated with the infant's
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23 primary care visits held in the Medical Services dataset, and (4) the mother's postal code of
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25 residence held in the Manitoba Health Insurance Registry. The cohort will include all mothers
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27 and infants who had at least one vaccination visit at one of the study sites between September
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29 1, 2015 and December 31, 2017; thus it, will include infants with and without feeding data. For
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31 those without feeding data, the relevant data fields in the Manitoba Infant Feeding Database will
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33 read 'missing'. We will use multivariable logistic regression models to identify characteristics
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35 associated with having missing data in the MIFD.
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Table 1. Numbers of mother-infant dyads with infant feeding data captured in the Manitoba Infant Feeding Database at each vaccination visit, per year

	2-Month			4-Month			6-Month		
	Estimated No. of Children ^A	Percent with 2-Month Vaccination ^B	No. of Dyads in the MIFD Per Year ^C	No. of Children ^A	Percent with 4-Month Vaccination	Estimated No. of Dyads Captured Per Year ^D	No. of Children ^A	Percent with 6-Month Vaccination	Estimated No. of Dyads Captured Per Year ^D
Urban Clinic	1000	90%	921	1000	86%	643	1000	78%	585
Rural Agricultural Site 1	100	90%	68	100	88%	66	100	75%	56
Rural Agricultural Site 2	100	90%	65	100	82%	61	100	78%	58
Rural Remote Site 1	400	90%	155	400	83%	249	400	72%	216
Rural Remote Site 2	75	90%	53	75	82%	46	75	73%	41
Rural Remote Site 3	75	90%	52	75	80%	45	75	73%	41
TOTAL	1750		1314	1750		1110	1750		997

MIFD: Manitoba Infant Feeding Database

^A Estimated number of children seen at each study site during a one year period based on information provided by clinic administrators. Precise numbers of children seen at each clinic will be determined once the MIFD is linked with the Manitoba Population Research Data Repository

^B Vaccination rates estimated for the first year of the study period from previous years' administrative health data held in the Manitoba Population Research Data Repository.

^C All mother-infant dyads who attend a vaccination visit will be invited to participate in the study. Between September 1, 2015 and December 31, 2016, roughly 75% of them enrolled in the study. This column presents the number of mother-infant dyads who have consented to participate in the study and whose infant feeding data was captured in the Manitoba Infant Feeding Database.

^D Based on current enrollment rates (75%) and vaccination rates, this column represents the anticipated number of mother-infant dyads whose data will be captured at the 4- and 6-month vaccination visits.

Box 2. Datasets in the Manitoba Infant Feeding Database

<u>Infant Feeding Dataset</u>	<u>Identifying Dataset</u>
<ul style="list-style-type: none"> • Unique Study ID • Infant feeding status at vaccination visit • Infant age at cessation of exclusive breastfeeding • Infant age at cessation of partial breastfeeding • Whether infant was supplemented during hospital stay 	<ul style="list-style-type: none"> • Unique Study ID • Mother's Personal Health Identification Number (PHIN) • Infant's PHIN • Infant's birth date • Infant's sex • Mother's postal code

Variable Construction

Using the study cohort, we will develop variables to address research questions 3-5.

Table 2 presents each of the outcome variables we will examine in these analyses. Because the data include all contacts with the healthcare system, we will be able to follow infants as they access healthcare services across the province; we will be able to track all vaccinations for infants in the study, regardless of whether or not that vaccination was given at one of the study sites. We will construct a set of three variables – one for each vaccination visit – to describe whether we captured infant feeding data from the dyad. For each visit, the variable will tell us (1) if feeding data were recorded, (2) if a vaccination visit was recorded at a study site but feeding data are missing, (3) if a vaccination visit was recorded at a non-study site, and (4) whether an infant has a vaccination recorded for that time point.

A feeding history for each infant will be constructed using data from the hospital discharge abstract and feeding data collected at each vaccination visit. The feeding history will indicate whether an infant is exclusively breastfeeding, partially breastfeeding, or exclusively formula feeding at four contacts with the healthcare system: birth hospital discharge, 2-, 4-, and 6-month vaccination visits (definitions presented in Table 2). The data collected on the Teleform

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3 will also be used to determine (1) the infant's age when a food other than human milk was first
4 introduced (cessation of exclusive breastfeeding), and (2) the infant's age when the dyad stopped
5 breastfeeding entirely (breastfeeding cessation). Taken together, this information can be used to
6 identify each infant's duration of exclusive and partial breastfeeding.
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12 In addition to infant feeding status, we will construct a dichotomous variable that
13 describes infant feeding history. An infant feeding history can be constructed from the available
14 data for each infant if (a) the date of exclusive and partial breastfeeding cessation are both
15 recorded, (b) the infant had all age-appropriate vaccination visits and was still breastfeeding at
16 the last recorded visit (in this instance, the data are right censored), or (c) feeding data are
17 recorded for each visit, regardless of feeding practice. Because we will have data on every infant,
18 we will be able describe how those with missing feeding data or those whose data were not
19 captured in the database differ from infants with feeding data recorded at each contact with the
20 healthcare system. Table 3 presents the explanatory variables that we will use in these analyses.
21 Explanatory variables will be developed using Repository data from the mother and/or infant.
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Table 2. Outcome Variables for Analyses

<i>Data Capture Variables</i>	
Infant Feeding Data Captured, 2-Month Vaccination Visit	<ol style="list-style-type: none"> 1. Infant feeding data recorded in the database at 2-month visit 2. Infant has 2-month vaccination recorded at a study site but does not have feeding data captured in database 3. Infant has a 2-month vaccination recorded at a non-study site 4. Infant does not have 2-month vaccination visit recorded <p>Sub-Cohort: All infants in our cohort >2 months of age</p>
Infant Feeding Data Captured, 4-Month Vaccination Visit	<ol style="list-style-type: none"> 1. Infant feeding data recorded in the database at 4-month visit 2. Infant has 4-month vaccination recorded at a study site but does not have feeding data captured in database 3. Infant has a 4-month vaccination recorded at a non-study site 4. Infant does not have 4-month vaccination visit recorded <p>Sub-Cohort: All infants in our cohort >4 months of age</p>
Infant Feeding Data Captured, 6-Month Vaccination Visit	<ol style="list-style-type: none"> 1. Infant feeding data recorded in the database at 6-month visit 2. Infant has 6-month vaccination recorded at a study site but does not have feeding data captured in database 3. Infant has a 6-month vaccination recorded at a non-study site 4. Infant does not have 6-month vaccination visit recorded <p>Sub-Cohort: All infants in our cohort >6 months of age</p>
<i>Infant Feeding Status Variables</i>	
Infant feeding status	<ol style="list-style-type: none"> 1. Exclusively breastfeeding at vaccination visit (at 2, 4, and 6 months) <ol style="list-style-type: none"> a. Question 9: Mother only selects “breast milk” b. Question 10: Mother answers “No” c. Question 11: Mother answers “Never” d. Question 12: Mother answers “Not applicable” e. Question 13: Mother answers “I am still breastfeeding” 2. Partially breastfeeding at vaccination visit (at 2, 4, and 6 months) <ol style="list-style-type: none"> a. Question 9: Mother selects breast milk (may select other options as well) b. Question 10: Mother answers either “Yes” or “No” c. Question 11: Mother selects any option d. Question 12: Mother provides any answer e. Question 13: Mother answers “I am still breastfeeding” 3. Infant age when exclusive breastfeeding ceased (at 2, 4, and 6 months) <ol style="list-style-type: none"> a. Question 12: Mother’s response 4. Infant age when partial breastfeeding ceased (at 2, 4, and 6 months) <ol style="list-style-type: none"> a. Question 13: Mother’s response 5. Infant was only supplemented with formula in hospital; infant was only breastfed after hospital discharge <ol style="list-style-type: none"> a. Question 9: Mother selects “breast milk”; she does not select “other liquids” and she does not select “solids/other foods.” She may or may not select “formula”. b. Question 10: Mother answers either “Yes” or “No” c. Question 11: Mother only selects “In hospital” d. Question 12: Mother provides any answer e. Question 13: Mother answers “I am still breastfeeding”
Complete infant feeding data for age	Constructed using data from the hospital discharge abstract and 2-, 4-, and 6-month vaccination visit data. For each infant we will first identify all vaccinations for which the infant is eligible, based on age (e.g., for a 5-month old infant, we will identify whether it has records for both a 2 and 4 month vaccination visits). Then

we will identify whether an infant feeding history can be constructed from the available data.

A feeding history can be constructed if:

- An infant has all age-appropriate vaccinations and is still breastfeeding at the latest recorded vaccination visit; breastfeeding cessation is censored; or
- Feeding data identify that the infant stopped breastfeeding prior to the recorded vaccination visit. Feeding data are missing for vaccination visits that follow breastfeeding cessation; or
- Feeding data are recorded for every vaccination visit, regardless of feeding practice;

A feeding history cannot be constructed if:

- All vaccination visits happen at study site and either partial or exclusive breastfeeding cessation cannot be determined due to missing infant feeding;
- 1 or more vaccination visits recorded at non-study site and either partial or exclusive breastfeeding cessation cannot be determined due to missing feeding data.
- Data on one or more vaccination visits is missing and either partial or exclusive breastfeeding cessation cannot be determined due to missing feeding data.

Table 3. Explanatory Variables

<i>Maternal Characteristics</i>	
Registry	<ul style="list-style-type: none"> • Maternal age • Maternal postal code of residence: used to identify whether the mother is living in urban or rural setting and used to identify distance mother needs to travel to obtain a vaccination for her child • Residential mobility: Number of times a mother moved in the 5 years before the birth of her child
Postal Code Conversion	<ul style="list-style-type: none"> • Average income for the census dissemination area where the mother is living at the time of her child's birth. Average is based on between 400 and 700 individuals and provides a measure for the mother's neighborhood-level socioeconomic status
Medical Claims	<ul style="list-style-type: none"> • Access to prenatal care during pregnancy
Hospital Discharge Abstract Database	<ul style="list-style-type: none"> • Type of birth: vaginal or caesarean-section
<i>Infant Characteristics</i>	
Registry	<ul style="list-style-type: none"> • Infant's birth date • Infant's sex
Hospital Discharge Abstract Database	<ul style="list-style-type: none"> • Apgar score • Birth weight • Gestational age • Breastfeeding at birth hospital discharge

Data Analysis Plan

We will generate descriptive statistics to identify the percentage of infants in the cohort with feeding data at 2-, 4-, and 6-month vaccination visits, and test whether data capture rates differ across time (research question 3). We will also test whether the percentage of infants with captured data differs by urban/rural status of the study site where they were vaccinated (research question 4). For each time point, we will calculate the socioeconomic distribution of infants across four categories: (1) infant has feeding data, (2) infant has vaccination recorded at a study site but does not have feeding data, (3) infant has a vaccination recorded at a non-study site, and (4) infant does not have a vaccination recorded.

We will calculate the percentage of infant feeding data that are missing due to the infant receiving one or two vaccinations at a non-study site. Identifying the frequency with which this occurs will provide an estimate of the percentage of infants that could have complete infant feeding data if Manitoba had a universal system that captured infant feeding information.

Characteristics associated with having infant feeding data captured in the database will be examined using logistic regression models for the 2-, 4-, and 6-month visits (research question 5). The outcome will be a dichotomous variable identifying whether or not a mother-infant dyad's infant feeding information is captured in the database. Models will include the variables listed in Table 3. Each model will include a sub-cohort of age-appropriate infants; for example, analyses examining data collected at the 4-month vaccination visit will exclude anyone ≥ 4 months of age. Results from these analyses will indicate whether mother-infant dyads captured by this strategy differ systematically from those who have missing data.

Finally, we will examine characteristics associated with whether or not we can construct an age-appropriate infant feeding history using data held in the Manitoba Infant Feeding

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3 Database. The outcome variable will describe whether or not a complete infant feeding history
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5 can be constructed based on available data. Explanatory variables will include those listed in
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7 Table 3.
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10 11 12 **Ethics and Dissemination**

13 *Ethical Considerations*

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15 The research team has completed the Tri-Council Course on Research Ethics. We have
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17 obtained approvals from the Health Research Ethics Board at the University of Manitoba, the
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19 Health Information Privacy Committee of Manitoba Health, and the ethics committees in
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21 participating regional health authorities. Participation in the study is voluntary. Study
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23 participants are informed of the purpose of the study, potential risks associated with participation
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25 (compromise of data), their rights and obligations as participants, and their ultimate right to
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27 withdraw at any point without negative consequences. We ask study participants for consent to
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29 link their data with the Repository. Participants are informed that they will not be identifiable in
30
31 any reports or publications. Informed consent is obtained from participants prior to data
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33 collection. Identified data is housed on a password protected server in a secure data environment
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35 at the research office. The data is sent to Manitoba Health for de-identification and encryption.
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37 Only the data analysts have access to the de-identified data. Analyses using the de-identified data
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39 will be conducted in the secure data environment at the Manitoba Centre for Health Policy.
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49 *Integrated Knowledge Translation and Dissemination of Findings*

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51 The research team has adopted an integrative knowledge translation approach. In addition
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53 to academic researchers, the broader team comprises an interdisciplinary group of stakeholders
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55 from government departments, public health offices, and regional health authorities. Over a 6-
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3 month pre-funding planning period, the team worked together to develop a research plan and to
4 secure peer-reviewed funding through a Research Manitoba New Investigator Operating Grant.
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6 While the core research team leads the study, the stakeholders are serving as advisory group
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8 members to ensure that findings can be applied to the population-based infant feeding data
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10 collection strategy. The advisory group also strategizes with the core research team on methods
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12 for disseminating findings to healthcare workers and other stakeholders in and outside of
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14 Manitoba.
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20 Even at this early stage, there has been great interest in the study from stakeholders in
21 government and public health. To date, we have presented the research plan and preliminary
22 findings to public health officers in each regional health authority active in the study, and we
23 have participated in two provincial meetings on breastfeeding practices. We have also widely
24 disseminated the study aims and early findings in the academic community at the University of
25 Manitoba. Near the end of the funding period, the team will host a province-wide workshop that
26 will bring together public health nurses, clinic staff members, and stakeholders to discuss the
27 study findings and experiences with implementing the data collection mechanism. Two advisory
28 group members are actively involved with the Breastfeeding Committee for Canada and will
29 arrange for webinars to disseminate findings through this organization. Findings will be
30 presented at national and/or international conference(s) and will be submitted for peer-review
31 publication to inform further research around infant feeding data collection and provide evidence
32 for building new population-based data collection systems.
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Figure Captions:**Figure 1. Graphical Representation of the Manitoba Population Health Research Data Repository**

The Repository, held at the Manitoba Centre for Health Policy, is a collection of over 70 databases containing up to 30 years of information on Manitoba residents' health, education, receipt of social services, and interactions with the justice system. De-identified individual-level data can be linked across all Repository datasets.

Figure 2. Manitoba Infant Feeding Database Data Flow Diagram

Data are collected at vaccination visits using the Teleform and faxed to a central office. The identifiable data file contains two datasets: (1) Infant Feeding Data (a dataset that includes infant feeding information and study ID), and (2) Identifying Data (a dataset that includes identifying information and study ID). The Identifying Data are sent to Manitoba Health for de-identification and attachment of scrambled Personal Health Identification Number (PHIN). Manitoba Health generates a cross walk file with instructions for data linkage. The Infant Feeding Data are sent to the Manitoba Population Research Data Repository. The Scrambled PHIN, study ID, and crosswalk file are used to link infant feeding data with the rest of the administrative data held in the Repository. The linked databases form the analytic data for the study.

Author Contributions:

The study was conceived by NCN, the principal investigator on the original funded grant. NCN, LW, MH, AK, and CG participated in designing the study and were listed as collaborators on the grant. NCN, JC, and LW were involved in recruiting participating study sites, and NCN and JC are working with study sites on data collection processes. JC and JP are involved in data cleaning and verification. NCN, LK, and JEE drafted the manuscript. All authors (NCN, LW, LK, JC, MH, CG, AK, JP, CP, DG, LL, JEE, and SS) contributed to critically revising the manuscript for important intellectual content, gave their final approval, and agree to be accountable for all aspects of the work. All authors (NCN, LW, LK, JC, MH, CG, AK, JP, CP, DG, LL, JEE, and SS) will participate in future interpretation of the data and drafting of further manuscripts arising from this work.

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6 37). Data used in this study are from the Population Health Research Data Repository and were
7 derived from data provided by Manitoba Health, Seniors and Active Living. The results and
8 conclusions are those of the authors and no official endorsement by MCHP, Manitoba Health,
9 Seniors and Active Living is intended or should be inferred.
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20 21 **Competing Interests:**

22 The authors declare that they have no competing interests.
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Manitoba Population Research Data Repository

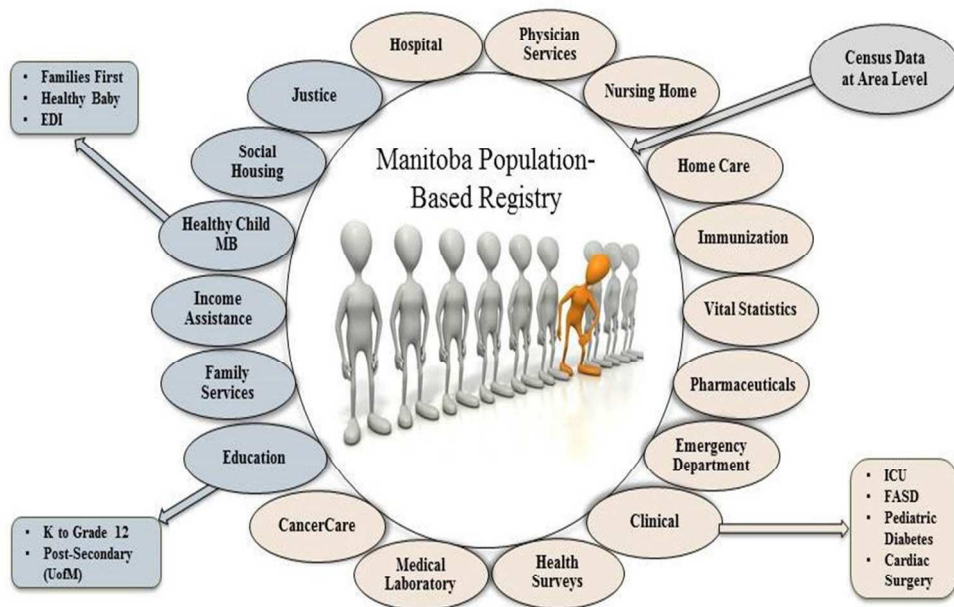


Figure 1. Graphical Representation of the Manitoba Population Health Research Data Repository
 The Repository, held at the Manitoba Centre for Health Policy, is a collection of over 70 databases containing up to 30 years of information on Manitoba residents' health, education, receipt of social services, and interactions with the justice system. De-identified individual-level data can be linked across all Repository datasets.

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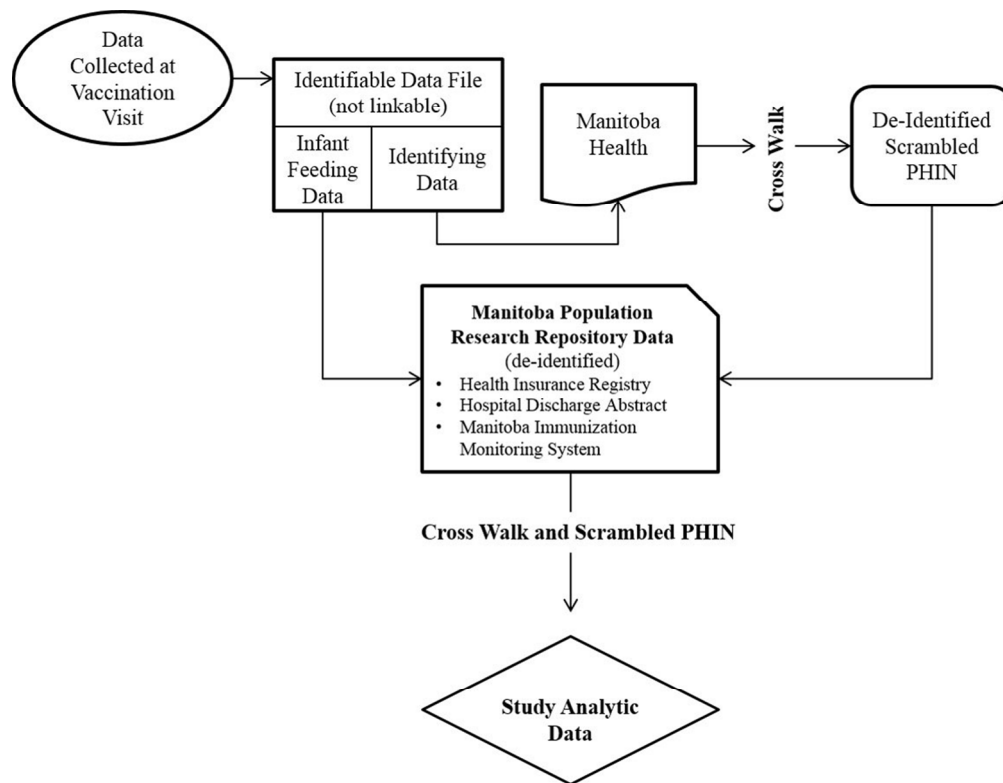


Figure 2. Manitoba Infant Feeding Database Data Flow Diagram

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Mother Father Other caregiver

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DAY		MONTH		YEAR			

07. Please enter the first 3-characters of your 6-character postal code:

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08. Is your baby a girl or a boy?

Boy Girl

09. What has your baby been fed?
Please select all that apply.

Breast milk
 Formula
 Other liquids (juice, cow's milk, goat's milk, tea, etc)
 Solids / Other foods

10. Has your baby ever had formula?

Yes No

11. When was your baby fed formula?
Please select all that apply.

In hospital At home Never

12. How many weeks old was your baby when you first fed formula/other liquids/other food?

Since birth

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 weeks old Not applicable

13. How many weeks old was your baby when you completely stopped breastfeeding?

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 weeks I am still breastfeeding
 I have only formula fed

BMJ Open

Protocol for Establishing an Infant Feeding Database Linkable with Population-Based Administrative Data: A Prospective Cohort Study in Manitoba, Canada

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Title: Protocol for Establishing an Infant Feeding Database Linkable with Population-Based Administrative Data: A Prospective Cohort Study in Manitoba, Canada

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ABSTRACT

Introduction

Breastfeeding is associated with many health benefits for mothers and infants. But despite extensive public health efforts to promote breastfeeding, many mothers do not achieve their own breastfeeding goals; and, inequities in breastfeeding rates persist between high- and low-income mother-infant dyads. Developing targeted programs to support breastfeeding dyads and reduce inequities between mothers of different socioeconomic status are a priority for public health practitioners and health policy decision makers; however, many jurisdictions lack the timely and comprehensive population-level data on infant feeding practices required to monitor trends in breastfeeding initiation and duration. This protocol describes the establishment of a population-based infant feeding database in the Canadian province of Manitoba, providing opportunities to develop and evaluate breastfeeding support programs.

Methods and Analysis

Routinely collected administrative health data on mothers' infant feeding practices will be captured during regular vaccination visits using the Teleform fax tool, which converts hand-written information to an electronic format. The infant feeding data will be linked to the Manitoba Population Research Data Repository, a comprehensive collection of population-based information spanning health, education, and social services domains. The linkage will allow us to answer research questions about infant feeding practices and to evaluate how effective current initiatives promoting breastfeeding are.

Ethics and Dissemination

Approvals have been granted by the Health Research Ethics Board at the University of Manitoba. Our integrative knowledge translation approach will involve disseminating findings

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through government and community briefings, presenting at academic conferences, and publishing in scientific journals.

For peer review only

Strengths & Limitations

- This study is among the first to establish a mechanism for collecting infant feeding data at a population level in Canada, providing longitudinal data to study the impact of policy, programs and services on infant feeding practices.
- Our ability to link the infant feeding database with a large repository of administrative data spanning several domains increases the number of confounding characteristics we can adjust for in our analyses.
- Using linked whole-population data means there will be minimal loss to follow-up, and allows us to compare individuals captured in the infant feeding database with individuals who were not.
- Using vaccination visits as the point of contact for data collection means some individuals will be missed (although more than 90% of infants receive the recommended vaccinations at 2 months of age).
- Collecting data on infant feeding routinely relies on maternal report, which can be subject to social desirability bias.

Introduction

Breastfeeding is associated with numerous health benefits for mothers and their infants.[1–7] The World Health Organization, UNICEF, and other health authorities recommend exclusive breastfeeding for the first six months of life, followed by continued feeding of breastmilk along with complementary foods for two years and beyond.[8–12] However, in spite of extensive public health efforts to support breastfeeding, two challenges remain: (1) many mothers do not achieve their own breastfeeding goals; and (2) inequities in breastfeeding outcomes persist between mother-baby dyads living in marginalized circumstances and their more advantaged counterparts.[13–15] Findings from the Canadian Maternity Experiences Survey showed that although breastfeeding initiation rates were relatively high in Canada, exclusive breastfeeding duration fell short of globally recommended standards, with only 14.4% of mother-baby dyads breastfeeding exclusively at 6 months after birth.[16] Based on these figures, developing targeted programs and interventions to support breastfeeding dyads and reduce breastfeeding inequities have become a priority for public health practitioners and health policy decision makers.[17,18] However, many jurisdictions lack the timely and comprehensive population-level data on infant feeding practices required to monitor trends in breastfeeding initiation and duration.

Current State of Infant Feeding Surveillance

In North America, much of the data on infant feeding practices are collected through primary data collection methods such as cross-sectional surveys and cohort studies. Most global surveillance of longitudinal infant feeding is accomplished through periodic surveys of populations, often at the time of hospital discharge or in the postpartum period.[19–22] These methods of epidemiological surveillance have some important limitations:[23–27]

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3 1. Significant resources are required to design and implement novel high-quality cohort
4 studies;
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8 2. Families living in disadvantaged social and economic circumstances – such as low-income
9 households and families with high residential mobility – may be under-represented in survey
10 research;
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12
- 13 3. Lack of whole-population data makes generalizability challenging and limits planners’
14 ability to conduct small area-level analyses;
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- 17 4. Relying on survey data collected for a single purpose makes it difficult to track outcomes
18 across the life span.
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25 In light of these and other limitations, researchers are turning to routinely collected
26 administrative health data to conduct a wide variety of epidemiological research studies.[27]
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29 30 *How Can Administrative Health and Social Data Help Address Evidence Gaps?* 31

32
33 Contacts with the health and social services systems generate data in the form of
34 administrative records. Linking these routinely collected records across sectors is a powerful tool
35 for conducting large-scale, longitudinal epidemiological research.[23,25–28] For example,
36
37 researchers in Europe and Australia have been using linked administrative health data to monitor
38 breastfeeding initiation and duration rates for the last two decades.[29–32] In Canada, studies
39 have used breastfeeding initiation data obtained from the birth hospital discharge abstracts to
40 track trends and inequities in breastfeeding initiation, and examine outcomes associated with
41 initiating breastfeeding during the first days of life.[13,33] Although providers routinely ask
42 questions about infant feeding practices during well-baby visits throughout the first year of life,
43 including questions about breastfeeding duration, this information is seldom integrated into a
44 centralized database. Thus, researchers and program planners lack comprehensive data on infant
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3 feeding practices once the mother-baby dyad is discharged from the birth hospital stay.

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5 Therefore, there is a critical need to identify a mechanism whereby infant feeding information
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8 that is routinely collected during well-baby visits can be consolidated in a whole-population
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10
11 database.

12 13 ***Research Objective***

14
15 The objective of this work is to establish a mechanism for collecting infant feeding
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17 information during routine contacts with the healthcare system, which can then be linked with a
18
19 centralized data repository of administrative health data. Specifically, it will evaluate whether a
20
21 Teleform fax system is a viable mechanism for (a) collecting infant feeding data when infants
22
23 receive their 2-, 4-, and 6-month vaccinations, and (b) automatically depositing that information
24
25 into the new Manitoba Infant Feeding Database (MIFD), and linking it at the individual level
26
27 with the Manitoba Population Research Data Repository, an established repository of
28
29 administrative health and social data.
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35 We will address the following research questions:

- 36
37 1. What percent of data collected using the Teleform have transcription errors when
38
39 automatically read into an electronic format, requiring manual verification and edits?
- 40
41 2. What are the patterns of missing data in the Manitoba Infant Feeding Database?
- 42
43 3. What percent of infants are captured at the 2-, 4-, and 6-month vaccination visits?
- 44
45 4. Do data capture rates differ by rural/urban status of the study sites?
- 46
47 5. What maternal characteristics (maternal age, income, residential mobility) and infant
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49 characteristics (sex, small for gestational age, large for gestational age, Apgar score) are
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51 associated with data captured at the 2-, 4-, and 6-month vaccination visits?
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Methods and Analysis

Setting

The study funding period began in October 2014 and ends in August 2018. The study takes place in Manitoba, a central Canadian province with approximately 1.3 million residents. For the past four years, the annual number of births in the province has ranged between 15,000 and 17,000 births. Just over 80% of mother-infant dyads initiate breastfeeding during the birth hospital stay; however, initiation rates follow a socioeconomic gradient where low-income dyads are less likely to initiate breastfeeding compared with their higher-income counterparts.[13–15]

A unique and advantageous feature of establishing an infant feeding database in Manitoba is our ability to link the new Manitoba Infant Feeding Database to the established Manitoba Population Research Data Repository.[34,35] The Repository contains more than 30 years of population-based, individual-level information on all Manitobans who are registered with the province of Manitoba's universal health insurance program; thus, the Repository contains information on 99.9% of Manitobans residents. Each time a Manitoba resident is in contact with the healthcare system, the information from that contact is recorded and held in the Repository. The Repository data are de-identified using strict protocols to preserve residents' anonymity, but can be linked longitudinally and across sectors using a scrambled personal identification number.[23,25,27] Besides health information, the Repository includes administrative records from social services and government programs, children's education records, and contacts with the criminal justice system (Figure 1).[23,25] The Repository data have been validated and used extensively for maternal and child health research studies.[36–40]

Identifying Opportunities for Data Collection at Routine Vaccination Visits

We began by identifying infant vaccination visits as a consistent and opportune routine point of contact with the healthcare system whereby population-based information on infant feeding could be collected. In Manitoba, more than 90% of infants complete their 2-month vaccination schedules and 78% complete their 1-year vaccination schedules.[41] Thus, using this point of contact, infant feeding information could be collected from nearly every mother-baby dyad in the province. With consideration for the funding timeline, we selected the 2-, 4-, and 6-month vaccination visits as infant feeding data collection time points.

Optimizing the Teleform Fax Tool for Data Collection

In order to place a minimum burden on mothers and healthcare workers, ensure that the questions could be answered quickly and easily, and maximize the possibility that such a system could be routinely implemented across the province, we conducted a literature search to identify a short set of questions that would yield rich data on infant feeding practices post-hospital discharge.[42] During the summer of 2015, we piloted a draft version of the questions (Box 1) by conducting three focus groups with new mothers: one urban group comprising 8 mothers, one group of 9 mothers in a rural agricultural community, and one group of 12 mothers from a remote rural community.

Box 1. Infant Feeding Questions Pilot Tested with Manitoba Mothers

1. What has your baby been fed since birth?
 - a. Only Breastmilk. (End of questions)
 - b. Only formula/other food. (End of questions)
 - c. Breastmilk and formula/other food. (Go to question 2)
2. During the past week, what did you feed your baby?
 - a. Breastmilk only. (Go to question 3)
 - b. Breastmilk and formula/other food. (Go to question 4)
 - c. Only formula/other food. (Go to question 5)
3. Was your baby only supplemented in the hospital?
 - a. Yes, my baby was only supplemented in the hospital. Otherwise I have only breastfed (End of questions)
 - b. No, my baby was supplemented in the hospital and at home. (Go to question 4)
4. How many weeks old was your baby when you first fed formula/other food?
5. How many weeks old was your baby when you completely stopped breastfeeding?

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6 During the focus groups, the mothers each answered the questions on infant feeding
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8 practices and then discussed as a group how they interpreted each question. They provided
9
10 feedback on question structure and order to improve the clarity of questions and reduce response
11
12 burden. The final set of questions included in the Teleform to measure infant feeding practices
13
14 were selected based on the focus group feedback; these are based on questions used in other
15
16 prospective studies that follow mother-infant dyads from birth through the first year of life,
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18 aimed at measuring breastfeeding duration.[43,44] As well, these questions will capture data that
19
20 will allow us to construct variables on infant feeding in alignment with the World Health
21
22 Organization's definitions of breastfeeding.[45–48]
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28 Our questions ask mothers to report duration of exclusive breastfeeding and
29
30 complementary breastfeeding. Research has shown maternal recall of breastfeeding duration is
31
32 high when the recall period is less than one year.[49] The Teleform does not rely exclusively on
33
34 24 hour recall to measure infant feeding practices since some studies have shown that 24 hour
35
36 recall may overestimate prevalence of exclusive breastfeeding and thus recommend that infant
37
38 feeding be prospectively measured with a combination of current status and recall since
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40 birth.[50–55]
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46 The Teleform also collects data for linkage purposes, including (1) the mother's and
47
48 infant's Personal Health Identification Numbers (PHINs; unique, person-level identifiers held in
49
50 the Repository), (2) the infant's birth date, (3) the infant's sex, and (4) the mother's postal code.
51
52 The final version of the Teleform is presented as a supplemental file.
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56 *Recruitment and Data Collection*

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3 Recruitment and data collection began in September 2015 and will continue until
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5
6 December 2017. Six study sites are enrolled: one urban clinic where 75% of all urban-dwelling
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8 children in Manitoba receive their vaccinations, two rural public health offices located in
9
10 agricultural communities, and three rural public health offices located in rural remote settings.
11
12 Over the past three years, the annual number of children vaccinated across all six sites ranged
13
14 between 1500 and 2000 children.
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18 Mothers who bring their infants to study site clinics for vaccination visits are asked by
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20 clinic staff members to participate in the study. Clinic staff provide them with documents
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22 describing the study and its purpose, along with informed consent documentation. Mothers who
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24 review the documents and give written informed consent are enrolled in the study. Study
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26 participants are asked to complete the Teleform at their infants' 2-, 4-, and 6-month vaccination
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28 visits. Mothers fill out the Teleform during the visit, and then return it to staff before leaving the
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30 clinic. Data collected with the Teleform are faxed by the clinic staff to the research study office
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32 located within a government agency. There, the data are automatically extracted from the faxed
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34 form and an image of the form is placed on a password-protected network in a secure data
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36 environment with restricted card access. Data quality checks are run manually to identify
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38 transcription errors and missing data. For each data field, we are documenting the percentage
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40 with transcription errors, requiring manual verification, and needing manual edits to address
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42 research question 1.
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48 Table 1 presents preliminary summary enrollment figures and vaccination rates of infants
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50 at each study site (September 2015 to December 2016). During this period, approximately 75%
51
52 of mothers consented to provide feeding data for the study. At the end of the data collection
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3 phase, we will conduct descriptive summary statistics to identify patterns of transcription errors
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5 and missing data to answer our first two research questions.
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8 9 ***Linking Infant Feeding Data with the Manitoba Population Research Data Repository***

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11 The Manitoba Infant Feeding Database is composed of two datasets: (1) the Infant
12 Feeding Dataset consisting of infant feeding data and individuals' unique study ID; and (2) the
13 Identifying Dataset comprising mothers' and infants' PHINs, infant's date of birth, infant's sex,
14 mother's postal code, and infant's unique study ID. Box 2 depicts the information held in the two
15 datasets. Figure 2 shows the data flow process from point of data collection to acquisition into
16 the Manitoba Population Research Data Repository for data analyses.
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26 The Manitoba Infant Feeding Database will be held in and linked to the Manitoba
27 Population Research Data Repository. Figure 1 shows a graphical summary of the Repository, a
28 collection of over 70 databases containing information on health, education, receipt of social
29 services, and interactions with the justice system. The Manitoba Health Insurance Registry
30 includes individuals' unique scrambled PHINs and a Family Registration Number, which allows
31 linkages between mothers and their infants. Using scrambled PHINs and crosswalk files
32 generated by Manitoba Health, individual-level data can be linked across all datasets held in the
33 Repository in a de-identified way.
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45 46 ***Study Cohort Development***

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48 We will construct the study cohort using the whole-population data held in the
49 Repository. The crosswalk file generated by Manitoba Health will be used to link mothers and
50 infants, and to link infants' feeding data with their health records in the Repository. Specifically,
51 infant feeding data will be linked with the following administrative health data: (1) the dyad's
52 birth hospital discharge data, (2) the infant's vaccination records held in the Manitoba
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3 Immunization Monitoring System, (3) medical billing records associated with the infant's
4 primary care visits held in the Medical Services dataset, and (4) the mother's postal code of
5 residence held in the Manitoba Health Insurance Registry. The cohort will include all mothers
6 and infants who had at least one vaccination visit at one of the study sites between September
7 1, 2015 and December 31, 2017; thus it, will include infants with and without feeding data. For
8 those without feeding data, the relevant data fields in the Manitoba Infant Feeding Database will
9 read 'missing'. We will use multivariable logistic regression models to identify characteristics
10 associated with having missing data in the MIFD.
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Table 1. Numbers of mother-infant dyads with infant feeding data captured in the Manitoba Infant Feeding Database at each vaccination visit, per year

	2-Month			4-Month			6-Month		
	Estimated No. of Children ^A	Percent with 2-Month Vaccination ^B	No. of Dyads in the MIFD Per Year ^C	No. of Children ^A	Percent with 4-Month Vaccination	Estimated No. of Dyads Captured Per Year ^D	No. of Children ^A	Percent with 6-Month Vaccination	Estimated No. of Dyads Captured Per Year ^D
Urban Clinic	1000	90%	921	1000	86%	643	1000	78%	585
Rural Agricultural Site 1	100	90%	68	100	88%	66	100	75%	56
Rural Agricultural Site 2	100	90%	65	100	82%	61	100	78%	58
Rural Remote Site 1	400	90%	155	400	83%	249	400	72%	216
Rural Remote Site 2	75	90%	53	75	82%	46	75	73%	41
Rural Remote Site 3	75	90%	52	75	80%	45	75	73%	41
TOTAL	1750		1314	1750		1110	1750		997

MIFD: Manitoba Infant Feeding Database

^A Estimated number of children seen at each study site during a one year period based on information provided by clinic administrators. Precise numbers of children seen at each clinic will be determined once the MIFD is linked with the Manitoba Population Research Data Repository

^B Vaccination rates estimated for the first year of the study period from previous years' administrative health data held in the Manitoba Population Research Data Repository.

^C All mother-infant dyads who attend a vaccination visit will be invited to participate in the study. Between September 1, 2015 and December 31, 2016, roughly 75% of them enrolled in the study. This column presents the number of mother-infant dyads who have consented to participate in the study and whose infant feeding data was captured in the Manitoba Infant Feeding Database.

^D Based on current enrollment rates (75%) and vaccination rates, this column represents the anticipated number of mother-infant dyads whose data will be captured at the 4- and 6-month vaccination visits.

Box 2. Datasets in the Manitoba Infant Feeding Database

<u>Infant Feeding Dataset</u>	<u>Identifying Dataset</u>
<ul style="list-style-type: none"> • Unique Study ID • Infant feeding status at vaccination visit • Infant age at cessation of exclusive breastfeeding • Infant age at cessation of breastfeeding • Whether infant was supplemented during hospital stay 	<ul style="list-style-type: none"> • Unique Study ID • Mother's Personal Health Identification Number (PHIN) • Infant's PHIN • Infant's birth date • Infant's sex • Mother's postal code

Variable Construction

Using the study cohort, we will develop variables to address research questions 3-5.

Table 2 presents each of the outcome variables we will examine in these analyses. Because the data include all contacts with the healthcare system, we will be able to follow infants as they access healthcare services across the province; we will be able to track all vaccinations for infants in the study, regardless of whether or not that vaccination was given at one of the study sites. We will construct a set of three variables – one for each vaccination visit – to describe whether we captured infant feeding data from the dyad. For each visit, the variable will tell us (1) if feeding data were recorded, (2) if a vaccination visit was recorded at a study site but feeding data are missing, (3) if a vaccination visit was recorded at a non-study site, and (4) whether an infant has a vaccination recorded for that time point.

A feeding history for each infant will be constructed using data from the hospital discharge abstract and feeding data collected at each vaccination visit. The feeding history will indicate whether an infant is exclusively breastfeeding, complementary breastfeeding, or exclusively formula feeding at four contacts with the healthcare system: birth hospital discharge, 2-, 4-, and 6-month vaccination visits (definitions presented in Table 2). We use the WHO definitions for infant feeding status at each time point:

- *Exclusive Breastfeeding* – an infant is only fed breast milk (including milk expressed or from a wet nurse), and not fed anything else; and
- *Complementary Feeding* – an infant is fed breast milk (including milk expressed or from a wet nurse) and solid or semi-solid foods, allowing for any food or liquid including non-human milk and formula.[45–48]

The data collected on the Teleform will also be used to determine (1) the infant's age when a food other than human milk was first introduced (cessation of exclusive breastfeeding), and (2) the infant's age when the dyad stopped breastfeeding entirely (breastfeeding cessation). Taken together, this information can be used to identify each infant's duration of exclusive and complementary breastfeeding.

In addition to infant feeding status, we will construct a dichotomous variable that describes infant feeding history. An infant feeding history can be constructed from the available data for each infant if (a) the date of exclusive and breastfeeding cessation are both recorded, (b) the infant had all age-appropriate vaccination visits and was still breastfeeding at the last recorded visit (in this instance, the data are right censored), or (c) feeding data are recorded for each visit, regardless of feeding practice. Because we will have data on every infant, we will be able describe how those with missing feeding data or those whose data were not captured in the database differ from infants with feeding data recorded at each contact with the healthcare system. Table 3 presents the explanatory variables that we will use in these analyses.

Explanatory variables will be developed using Repository data from the mother and/or infant.

Table 2. Outcome Variables for Analyses

<i>Data Capture Variables</i>	
Infant Feeding Data Captured, 2-Month Vaccination Visit	<ol style="list-style-type: none"> 1. Infant feeding data recorded in the database at 2-month visit 2. Infant has 2-month vaccination recorded at a study site but does not have feeding data captured in database 3. Infant has a 2-month vaccination recorded at a non-study site 4. Infant does not have 2-month vaccination visit recorded <p>Sub-Cohort: All infants in our cohort >2 months of age</p>
Infant Feeding Data Captured, 4-Month Vaccination Visit	<ol style="list-style-type: none"> 1. Infant feeding data recorded in the database at 4-month visit 2. Infant has 4-month vaccination recorded at a study site but does not have feeding data captured in database 3. Infant has a 4-month vaccination recorded at a non-study site 4. Infant does not have 4-month vaccination visit recorded <p>Sub-Cohort: All infants in our cohort >4 months of age</p>
Infant Feeding Data Captured, 6-Month Vaccination Visit	<ol style="list-style-type: none"> 1. Infant feeding data recorded in the database at 6-month visit 2. Infant has 6-month vaccination recorded at a study site but does not have feeding data captured in database 3. Infant has a 6-month vaccination recorded at a non-study site 4. Infant does not have 6-month vaccination visit recorded <p>Sub-Cohort: All infants in our cohort >6 months of age</p>
<i>Infant Feeding Status Variables</i>	
Infant feeding status	<ol style="list-style-type: none"> 1. Exclusively breastfeeding at vaccination visit (at 2, 4, and 6 months) <ol style="list-style-type: none"> a. Question 9: Mother only selects “breast milk” b. Question 10: Mother answers “No” c. Question 11: Mother answers “Never” d. Question 12: Mother answers “Not applicable” e. Question 13: Mother answers “I am still breastfeeding” 2. Complementary breastfeeding at vaccination visit (at 2, 4, and 6 months) <ol style="list-style-type: none"> a. Question 9: Mother selects breast milk (may select other options as well) b. Question 10: Mother answers either “Yes” or “No” c. Question 11: Mother selects any option d. Question 12: Mother provides any answer e. Question 13: Mother answers “I am still breastfeeding” 3. Infant age when exclusive breastfeeding ceased (at 2, 4, and 6 months) <ol style="list-style-type: none"> a. Question 12: Mother’s response 4. Infant age when breastfeeding ceased (at 2, 4, and 6 months) <ol style="list-style-type: none"> a. Question 13: Mother’s response 5. Infant was only supplemented with formula in hospital; infant was only breastfed after hospital discharge <ol style="list-style-type: none"> a. Question 9: Mother selects “breast milk”; she does not select “other liquids” and she does not select “solids/other foods.” She may or may not select “formula”. b. Question 10: Mother answers either “Yes” or “No” c. Question 11: Mother only selects “In hospital” d. Question 12: Mother provides any answer e. Question 13: Mother answers “I am still breastfeeding”
Complete infant feeding data for age	Constructed using data from the hospital discharge abstract and 2-, 4-, and 6-month vaccination visit data. For each infant we will first identify all vaccinations for which the infant is eligible, based on age (e.g., for a 5-month old infant, we will identify whether it has records for both a 2 and 4 month vaccination visits). Then

we will identify whether an infant feeding history can be constructed from the available data.

A feeding history can be constructed if:

- An infant has all age-appropriate vaccinations and is still breastfeeding at the latest recorded vaccination visit; breastfeeding cessation is censored; or
- Feeding data identify that the infant stopped breastfeeding prior to the recorded vaccination visit. Feeding data are missing for vaccination visits that follow breastfeeding cessation; or
- Feeding data are recorded for every vaccination visit, regardless of feeding practice;

A feeding history cannot be constructed if:

- All vaccination visits happen at study site and either exclusive breastfeeding cessation or any breastfeeding cessation cannot be determined due to missing infant feeding;
- 1 or more vaccination visits recorded at non-study site and either exclusive or any breastfeeding cessation cannot be determined due to missing feeding data.
- Data on one or more vaccination visits is missing and either exclusive or any breastfeeding cessation cannot be determined due to missing feeding data.

Table 3. Explanatory Variables

<i>Parental Characteristics</i>	
Registry	<ul style="list-style-type: none"> • Maternal age • Maternal postal code of residence: used to identify whether the mother is living in urban or rural setting and used to identify distance mother needs to travel to obtain a vaccination for her child • Residential mobility: Number of times a mother moved in the 5 years before the birth of her child
Postal Code Conversion	<ul style="list-style-type: none"> • Average income for the census dissemination area where the mother is living at the time of her child's birth. Average is based on between 400 and 700 individuals and provides a measure for the mother's neighborhood-level socioeconomic status
Medical Claims	<ul style="list-style-type: none"> • Maternal access to prenatal care during pregnancy
Hospital Discharge Abstract Database	<ul style="list-style-type: none"> • Type of birth: vaginal or caesarean-section
Education	<ul style="list-style-type: none"> • Maternal educational attainment (high school completion) • Paternal educational attainment (high school completion)
Newcomer Status	<ul style="list-style-type: none"> • Whether the mother moved to Manitoba from another country within the last 5 years
<i>Infant Characteristics</i>	
Registry	<ul style="list-style-type: none"> • Infant's birth date • Infant's sex
Hospital Discharge Abstract Database	<ul style="list-style-type: none"> • Apgar score • Birth weight • Gestational age • Breastfeeding at birth hospital discharge

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For peer review only

Data Analysis Plan

We will generate descriptive statistics to identify the percentage of infants in the cohort with feeding data at 2-, 4-, and 6-month vaccination visits, and test whether data capture rates differ across time (research question 3). We will also test whether the percentage of infants with captured data differs by urban/rural status of the study site where they were vaccinated (research question 4). For each time point, we will calculate the socioeconomic distribution of infants across four categories: (1) infant has feeding data, (2) infant has vaccination recorded at a study site but does not have feeding data, (3) infant has a vaccination recorded at a non-study site, and (4) infant does not have a vaccination recorded.

We will calculate the percentage of infant feeding data that are missing due to the infant receiving one or two vaccinations at a non-study site. Identifying the frequency with which this occurs will provide an estimate of the percentage of infants that could have complete infant feeding data if Manitoba had a universal system that captured infant feeding information.

Characteristics associated with having infant feeding data captured in the database will be examined using logistic regression models for the 2-, 4-, and 6-month visits (research question 5). The outcome will be a dichotomous variable identifying whether or not a mother-infant dyad's infant feeding information is captured in the database. Models will include the variables listed in Table 3. Each model will include a sub-cohort of age-appropriate infants; for example, analyses examining data collected at the 4-month vaccination visit will exclude anyone ≥ 4 months of age. Results from these analyses will indicate whether mother-infant dyads captured by this strategy differ systematically from those who have missing data.

Finally, we will examine characteristics associated with whether or not we can construct an age-appropriate infant feeding history using data held in the Manitoba Infant Feeding

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3 Database. The outcome variable will describe whether or not a complete infant feeding history
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5 can be constructed based on available data. Explanatory variables will include those listed in
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7 Table 3.
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10 11 12 **Ethics and Dissemination**

13 *Ethical Considerations*

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15 The research team has completed the Tri-Council Course on Research Ethics. We have
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17 obtained approvals from the Health Research Ethics Board at the University of Manitoba, the
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19 Health Information Privacy Committee of Manitoba Health, and the ethics committees in
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21 participating regional health authorities. Participation in the study is voluntary. Study
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23 participants are informed of the purpose of the study, potential risks associated with participation
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25 (compromise of data), their rights and obligations as participants, and their ultimate right to
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27 withdraw at any point without negative consequences. We ask study participants for consent to
28
29 link their data with the Repository. Participants are informed that they will not be identifiable in
30
31 any reports or publications. Informed consent is obtained from participants prior to data
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33 collection. Identified data is housed on a password protected server in a secure data environment
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35 at the research office. The data is sent to Manitoba Health for de-identification and encryption.
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37 Only the data analysts have access to the de-identified data. Analyses using the de-identified data
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39 will be conducted in the secure data environment at the Manitoba Centre for Health Policy.
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48 *Integrated Knowledge Translation and Dissemination of Findings*

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50 The research team has adopted an integrative knowledge translation approach. In addition
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52 to academic researchers, the broader team comprises an interdisciplinary group of stakeholders
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54 from government departments, public health offices, and regional health authorities. Over a 6-
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3 month pre-funding planning period, the team worked together to develop a research plan and to
4 secure peer-reviewed funding through a Research Manitoba New Investigator Operating Grant.
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6 While the core research team leads the study, the stakeholders are serving as advisory group
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8 members to ensure that findings can be applied to the population-based infant feeding data
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10 collection strategy. The advisory group also strategizes with the core research team on methods
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12 for disseminating findings to healthcare workers and other stakeholders in and outside of
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14 Manitoba.
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20 Even at this early stage, there has been great interest in the study from stakeholders in
21 government and public health. To date, we have presented the research plan and preliminary
22 findings to public health officers in each regional health authority active in the study, and we
23 have participated in two provincial meetings on breastfeeding practices. We have also widely
24 disseminated the study aims and early findings in the academic community at the University of
25 Manitoba. Near the end of the funding period, the team will host a province-wide workshop that
26 will bring together public health nurses, clinic staff members, and stakeholders to discuss the
27 study findings and experiences with implementing the data collection mechanism. Two advisory
28 group members are actively involved with the Breastfeeding Committee for Canada and will
29 arrange for webinars to disseminate findings through this organization. Findings will be
30 presented at national and/or international conference(s) and will be submitted for peer-review
31 publication to inform further research around infant feeding data collection and provide evidence
32 for building new population-based data collection systems.
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Figure Captions:**Figure 1. Graphical Representation of the Manitoba Population Health Research Data Repository**

The Repository, held at the Manitoba Centre for Health Policy, is a collection of over 70 databases containing up to 30 years of information on Manitoba residents' health, education, receipt of social services, and interactions with the justice system. De-identified individual-level data can be linked across all Repository datasets.

Figure 2. Manitoba Infant Feeding Database Data Flow Diagram

Data are collected at vaccination visits using the Teleform and faxed to a central office. The identifiable data file contains two datasets: (1) Infant Feeding Data (a dataset that includes infant feeding information and study ID), and (2) Identifying Data (a dataset that includes identifying information and study ID). The Identifying Data are sent to Manitoba Health for de-identification and attachment of scrambled Personal Health Identification Number (PHIN). Manitoba Health generates a cross walk file with instructions for data linkage. The Infant Feeding Data are sent to the Manitoba Population Research Data Repository. The Scrambled PHIN, study ID, and crosswalk file are used to link infant feeding data with the rest of the administrative data held in the Repository. The linked databases form the analytic data for the study.

Author Contributions:

The study was conceived by NCN, the principal investigator on the original funded grant. NCN, LW, MH, AK, and CG participated in designing the study and were listed as collaborators on the grant. NCN, JC, and LW were involved in recruiting participating study sites, and NCN and JC are working with study sites on data collection processes. JC and JP are involved in data cleaning and verification. NCN, LK, and JEE drafted the manuscript. All authors (NCN, LW, LK, JC, MH, CG, AK, JP, CP, DG, LL, JEE, and SS) contributed to critically revising the manuscript for important intellectual content, gave their final approval, and agree to be accountable for all aspects of the work. All authors (NCN, LW, LK, JC, MH, CG, AK, JP, CP, DG, LL, JEE, and SS) will participate in future interpretation of the data and drafting of further manuscripts arising from this work.

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8 conclusions are those of the authors and no official endorsement by MCHP, Manitoba Health,
9 Seniors and Active Living is intended or should be inferred.
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20 **Competing Interests:**

21 The authors declare that they have no competing interests.
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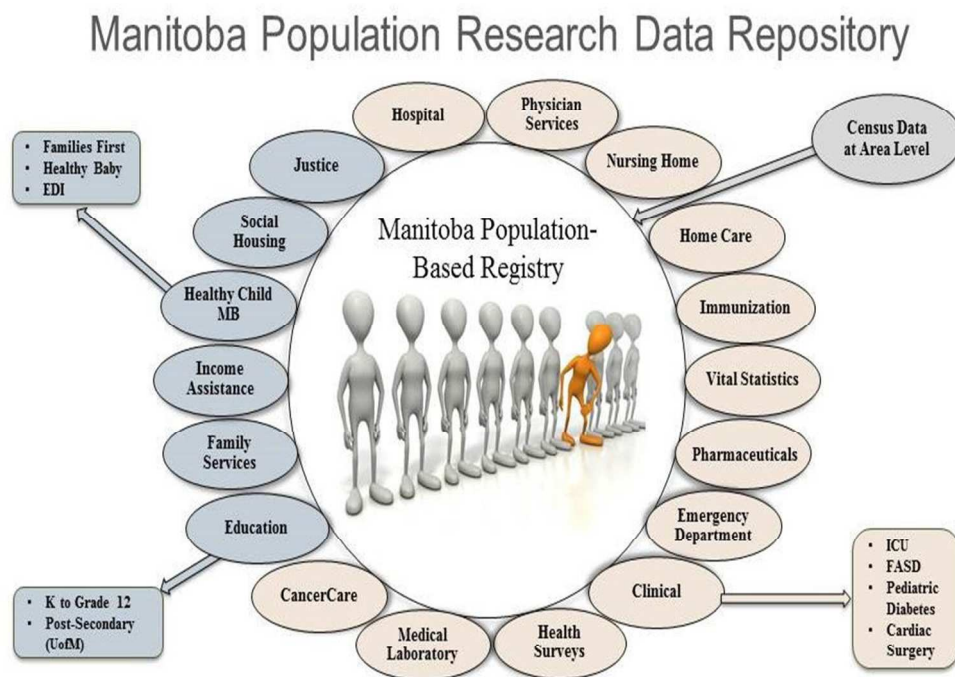


Figure 1. Graphical Representation of the Manitoba Population Health Research Data Repository
 The Repository, held at the Manitoba Centre for Health Policy, is a collection of over 70 databases containing up to 30 years of information on Manitoba residents' health, education, receipt of social services, and interactions with the justice system. De-identified individual-level data can be linked across all Repository datasets.

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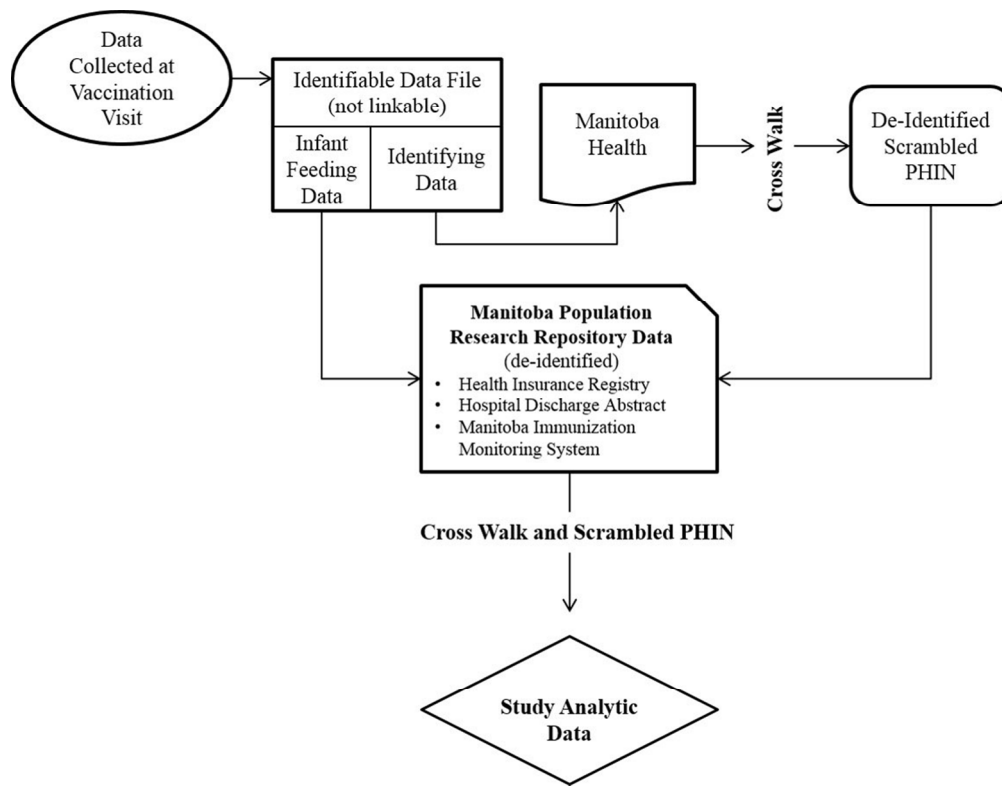


Figure 2. Manitoba Infant Feeding Database Data Flow Diagram

Data are collected at vaccination visits using the Teleform and faxed to a central office. The identifiable data file contains two datasets: (1) Infant Feeding Data (a dataset that includes infant feeding information and study ID), and (2) Identifying Data (a dataset that includes identifying information and study ID). The Identifying Data are sent to Manitoba Health for de-identification and attachment of scrambled Personal Health Identification Number (PHIN). Manitoba Health generates a cross walk file with instructions for data linkage. The Infant Feeding Data are sent to the Manitoba Population Research Data Repository. The Scrambled PHIN, study ID, and crosswalk file are used to link infant feeding data with the rest of the administrative data held in the Repository. The linked databases form the analytic data for the study.

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01. Please enter TODAY's date:

				2	0		
DAY		MONTH		YEAR			

02. What is your relationship to the baby:

Mother Father Other caregiver

03. In the boxes provided, please print **baby's** 6-digit Health Registration Number:

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04. In the boxes provided, please print **baby's** 9-digit Personal Health Identification Number:

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05. In the boxes provided, please print **mother's** 9-digit Personal Health Identification Number:

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06. Please enter baby's birth date:

				2	0		
DAY		MONTH		YEAR			

07. Please enter the first 3-characters of your 6-character postal code:

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08. Is your baby a girl or a boy?

Boy Girl

09. What has your baby been fed?
Please select all that apply.

Breast milk
 Formula
 Other liquids (juice, cow's milk, goat's milk, tea, etc)
 Solids / Other foods

10. Has your baby ever had formula?

Yes No

11. When was your baby fed formula?
Please select all that apply.

In hospital At home Never

12. How many weeks old was your baby when you first fed formula/other liquids/other food?

Since birth

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 weeks old Not applicable

13. How many weeks old was your baby when you completely stopped breastfeeding?

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 weeks I am still breastfeeding
 I have only formula fed

BMJ Open

Protocol for Establishing an Infant Feeding Database Linkable with Population-Based Administrative Data: A Prospective Cohort Study in Manitoba, Canada

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For peer review only

ABSTRACT

Introduction

Breastfeeding is associated with many health benefits for mothers and infants. But despite extensive public health efforts to promote breastfeeding, many mothers do not achieve their own breastfeeding goals; and, inequities in breastfeeding rates persist between high- and low-income mother-infant dyads. Developing targeted programs to support breastfeeding dyads and reduce inequities between mothers of different socioeconomic status are a priority for public health practitioners and health policy decision makers; however, many jurisdictions lack the timely and comprehensive population-level data on infant feeding practices required to monitor trends in breastfeeding initiation and duration. This protocol describes the establishment of a population-based infant feeding database in the Canadian province of Manitoba, providing opportunities to develop and evaluate breastfeeding support programs.

Methods and Analysis

Routinely collected administrative health data on mothers' infant feeding practices will be captured during regular vaccination visits using the Teleform fax tool, which converts hand-written information to an electronic format. The infant feeding data will be linked to the Manitoba Population Research Data Repository, a comprehensive collection of population-based information spanning health, education, and social services domains. The linkage will allow us to answer research questions about infant feeding practices and to evaluate how effective current initiatives promoting breastfeeding are.

Ethics and Dissemination

Approvals have been granted by the Health Research Ethics Board at the University of Manitoba. Our integrative knowledge translation approach will involve disseminating findings

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through government and community briefings, presenting at academic conferences, and publishing in scientific journals.

For peer review only

Strengths & Limitations

- This study is among the first to establish a mechanism for collecting infant feeding data at a population level in Canada, providing longitudinal data to study the impact of policy, programs and services on infant feeding practices.
- Our ability to link the infant feeding database with a large repository of administrative data spanning several domains increases the number of confounding characteristics we can adjust for in our analyses.
- Using linked whole-population data means there will be minimal loss to follow-up, and allows us to compare individuals captured in the infant feeding database with individuals who were not.
- Using vaccination visits as the point of contact for data collection means some individuals will be missed (although more than 90% of infants receive the recommended vaccinations at 2 months of age).
- Collecting data on infant feeding routinely relies on maternal report, which can be subject to social desirability bias.

Introduction

Breastfeeding is associated with numerous health benefits for mothers and their infants.[1–7] The World Health Organization, UNICEF, and other health authorities recommend exclusive breastfeeding for the first six months of life, followed by continued feeding of breastmilk along with complementary foods for two years and beyond.[8–12] However, in spite of extensive public health efforts to support breastfeeding, two challenges remain: (1) many mothers do not achieve their own breastfeeding goals; and (2) inequities in breastfeeding outcomes persist between mother-baby dyads living in marginalized circumstances and their more advantaged counterparts.[13–15] Findings from the Canadian Maternity Experiences Survey showed that although breastfeeding initiation rates were relatively high in Canada, exclusive breastfeeding duration fell short of globally recommended standards, with only 14.4% of mother-baby dyads breastfeeding exclusively at 6 months after birth.[16] Based on these figures, developing targeted programs and interventions to support breastfeeding dyads and reduce breastfeeding inequities have become a priority for public health practitioners and health policy decision makers.[17,18] However, many jurisdictions lack the timely and comprehensive population-level data on infant feeding practices required to monitor trends in breastfeeding initiation and duration.

Current State of Infant Feeding Surveillance

In North America, much of the data on infant feeding practices are collected through primary data collection methods such as cross-sectional surveys and cohort studies. Most global surveillance of longitudinal infant feeding is accomplished through periodic surveys of populations, often at the time of hospital discharge or in the postpartum period.[19–22] These methods of epidemiological surveillance have some important limitations:[23–27]

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3 1. Significant resources are required to design and implement novel high-quality cohort
4 studies;
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8 2. Families living in disadvantaged social and economic circumstances – such as low-income
9 households and families with high residential mobility – may be under-represented in survey
10 research;
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12
- 13 3. Lack of whole-population data makes generalizability challenging and limits planners’
14 ability to conduct small area-level analyses;
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- 17 4. Relying on survey data collected for a single purpose makes it difficult to track outcomes
18 across the life span.
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25 In light of these and other limitations, researchers are turning to routinely collected
26 administrative health data to conduct a wide variety of epidemiological research studies.[27]
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29 30 *How Can Administrative Health and Social Data Help Address Evidence Gaps?* 31

32
33 Contacts with the health and social services systems generate data in the form of
34 administrative records. Linking these routinely collected records across sectors is a powerful tool
35 for conducting large-scale, longitudinal epidemiological research.[23,25–28] For example,
36
37 researchers in Europe and Australia have been using linked administrative health data to monitor
38 breastfeeding initiation and duration rates for the last two decades.[29–32] In Canada, studies
39 have used breastfeeding initiation data obtained from the birth hospital discharge abstracts to
40 track trends and inequities in breastfeeding initiation, and examine outcomes associated with
41 initiating breastfeeding during the first days of life.[13,33] Although providers routinely ask
42 questions about infant feeding practices during well-baby visits throughout the first year of life,
43 including questions about breastfeeding duration, this information is seldom integrated into a
44 centralized database. Thus, researchers and program planners lack comprehensive data on infant
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3 feeding practices once the mother-baby dyad is discharged from the birth hospital stay.

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5 Therefore, there is a critical need to identify a mechanism whereby infant feeding information
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8 that is routinely collected during well-baby visits can be consolidated in a whole-population
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11 database.

12 13 **Research Objective**

14
15 The objective of this work is to establish a mechanism for collecting infant feeding
16
17 information during routine contacts with the healthcare system, which can then be linked with a
18
19 centralized data repository of administrative health data. Specifically, it will evaluate whether a
20
21 Teleform fax system is a viable mechanism for (a) collecting infant feeding data when infants
22
23 receive their 2-, 4-, and 6-month vaccinations, and (b) automatically depositing that information
24
25 into the new Manitoba Infant Feeding Database (MIFD), and linking it at the individual level
26
27 with the Manitoba Population Research Data Repository, an established repository of
28
29 administrative health and social data.
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35 We will address the following research questions:

- 36
37 1. What percent of data collected using the Teleform have transcription errors when
38
39 automatically read into an electronic format, requiring manual verification and edits?
- 40
41 2. What are the patterns of missing data in the Manitoba Infant Feeding Database?
- 42
43 3. What percent of infants are captured at the 2-, 4-, and 6-month vaccination visits?
- 44
45 4. Do data capture rates differ by rural/urban status of the study sites?
- 46
47 5. What maternal characteristics (maternal age, income, residential mobility) and infant
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49 characteristics (sex, small for gestational age, large for gestational age, Apgar score) are
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51 associated with data captured at the 2-, 4-, and 6-month vaccination visits?
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Methods and Analysis

Setting

The study funding period began in October 2014 and ends in August 2018. The study takes place in Manitoba, a central Canadian province with approximately 1.3 million residents. For the past four years, the annual number of births in the province has ranged between 15,000 and 17,000 births. Just over 80% of mother-infant dyads initiate breastfeeding during the birth hospital stay; however, initiation rates follow a socioeconomic gradient where low-income dyads are less likely to initiate breastfeeding compared with their higher-income counterparts.[13–15]

A unique and advantageous feature of establishing an infant feeding database in Manitoba is our ability to link the new Manitoba Infant Feeding Database to the established Manitoba Population Research Data Repository.[34,35] The Repository contains more than 30 years of population-based, individual-level information on all Manitobans who are registered with the province of Manitoba's universal health insurance program; thus, the Repository contains information on 99.9% of Manitobans residents. Each time a Manitoba resident is in contact with the healthcare system, the information from that contact is recorded and held in the Repository. The Repository data are de-identified using strict protocols to preserve residents' anonymity, but can be linked longitudinally and across sectors using a scrambled personal identification number.[23,25,27] Besides health information, the Repository includes administrative records from social services and government programs, children's education records, and contacts with the criminal justice system.[23,25] The Repository data have been validated and used extensively for maternal and child health research studies.[36–40]

Identifying Opportunities for Data Collection at Routine Vaccination Visits

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3 We began by identifying infant vaccination visits as a consistent and opportune routine
4 point of contact with the healthcare system whereby population-based information on infant
5 feeding could be collected. In Manitoba, more than 90% of infants complete their 2-month
6 vaccination schedules and 78% complete their 1-year vaccination schedules.[41] Thus, using this
7 point of contact, infant feeding information could be collected from nearly every mother-baby
8 dyad in the province. With consideration for the funding timeline, we selected the 2-, 4-, and 6-
9 month vaccination visits as infant feeding data collection time points.
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20 21 *Selecting and Optimizing a Tool for Data Collection: The Teleform Fax Tool*

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23 It was important to choose a tool that falls within the requirements of the personal health
24 information legislation in Manitoba and that could be widely applied across the province.
25
26 Manitoba does not currently have an online system that complies with privacy legislation for
27 personal health information sharing; online data collection and sharing would also not be feasible
28 in many of Manitoba's rural and remote communities where internet connectivity is poor or non-
29 existent. We selected the Teleform Fax Tool[42] since it is compliant with Manitoba's personal
30 health information legislation and can be used without internet access. Fax technology is also
31 routinely used to collect health information in jurisdictions across Canada,[43–46] and as such, is
32 an accepted tool for collecting survey data.
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45 In order to place a minimum burden on mothers and healthcare workers, ensure that the
46 Teleform questions could be answered quickly and easily, and maximize the possibility that such
47 a system could be routinely implemented across the province, we conducted a literature search to
48 identify a short set of questions that would yield rich data on infant feeding practices post-
49 hospital discharge.[47] During the summer of 2015, we piloted a draft version of the questions
50 (Box 1) by conducting three focus groups with new mothers: one urban group comprising 8
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mothers, one group of 9 mothers in a rural agricultural community, and one group of 12 mothers from a remote rural community.

Box 1. Infant Feeding Questions Pilot Tested with Manitoba Mothers

1. What has your baby been fed since birth?
 - a. Only Breastmilk. (End of questions)
 - b. Only formula/other food. (End of questions)
 - c. Breastmilk and formula/other food. (Go to question 2)
2. During the past week, what did you feed your baby?
 - a. Breastmilk only. (Go to question 3)
 - b. Breastmilk and formula/other food. (Go to question 4)
 - c. Only formula/other food. (Go to question 5)
3. Was your baby only supplemented in the hospital?
 - a. Yes, my baby was only supplemented in the hospital. Otherwise I have only breastfed (End of questions)
 - b. No, my baby was supplemented in the hospital and at home. (Go to question 4)
4. How many weeks old was your baby when you first fed formula/other food?
5. How many weeks old was your baby when you completely stopped breastfeeding?

During the focus groups, the mothers each answered the questions on infant feeding practices and then discussed as a group how they interpreted each question. They provided feedback on question structure and order to improve the clarity of questions and reduce response burden. The final set of questions included in the Teleform to measure infant feeding practices were selected based on the focus group feedback; these are based on questions used in other prospective studies that follow mother-infant dyads from birth through the first year of life, aimed at measuring breastfeeding duration.[48,49] As well, these questions will capture data that will allow us to construct variables on infant feeding in alignment with the World Health Organization's definitions of breastfeeding.[50–53]

Our questions ask mothers to report duration of exclusive breastfeeding and complementary breastfeeding. Research has shown maternal recall of breastfeeding duration is high when the recall period is less than one year.[54] The Teleform does not rely exclusively on 24 hour recall to measure infant feeding practices since some studies have shown that 24 hour

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3 recall may overestimate prevalence of exclusive breastfeeding and thus recommend that infant
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5 feeding be prospectively measured with a combination of current status and recall since
6
7 birth.[55–60]
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11 The Teleform also collects data for linkage purposes, including (1) the mother's and
12
13 infant's Personal Health Identification Numbers (PHINs; unique, person-level identifiers held in
14
15 the Repository), (2) the infant's birth date, (3) the infant's sex, and (4) the mother's postal code.
16
17 The final version of the Teleform is presented in Supplementary File 1.
18
19

20 21 22 ***Recruitment and Data Collection*** 23

24
25 Recruitment and data collection began in September 2015 and will continue until
26
27 December 2017. Six study sites are enrolled: one urban clinic where 75% of all urban-dwelling
28
29 children in Manitoba receive their vaccinations, two rural public health offices located in
30
31 agricultural communities, and three rural public health offices located in rural remote settings.
32
33 Over the past three years, the annual number of children vaccinated across all six sites ranged
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35 between 1500 and 2000 children.
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39 Mothers who bring their infants to study site clinics for vaccination visits are asked by
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41 clinic staff members to participate in the study. Clinic staff provide them with documents
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43 describing the study and its purpose, along with informed consent documentation. Mothers who
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45 review the documents and give written informed consent are enrolled in the study. Study
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47 participants are asked to complete the Teleform at their infants' 2-, 4-, and 6-month vaccination
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49 visits. Mothers fill out the Teleform during the visit, and then return it to staff before leaving the
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51 clinic. Data collected with the Teleform are faxed by the clinic staff to the research study office
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53 located within a government agency. There, the data are automatically extracted from the faxed
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55 form and an image of the form is placed on a password-protected network in a secure data
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3 environment with restricted card access. Data quality checks are run manually to identify
4 transcription errors and missing data. For each data field, we are documenting the percentage
5 with transcription errors, requiring manual verification, and needing manual edits to address
6 research question 1.
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11
12 Table 1 presents preliminary summary enrollment figures and vaccination rates of infants
13 at each study site (September 2015 to December 2016). During this period, approximately 75%
14 of mothers consented to provide feeding data for the study. At the end of the data collection
15 phase, we will conduct descriptive summary statistics to identify patterns of transcription errors
16 and missing data to answer our first two research questions.
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24 ***Linking Infant Feeding Data with the Manitoba Population Research Data Repository***

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26 The Manitoba Infant Feeding Database is composed of two datasets: (1) the Infant
27 Feeding Dataset consisting of infant feeding data and individuals' unique study ID; and (2) the
28 Identifying Dataset comprising mothers' and infants' PHINs, infant's date of birth, infant's sex,
29 mother's postal code, and infant's unique study ID. Box 2 depicts the information held in the two
30 datasets. Figure 1 shows the data flow process from point of data collection to acquisition into
31 the Manitoba Population Research Data Repository for data analyses.
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42 The Manitoba Infant Feeding Database will be held in and linked to the Manitoba
43 Population Research Data Repository. The Repository is a collection of over 70 databases
44 containing information on health, education, receipt of social services, and interactions with the
45 justice system. The Manitoba Health Insurance Registry includes individuals' unique scrambled
46 PHINs and a Family Registration Number, which allows linkages between mothers and their
47 infants. Using scrambled PHINs and crosswalk files generated by Manitoba Health, individual-
48 level data can be linked across all datasets held in the Repository in a de-identified way.
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Study Cohort Development

We will construct the study cohort using the whole-population data held in the Repository. The crosswalk file generated by Manitoba Health will be used to link mothers and infants, and to link infants' feeding data with their health records in the Repository. Specifically, infant feeding data will be linked with the following administrative health data: (1) the dyad's birth hospital discharge data, (2) the infant's vaccination records held in the Manitoba Immunization Monitoring System, (3) medical billing records associated with the infant's primary care visits held in the Medical Services dataset, and (4) the mother's postal code of residence held in the Manitoba Health Insurance Registry. The cohort will include all mothers and infants who had at least one vaccination visit at one of the study sites between September 1, 2015 and December 31, 2017; thus it, will include infants with and without feeding data. For those without feeding data, the relevant data fields in the Manitoba Infant Feeding Database will read 'missing'. We will use multivariable logistic regression models to identify characteristics associated with having missing data in the MIFD.

Table 1. Numbers of mother-infant dyads with infant feeding data captured in the Manitoba Infant Feeding Database at each vaccination visit, per year

	2-Month			4-Month			6-Month		
	Estimated No. of Children ^A	Percent with 2-Month Vaccination ^B	No. of Dyads in the MIFD Per Year ^C	No. of Children ^A	Percent with 4-Month Vaccination	Estimated No. of Dyads Captured Per Year ^D	No. of Children ^A	Percent with 6-Month Vaccination	Estimated No. of Dyads Captured Per Year ^D
Urban Clinic	1000	90%	921	1000	86%	643	1000	78%	585
Rural Agricultural Site 1	100	90%	68	100	88%	66	100	75%	56
Rural Agricultural Site 2	100	90%	65	100	82%	61	100	78%	58
Rural Remote Site 1	400	90%	155	400	83%	249	400	72%	216
Rural Remote Site 2	75	90%	53	75	82%	46	75	73%	41
Rural Remote Site 3	75	90%	52	75	80%	45	75	73%	41
TOTAL	1750		1314	1750		1110	1750		997

MIFD: Manitoba Infant Feeding Database

^A Estimated number of children seen at each study site during a one year period based on information provided by clinic administrators. Precise numbers of children seen at each clinic will be determined once the MIFD is linked with the Manitoba Population Research Data Repository

^B Vaccination rates estimated for the first year of the study period from previous years' administrative health data held in the Manitoba Population Research Data Repository.

^C All mother-infant dyads who attend a vaccination visit will be invited to participate in the study. Between September 1, 2015 and December 31, 2016, roughly 75% of them enrolled in the study. This column presents the number of mother-infant dyads who have consented to participate in the study and whose infant feeding data was captured in the Manitoba Infant Feeding Database.

^D Based on current enrollment rates (75%) and vaccination rates, this column represents the anticipated number of mother-infant dyads whose data will be captured at the 4- and 6-month vaccination visits.

Box 2. Datasets in the Manitoba Infant Feeding Database

<u>Infant Feeding Dataset</u>	<u>Identifying Dataset</u>
<ul style="list-style-type: none"> • Unique Study ID • Infant feeding status at vaccination visit • Infant age at cessation of exclusive breastfeeding • Infant age at cessation of breastfeeding • Whether infant was supplemented during hospital stay 	<ul style="list-style-type: none"> • Unique Study ID • Mother's Personal Health Identification Number (PHIN) • Infant's PHIN • Infant's birth date • Infant's sex • Mother's postal code

Variable Construction

Using the study cohort, we will develop variables to address research questions 3-5.

Table 2 presents each of the outcome variables we will examine in these analyses. Because the data include all contacts with the healthcare system, we will be able to follow infants as they access healthcare services across the province; we will be able to track all vaccinations for infants in the study, regardless of whether or not that vaccination was given at one of the study sites. We will construct a set of three variables – one for each vaccination visit – to describe whether we captured infant feeding data from the dyad. For each visit, the variable will tell us (1) if feeding data were recorded, (2) if a vaccination visit was recorded at a study site but feeding data are missing, (3) if a vaccination visit was recorded at a non-study site, and (4) whether an infant has a vaccination recorded for that time point.

A feeding history for each infant will be constructed using data from the hospital discharge abstract and feeding data collected at each vaccination visit. The feeding history will indicate whether an infant is exclusively breastfeeding, complementary breastfeeding, or exclusively formula feeding at four contacts with the healthcare system: birth hospital discharge, 2-, 4-, and 6-month vaccination visits (definitions presented in Table 2). We use the WHO definitions for infant feeding status at each time point:

- *Exclusive Breastfeeding* – an infant is only fed breast milk (including milk expressed or from a wet nurse), and not fed anything else; and
- *Complementary Feeding* – an infant is fed breast milk (including milk expressed or from a wet nurse) and solid or semi-solid foods, allowing for any food or liquid including non-human milk and formula.[50–53]

The data collected on the Teleform will also be used to determine (1) the infant's age when a food other than human milk was first introduced (cessation of exclusive breastfeeding), and (2) the infant's age when the dyad stopped breastfeeding entirely (breastfeeding cessation). Taken together, this information can be used to identify each infant's duration of exclusive and complementary breastfeeding.

In addition to infant feeding status, we will construct a dichotomous variable that describes infant feeding history. An infant feeding history can be constructed from the available data for each infant if (a) the date of exclusive and breastfeeding cessation are both recorded, (b) the infant had all age-appropriate vaccination visits and was still breastfeeding at the last recorded visit (in this instance, the data are right censored), or (c) feeding data are recorded for each visit, regardless of feeding practice. Because we will have data on every infant, we will be able describe how those with missing feeding data or those whose data were not captured in the database differ from infants with feeding data recorded at each contact with the healthcare system. Table 3 presents the explanatory variables that we will use in these analyses.

Explanatory variables will be developed using Repository data from the mother and/or infant.

Table 2. Outcome Variables for Analyses

<i>Data Capture Variables</i>	
Infant Feeding Data Captured, 2-Month Vaccination Visit	<ol style="list-style-type: none"> 1. Infant feeding data recorded in the database at 2-month visit 2. Infant has 2-month vaccination recorded at a study site but does not have feeding data captured in database 3. Infant has a 2-month vaccination recorded at a non-study site 4. Infant does not have 2-month vaccination visit recorded <p>Sub-Cohort: All infants in our cohort >2 months of age</p>
Infant Feeding Data Captured, 4-Month Vaccination Visit	<ol style="list-style-type: none"> 1. Infant feeding data recorded in the database at 4-month visit 2. Infant has 4-month vaccination recorded at a study site but does not have feeding data captured in database 3. Infant has a 4-month vaccination recorded at a non-study site 4. Infant does not have 4-month vaccination visit recorded <p>Sub-Cohort: All infants in our cohort >4 months of age</p>
Infant Feeding Data Captured, 6-Month Vaccination Visit	<ol style="list-style-type: none"> 1. Infant feeding data recorded in the database at 6-month visit 2. Infant has 6-month vaccination recorded at a study site but does not have feeding data captured in database 3. Infant has a 6-month vaccination recorded at a non-study site 4. Infant does not have 6-month vaccination visit recorded <p>Sub-Cohort: All infants in our cohort >6 months of age</p>
<i>Infant Feeding Status Variables</i>	
Infant feeding status	<ol style="list-style-type: none"> 1. Exclusively breastfeeding at vaccination visit (at 2, 4, and 6 months) <ol style="list-style-type: none"> a. Question 9: Mother only selects “breast milk” b. Question 10: Mother answers “No” c. Question 11: Mother answers “Never” d. Question 12: Mother answers “Not applicable” e. Question 13: Mother answers “I am still breastfeeding” 2. Complementary breastfeeding at vaccination visit (at 2, 4, and 6 months) <ol style="list-style-type: none"> a. Question 9: Mother selects breast milk (may select other options as well) b. Question 10: Mother answers either “Yes” or “No” c. Question 11: Mother selects any option d. Question 12: Mother provides any answer e. Question 13: Mother answers “I am still breastfeeding” 3. Infant age when exclusive breastfeeding ceased (at 2, 4, and 6 months) <ol style="list-style-type: none"> a. Question 12: Mother’s response 4. Infant age when breastfeeding ceased (at 2, 4, and 6 months) <ol style="list-style-type: none"> a. Question 13: Mother’s response 5. Infant was only supplemented with formula in hospital; infant was only breastfed after hospital discharge <ol style="list-style-type: none"> a. Question 9: Mother selects “breast milk”; she does not select “other liquids” and she does not select “solids/other foods.” She may or may not select “formula”. b. Question 10: Mother answers either “Yes” or “No” c. Question 11: Mother only selects “In hospital” d. Question 12: Mother provides any answer e. Question 13: Mother answers “I am still breastfeeding”
Complete infant feeding data for age	Constructed using data from the hospital discharge abstract and 2-, 4-, and 6-month vaccination visit data. For each infant we will first identify all vaccinations for which the infant is eligible, based on age (e.g., for a 5-month old infant, we will identify whether it has records for both a 2 and 4 month vaccination visits). Then

we will identify whether an infant feeding history can be constructed from the available data.

A feeding history can be constructed if:

- An infant has all age-appropriate vaccinations and is still breastfeeding at the latest recorded vaccination visit; breastfeeding cessation is censored; or
- Feeding data identify that the infant stopped breastfeeding prior to the recorded vaccination visit. Feeding data are missing for vaccination visits that follow breastfeeding cessation; or
- Feeding data are recorded for every vaccination visit, regardless of feeding practice;

A feeding history cannot be constructed if:

- All vaccination visits happen at study site and either exclusive breastfeeding cessation or any breastfeeding cessation cannot be determined due to missing infant feeding;
- 1 or more vaccination visits recorded at non-study site and either exclusive or any breastfeeding cessation cannot be determined due to missing feeding data.
- Data on one or more vaccination visits is missing and either exclusive or any breastfeeding cessation cannot be determined due to missing feeding data.

Table 3. Explanatory Variables

<i>Parental Characteristics</i>	
Registry	<ul style="list-style-type: none"> • Maternal age • Maternal postal code of residence: used to identify whether the mother is living in urban or rural setting and used to identify distance mother needs to travel to obtain a vaccination for her child • Residential mobility: Number of times a mother moved in the 5 years before the birth of her child
Postal Code Conversion	<ul style="list-style-type: none"> • Average income for the census dissemination area where the mother is living at the time of her child's birth. Average is based on between 400 and 700 individuals and provides a measure for the mother's neighborhood-level socioeconomic status
Medical Claims	<ul style="list-style-type: none"> • Maternal access to prenatal care during pregnancy
Hospital Discharge Abstract Database	<ul style="list-style-type: none"> • Type of birth: vaginal or caesarean-section
Education	<ul style="list-style-type: none"> • Maternal educational attainment (high school completion) • Paternal educational attainment (high school completion)
Newcomer Status	<ul style="list-style-type: none"> • Whether the mother moved to Manitoba from another country within the last 5 years
<i>Infant Characteristics</i>	
Registry	<ul style="list-style-type: none"> • Infant's birth date • Infant's sex
Hospital Discharge Abstract Database	<ul style="list-style-type: none"> • Apgar score • Birth weight • Gestational age • Breastfeeding at birth hospital discharge

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For peer review only

Data Analysis Plan

We will generate descriptive statistics to identify the percentage of infants in the cohort with feeding data at 2-, 4-, and 6-month vaccination visits, and test whether data capture rates differ across time (research question 3). We will also test whether the percentage of infants with captured data differs by urban/rural status of the study site where they were vaccinated (research question 4). For each time point, we will calculate the socioeconomic distribution of infants across four categories: (1) infant has feeding data, (2) infant has vaccination recorded at a study site but does not have feeding data, (3) infant has a vaccination recorded at a non-study site, and (4) infant does not have a vaccination recorded.

We will calculate the percentage of infant feeding data that are missing due to the infant receiving one or two vaccinations at a non-study site. Identifying the frequency with which this occurs will provide an estimate of the percentage of infants that could have complete infant feeding data if Manitoba had a universal system that captured infant feeding information.

Characteristics associated with having infant feeding data captured in the database will be examined using logistic regression models for the 2-, 4-, and 6-month visits (research question 5). The outcome will be a dichotomous variable identifying whether or not a mother-infant dyad's infant feeding information is captured in the database. Models will include the variables listed in Table 3. Each model will include a sub-cohort of age-appropriate infants; for example, analyses examining data collected at the 4-month vaccination visit will exclude anyone ≥ 4 months of age. Results from these analyses will indicate whether mother-infant dyads captured by this strategy differ systematically from those who have missing data.

Finally, we will examine characteristics associated with whether or not we can construct an age-appropriate infant feeding history using data held in the Manitoba Infant Feeding

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3 Database. The outcome variable will describe whether or not a complete infant feeding history
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5 can be constructed based on available data. Explanatory variables will include those listed in
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7 Table 3.
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10 11 12 **Ethics and Dissemination**

13 *Ethical Considerations*

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17 The research team has completed the Tri-Council Course on Research Ethics. We have
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19 obtained approvals from the Health Research Ethics Board at the University of Manitoba, the
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21 Health Information Privacy Committee of Manitoba Health, and the ethics committees in
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23 participating regional health authorities. Participation in the study is voluntary. Study
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25 participants are informed of the purpose of the study, potential risks associated with participation
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27 (compromise of data), their rights and obligations as participants, and their ultimate right to
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29 withdraw at any point without negative consequences. We ask study participants for consent to
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31 link their data with the Repository. Participants are informed that they will not be identifiable in
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33 any reports or publications. Informed consent is obtained from participants prior to data
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35 collection. Identified data is housed on a password protected server in a secure data environment
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37 at the research office. The data is sent to Manitoba Health for de-identification and encryption.
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39 Only the data analysts have access to the de-identified data. Analyses using the de-identified data
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41 will be conducted in the secure data environment at the Manitoba Centre for Health Policy.
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48 *Integrated Knowledge Translation and Dissemination of Findings*

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51 The research team has adopted an integrative knowledge translation approach. In addition
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53 to academic researchers, the broader team comprises an interdisciplinary group of stakeholders
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55 from government departments, public health offices, and regional health authorities. Over a 6-
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3 month pre-funding planning period, the team worked together to develop a research plan and to
4 secure peer-reviewed funding through a Research Manitoba New Investigator Operating Grant.
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6 While the core research team leads the study, the stakeholders are serving as advisory group
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8 members to ensure that findings can be applied to the population-based infant feeding data
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10 collection strategy. The advisory group also strategizes with the core research team on methods
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12 for disseminating findings to healthcare workers and other stakeholders in and outside of
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14 Manitoba.
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20 Even at this early stage, there has been great interest in the study from stakeholders in
21 government and public health. To date, we have presented the research plan and preliminary
22 findings to public health officers in each regional health authority active in the study, and we
23 have participated in two provincial meetings on breastfeeding practices. We have also widely
24 disseminated the study aims and early findings in the academic community at the University of
25 Manitoba. Near the end of the funding period, the team will host a province-wide workshop that
26 will bring together public health nurses, clinic staff members, and stakeholders to discuss the
27 study findings and experiences with implementing the data collection mechanism. Two advisory
28 group members are actively involved with the Breastfeeding Committee for Canada and will
29 arrange for webinars to disseminate findings through this organization. Findings will be
30 presented at national and/or international conference(s) and will be submitted for peer-review
31 publication to inform further research around infant feeding data collection and provide evidence
32 for building new population-based data collection systems.
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Figure Captions:

Figure 1. Manitoba Infant Feeding Database Data Flow Diagram

Data are collected at vaccination visits using the Teleform and faxed to a central office. The identifiable data file contains two datasets: (1) Infant Feeding Data (a dataset that includes infant feeding information and study ID), and (2) Identifying Data (a dataset that includes identifying information and study ID). The Identifying Data are sent to Manitoba Health for de-identification and attachment of scrambled Personal Health Identification Number (PHIN). Manitoba Health generates a cross walk file with instructions for data linkage. The Infant Feeding Data are sent to the Manitoba Population Research Data Repository. The Scrambled PHIN, study ID, and crosswalk file are used to link infant feeding data with the rest of the administrative data held in the Repository. The linked databases form the analytic data for the study.

Author Contributions:

The study was conceived by NCN, the principal investigator on the original funded grant. NCN, LW, MH, AK, and CG participated in designing the study and were listed as collaborators on the grant. NCN, JC, and LW were involved in recruiting participating study sites, and NCN and JC are working with study sites on data collection processes. JC and JP are involved in data cleaning and verification. NCN, LK, and JEE drafted the manuscript. All authors (NCN, LW, LK, JC, MH, CG, AK, JP, CP, DG, LL, JEE, and SS) contributed to critically revising the manuscript for important intellectual content, gave their final approval, and agree to be accountable for all aspects of the work. All authors (NCN, LW, LK, JC, MH, CG, AK, JP, CP, DG, LL, JEE, and SS) will participate in future interpretation of the data and drafting of further manuscripts arising from this work.

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7 derived from data provided by Manitoba Health, Seniors and Active Living. The results and
8 conclusions are those of the authors and no official endorsement by MCHP, Manitoba Health,
9 Seniors and Active Living is intended or should be inferred.
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20 21 **Competing Interests:**

22 The authors declare that they have no competing interests.
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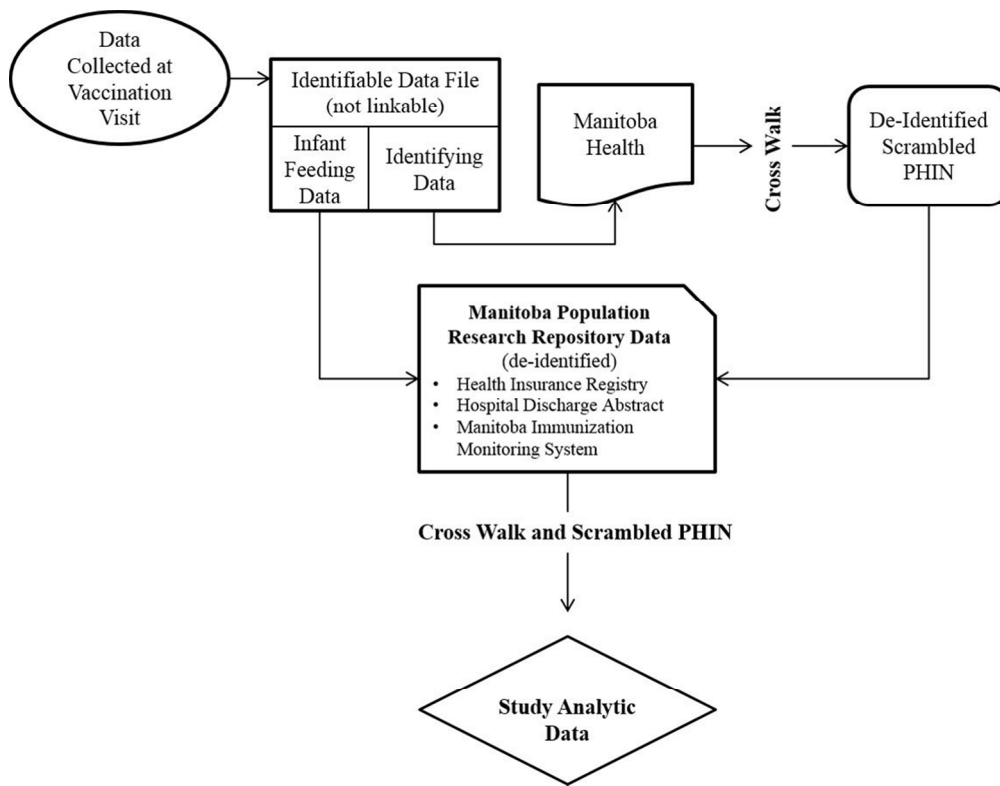


Figure 1. Manitoba Infant Feeding Database Data Flow Diagram

Data are collected at vaccination visits using the Teleform and faxed to a central office. The identifiable data file contains two datasets: (1) Infant Feeding Data (a dataset that includes infant feeding information and study ID), and (2) Identifying Data (a dataset that includes identifying information and study ID). The Identifying Data are sent to Manitoba Health for de-identification and attachment of scrambled Personal Health Identification Number (PHIN). Manitoba Health generates a cross walk file with instructions for data linkage. The Infant Feeding Data are sent to the Manitoba Population Research Data Repository. The scrambled PHIN, study ID, and crosswalk file are used to link infant feeding data with the rest of the administrative data held in the Repository. The linked databases form the analytic data for the study.

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Please print numbers neatly within squares without touching the lines, and fill in circles completely, using INK. Shade circles like this: ● Not like this: ⊗ ⊙ Once complete, please fax to 204-948-3768

01. Please enter TODAY's date:

				2	0		
DAY		MONTH		YEAR			

02. What is your relationship to the baby:

Mother Father Other caregiver

03. In the boxes provided, please print **baby's** 6-digit Health Registration Number:

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04. In the boxes provided, please print **baby's** 9-digit Personal Health Identification Number:

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05. In the boxes provided, please print **mother's** 9-digit Personal Health Identification Number:

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06. Please enter baby's birth date:

				2	0		
DAY		MONTH		YEAR			

07. Please enter the first 3-characters of your 6-character postal code:

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08. Is your baby a girl or a boy?

Boy Girl

09. What has your baby been fed?
Please select all that apply.

Breast milk
 Formula
 Other liquids (juice, cow's milk, goat's milk, tea, etc)
 Solids / Other foods

10. Has your baby ever had formula?

Yes No

11. When was your baby fed formula?
Please select all that apply.

In hospital At home Never

12. How many weeks old was your baby when you first fed formula/other liquids/other food?

Since birth

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 weeks old Not applicable

13. How many weeks old was your baby when you completely stopped breastfeeding?

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 weeks I am still breastfeeding
 I have only formula fed