

**School of Public Health**

**Breastfeeding practices and lactation mastitis in Western Nepal: A  
prospective cohort study**

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**This thesis is presented for the Degree of**

**Doctor of Philosophy**

**of**

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## **DECLARATION**

To the best of my knowledge and belief, this thesis contains no material previously published by any other person except where due acknowledgment has been made. This thesis contains no material that has been accepted for the award of any other degree or diploma in any university.

The thesis contains a series of four published papers on infant feeding practices in Western Nepal. The contribution of co-authors is presented in an appendix. The accepted final versions of the articles are included in the thesis to comply with copyright requirements of the Curtin University of the library and the publishers.

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Date: 13<sup>th</sup> May, 2016.

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## **ABSTRACT**

### **Background**

Exclusive breastfeeding has many short and long-term health benefits. Optimum breastfeeding can prevent 82,000 under-five deaths a year, globally. Low and middle income countries account for the majority of these under-five deaths. Nepal reports a high rate of under-five deaths annually. Nepal has near universal breastfeeding practice; nonetheless, exclusive breastfeeding remains low. The World Health Organisation recommends exclusive breastfeeding for six months, but the current reports on exclusive breastfeeding in Nepal are derived from 24-hour prevalence among infants aged 0-5 months and often misinterpreted as rates for six months. There is need of accurate measurement and reporting of infant feeding rates in Nepal.

### **Objectives**

With the above-mentioned background the objectives of the study were to: report the prevalence of early initiation of breastfeeding (within one hour of birth) and prelacteal feeding, and the factors associated with these practices; to document the rates of exclusive breastfeeding and investigate the association between breastfeeding promotion during postpartum period and exclusive breastfeeding; and to investigate the incidence of lactation mastitis and its association with breastfeeding outcomes in the Rupandehi district of Western Nepal.

### **Methods**

This study was a community-based prospective cohort study in which 735 postpartum mothers who had childbirth within 30 days postpartum, were recruited and followed up at regular intervals for six months during January, 2014 and October, 2014. The study was conducted in the Rupandehi district, which is located in the southern plains (Terai) of Western Nepal. A total of 15 village development committees in rural areas and 12 communities in urban areas were randomly selected. A list of mothers was prepared with the help of local female community health volunteers and health facilities. Mothers were selected randomly from the list

and invited to participate in the study. Data were collected using structured questionnaires by trained female enumerators.

Prevalence of the introduction of prelacteal feeds, any breastfeeding, early initiation of breastfeeding, exclusive breastfeeding, and problems during breastfeeding were reported as proportions at specific time points. The rate of exclusive breastfeeding was reported during one, four and six months to reflect the change in exclusive breastfeeding patterns with increasing age of infants using survival analysis. The incidence of lactation mastitis is reported. Factors associated with prelacteal feeds, early initiation of breastfeeding and lactation mastitis were reported using multiple logistic regression. The association between postpartum breastfeeding promotion and duration of exclusive breastfeeding was investigated using multivariable cox regression; lactation mastitis and exclusive breastfeeding practice were reported using multiple logistic regression.

## **Results**

All of the mothers reported breastfeeding at least once. Of the 735 mother-infant pairs, 310 (42.2%) reported early initiation, followed by breastfeeding initiation after 1hour– 6hours (39.5%), after 6 hours-24hours (9.8%), after 24hours-3 days (5.3%), more than three days (1.8%). Childbirth attended by a skilled birth attendant was positively associated with early initiation of breastfeeding. Similarly, mothers from the poorest families and “not introducing any prelacteal feeds” were associated with the increased rates of early initiation. Delivery by caesarean section and low birth weight of infants were associated with lower rates of early initiation.

Early supplementation of newborn with prelacteal feeds is another major practice that hinders exclusive breastfeeding in Nepal. A total of 225 (30.6%) of mothers reported providing prelacteal feeds to their infants with infant formula (94, 41.7%); and cow or buffalo milk (60, 26.6%) being the two most common types of feeds given to infants. Mothers who had an infant with low birth weight, who had caesarean delivery and who were from wealthy families had a higher likelihood of introduction of prelacteal feeds.

The rate of exclusive breastfeeding during the first month was 66.33% (N=735), which decreased sharply to 39.2% (n=715) during the fourth month and to 8.9% (n=711) during the sixth month. Similarly, rates of predominant breastfeeding changed according to infant's age. The predominant breastfeeding rates was higher during the first month, 88.6% (N=735) and dropped to 78.2% (n=715) during the fourth month and 26.3% (n=711) during the sixth month.

A total of 649 (35%) mothers reported receiving postpartum breastfeeding promotion. There was a significant association between the amount of such breastfeeding support received and exclusive breastfeeding duration (hazard ratio: 0.94; 95% confidence interval: 0.90, 0.97). There was a dose-response relationship between an increasing number of breastfeeding promotion messages provided to mothers and longer duration of exclusive breastfeeding.

Lactation problems are a novel finding in this study. A total of 27 (8.0%; 95% confidence interval: 5.1% to 10.8%) mothers reported having at least one episode of mastitis within the neonatal period. Prelacteal feeding and delivery by caesarean section were associated with a higher likelihood of mastitis.

A few important recommendations can be drawn from the current findings. Assistance at childbirth by health workers was associated with high rates of early initiation of breastfeeding. Therefore, capacity building of health workers in counselling and lactation support is imperative for breastfeeding promotion. Caesarean section has consistently remained the most significant barrier to breastfeeding in this study population. Mothers should be provided with support to initiate, establish and continue breastfeeding after caesarean section. Further expansion of such breastfeeding promotion activities to community level health facilities and maternity centres would help improve exclusive breastfeeding rates in Nepal.

## **Conclusions**

This prospective cohort study found that one third of mothers started prelacteal feeding, all of them breastfed, and only 42.2% started breastfeeding within the first hour of childbirth. The exclusive breastfeeding rate during the first month was 66.3%

which rapidly declined to 36.2% by the fourth month and to 8.9% by sixth month. A total of 8.0% mothers reported having lactation mastitis during the neonatal period. The current findings suggest that despite a universal breastfeeding practice, mothers were not able to sustain the initial high rates of exclusive breastfeeding. Health workers should make breastfeeding promotion during the postpartum period a routine practice in health care settings. The breastfeeding promotion programmes should focus on reducing prelacteal feeding and supporting mothers when they have lactation mastitis

## TABLE OF CONTENTS

<b>DECLARATION.....</b>	<b>I</b>
<b>ACKNOWLEDGEMENT .....</b>	<b>II</b>
<b>ABSTRACT.....</b>	<b>V</b>
<b>TABLE OF CONTENTS.....</b>	<b>IX</b>
<b>LIST OF TABLES .....</b>	<b>XIV</b>
<b>LIST OF FIGURES .....</b>	<b>XV</b>
<b>ABBREVIATIONS .....</b>	<b>XVI</b>
<b>CHAPTER 1 INTRODUCTION .....</b>	<b>1</b>
1.1 Overview .....	1
1.2 Study location.....	2
1.2.1 Overview of Nepal.....	2
1.2.2 Introduction to health services in Nepal .....	3
1.3 Study design .....	8
1.4 Aim and objectives .....	8
1.4.1 Aim of the study .....	8
1.4.2 Objectives of the study .....	8
1.5 Limitations of previous studies .....	9
1.6 Significance of current study.....	10
1.7 Scope of study .....	10
1.8 Outline of thesis.....	11
1.9 Definitions .....	12
1.9.1 Outcome variables .....	12
1.9.2 Independent variables .....	13

<b>CHAPTER 2</b>	<b>LITERATURE REVIEW .....</b>	<b>16</b>
2.1	Initiation of breastfeeding .....	16
2.1.1	Benefits of early initiation .....	16
2.1.2	Rates of early initiation.....	18
2.1.3	Factors associated with early initiation of breastfeeding.....	20
2.2	Prelacteal feeding .....	26
2.2.1	Disadvantages of prelacteal feeding .....	26
2.2.2	Prevalence and factors associated with prelacteal feeding .....	27
2.2.3	Types of prelacteal feeds given .....	28
2.2.4	Factors associated with the introduction of prelacteal feeding.....	29
2.3	Exclusive breastfeeding.....	35
2.3.1	Benefits of any and exclusive breastfeeding.....	35
2.3.2	Measurement and reported rates of exclusive breastfeeding in South Asia .....	40
2.3.3	Factors associated with exclusive breastfeeding .....	43
2.3.4	Postpartum breastfeeding promotion and Baby Friendly Hospital Initiative .....	50
2.4	Lactation problems .....	53
2.4.1	Problem magnitude .....	53
2.4.2	Risk factors of mastitis .....	54
2.4.3	Management of mastitis.....	55
2.4.4	Impact of mastitis on exclusive breastfeeding.....	56
2.5	International policies on exclusive breastfeeding.....	57

2.6	National policy and programmes related to breastfeeding in Nepal .....	58
<b>CHAPTER 3 METHODOLOGY .....</b>		<b>61</b>
3.1	Overview .....	61
3.2	Study setting .....	61
3.3	Study design .....	64
3.4	Sample size.....	64
3.5	Recruitment .....	65
3.6	Instruments for data collection .....	67
3.7	Data collection.....	68
3.8	Data editing and cleaning .....	69
3.9	Data analysis.....	69
3.9.1	Early initiation .....	69
3.9.2	Prelacteal feeding.....	70
3.9.3	Postpartum breastfeeding promotion and exclusive breastfeeding.....	70
3.9.4	Mastitis.....	70
3.10	Ethical considerations.....	71
<b>CHAPTER 4 RESULTS .....</b>		<b>72</b>
4.1	Response rate.....	72
4.2	Characteristics of participants .....	72
4.3	Early initiation and prelacteal feeding.....	73
4.4	Any and exclusive breastfeeding at one, four and six months .....	74
4.5	Mastitis and its management .....	76
4.6	Published papers.....	76
4.6.1	Paper -1: Factors associated with early initiation of breastfeeding in Western Nepal.....	77

4.6.2 Paper-2: Prevalence and factors associated with prelacteal feeding in Western Nepal.....	102
4.6.3 Paper -3: Postpartum breastfeeding promotion and duration of exclusive breastfeeding Western Nepal.....	123
4.6.4 Paper -4: Incidence of mastitis in the neonatal period in a traditional breastfeeding society: Results of a cohort study.....	143

**CHAPTER 5 SUMMARY, LIMITATIONS AND RECOMMENDATIONS .....164**

5.1 Summary of findings .....	164
5.1.1 Early initiation of breastfeeding .....	164
5.1.2 Prelacteal feeding.....	164
5.1.3 Any and exclusive breastfeeding rates.....	164
5.1.4 Mastitis.....	165
5.1.5 Limitations of current study.....	165
5.2 Recommendations .....	166
5.2.1 Implications for health promotion programmes .....	166
5.2.3 Implications for future research.....	169

**REFERENCES .....i**

**APPENDICES .....xx**

**i**

Appendix 1: STROBE Statement—checklist of items that should be included in reports of observational studies .....	xxii
Appendix 2: Summary of exclusive breastfeeding (EBF) study and reported statistics in four South Asian countries, 2000-2015 .....	xxix

Appendix 3: Methodological differences in measuring rates of exclusive breastfeeding in Nepal (Manuscript under review) .....	xxxix
Appendix 4: The supplemental use of infant formula in the context of universal breastfeeding practices in Western Nepal.....	lxiii
Appendix 5: Ethics approval: Curtin University .....	lxxxiv
Appendix 6: Ethics approval: Nepal Health Research Council .....	lxxxv
Appendix 7: Consent form.....	lxxxvi
Appendix 8: Questionnaires (English version).....	lxxxviii
Appendix 9: Author contribution form.....	cxviii
Appendix 10: Oral and poster presentation from the PhD Project .....	cxxii

## **LIST OF TABLES**

Table 1 Improvement in maternal health indicators during 1990-2013 in Nepal .....	4
Table 2 Independent studies on early initiation of breastfeeding in Nepal.....	20
Table 3 Independent studies on prelacteal feeding in Nepal .....	28
Table 4 Prevalence of exclusive breastfeeding from a cohort study using two measurement indicators, Nepal, 2014 .....	75

## LIST OF FIGURES

Figure 1 Reduction in the rates of deaths of neonates, infants and children in Nepal during 1990-2013 .....	4
Figure 2 Organisation of public health services at district level in Nepal .....	6
Figure 3 Measurement methods used in breastfeeding studies in South Asia (N=29) .....	42
Figure 4 Conceptual framework of factors associated with exclusive breastfeeding . .....	44
Figure 5 Breastfeeding messages during breastfeeding week, Nepal .....	60
Figure 6 Location of the study district in Nepal .....	63
Figure 7 Rupandehi district map .....	63
Figure 8 A health post located in a rural area, Rupandehi district.....	64
Figure 9 Recruitment process of participants.....	66
Figure 10 Interview flow chart.....	68
Figure 11 Baseline and loss to follow-up.....	72

## **ABBREVIATIONS**

AIDS	Acquired Immune Deficiency Syndrome
BFHI	Baby Friendly Hospital Initiative
CHD	Child Health Division
CI	Confidence Interval
FHD	Family Health Division
HIV	Human Immuno-deficiency Virus
HR	Hazard Ratio
IQ	Intelligent Quotient
MDG	Millennium Development Goals
MOHP	Ministry of Health and Population
NDHS	Nepal Demographic and Health Survey
NFHP	Nepal Family Health Programme
OR	Odds Ratio
RR	Relative Risk
SPSS	Statistical Package for Social Sciences
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
WHO	World Health Organisation

## CHAPTER 1 INTRODUCTION

### 1.1 Overview

Exclusive breastfeeding has many short and long-term nutrition and health benefits (Ip, Chung, Raman, Trikalinos, & Lau, 2009; Kramer, Aboud, Mironova, & et al., 2008). A 2016 estimate says that recommended breastfeeding at near universal level can prevent up to 82,000 under-five deaths annually (Victora et al., 2016). A child who is not exclusively breastfed<sup>1</sup> for the first six months is seven times more likely to die than their breastfed counterparts (Victora et al., 2016). In countries such as Nepal where neonatal mortality is high and is a major challenge to child survival, early and exclusive breastfeeding can contribute to reducing neonatal and infant deaths substantially (Clemens et al., 1999). About half of childhood respiratory illnesses and two-thirds of childhood diarrhoea admissions could be avoided if breastfeeding was practised at universal levels (Victora et al., 2016). Given its wide range of protective effects, breastfeeding has been described as a personalised medicine for infants (Victora et al., 2016).

The practice of breastfeeding is almost universal in Nepal, but exclusive breastfeeding rates decline substantially before the age of six months (Khanal, Sauer, & Zhao, 2013). Studies reporting exclusive breastfeeding rates based on the World Health Organisation (WHO) definition and measurement of the duration are limited in Nepal. The studies that have usually been published report period prevalence rates based on 24-hour recall, which does not provide the measurements that the WHO and Government of Nepal's target requires to monitor exclusive breastfeeding for six months (Binns & Lee, 2013). The reported 24-hour prevalence for exclusive breastfeeding for infants aged <6 months is 69.9% (Ministry of Health and Population (MOHP) [Nepal], New ERA, & ICF International Inc, 2012). Only one study has reported exclusive breastfeeding rates based on cohort study design with repeated measurement (Karkee, Lee, Khanal, & Binns, 2014a). That study

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<sup>1</sup> Exclusive breastfeeding: only 'breast milk (including expressed milk or from a wet nurse), vitamin or mineral syrups, medicine and oral rehydration salt, and no other liquid or solid food items

documented the rate of exclusive breastfeeding at 22 weeks as being 29.7%. However, that study was from central Nepal, which is more developed than other parts and is unlikely to represent other geographical regions. Accurate and current information on breastfeeding is important for health promotion and nutrition interventions in Nepal. Continued breastfeeding, including exclusive breastfeeding, may be influenced by the type and number of lactation problems experienced by mothers; the level and type of support provided during the postpartum period, and the influence of cultural practices such as prelacteal feeding. The knowledge of lactation problems will help support mothers to breastfeed successfully. Mastitis is one frequently-reported problem associated with breastfeeding in other countries (Scott, Robertson, Fitzpatrick, Knight, & Mulholland, 2008; Tang, Lee, Qiu, & Binns, 2013). An extensive literature search, undertaken for the purpose of this present study, did not yield any study on mastitis in the South Asia region.

## **1.2 Study location**

### **1.2.1 Overview of Nepal**

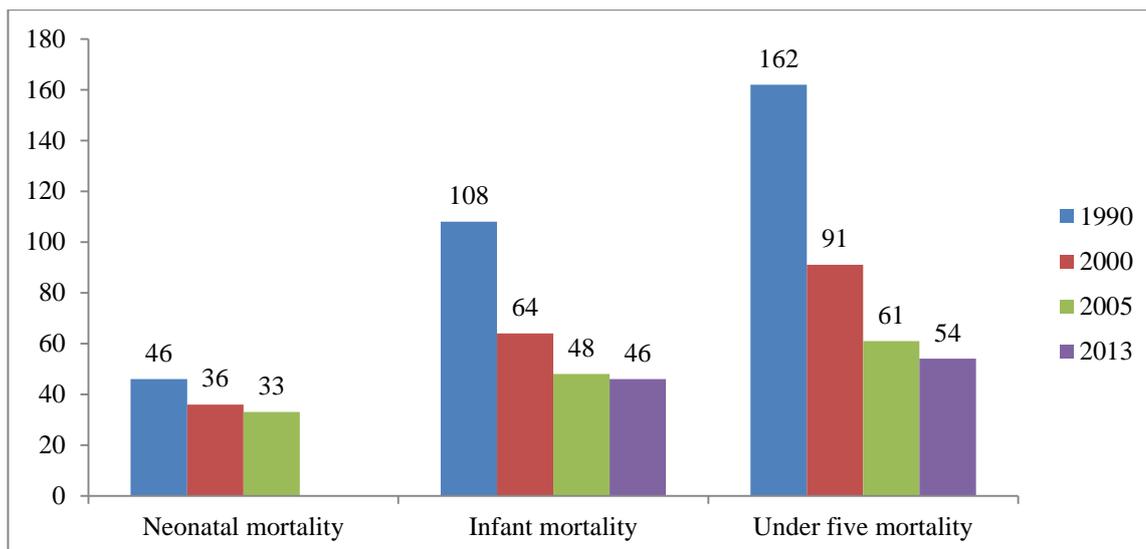
Nepal lies in South Asia bordering India in the east, west and south, and China (Tibet) in the north. It is one of the oldest countries in South Asia and has diverse geography that ranges from plains (Terai) in the south, hills in the middle and high mountains in the North. Due to difficult geographical terrain in the mountains and hills, most of the areas are uninhabited. Nearly, 51% of the population lives in the Terai region. The country is divided into 14 administrative zones and these are further divided into 75 districts. For administrative purposes, the country is further divided into village development committees and municipalities as the lowest administrative units. The village development committees are located in the rural areas and municipalities in the urban areas. The population of Nepal lives predominantly in rural areas with only 17% living in urban areas (Central Bureau of Statistics & Government of Nepal, 2012). According to United Nation's Development Program, the country ranks 145<sup>th</sup> based on human development index (United Nations Development Programme, 2016). The Human Development Report mentioned that the human development index, a composite measure of longevity,

education and income, was 0.458 in 2011 (United Nations Development Programme, 2014).

Nepal's population in 2011 was 30.5 million with an annual population growth rate of 1.35% (Central Bureau of Statistics & Government of Nepal, 2012). There are more than 125 ethnic groups and over 123 languages spoken in the country. Nepali is the most common language that the government uses for its official purpose. The population living in the Terai area, often referred to as the Madhesi community, are culturally similar to Indian culture whereas those living in the Himalayas are closer to the Tibetan culture. However, due to migration from the hilly and mountainous regions, the Terai region has about half of the population of the country. The vast majority of the population follows the Hindu religion (82%), followed by Buddhist, Muslim, Christian and Kirat. Due to religious syncretism, Hindu, Buddhism and Kirat have many similarities. Only 65.9% of the population is literate with the male literacy rate (75.1%) being higher than for female (57.8%). As of 2011, only 4.7% of Nepali women completed higher education, 24.6% secondary education, 29.2% primary education; 41.4% did not have any formal education (WHO, 2015).

### **1.2.2 Introduction to health services in Nepal**

Life expectancy at birth is 67 years for males and 70 for females (WHO, 2015). The country has a relatively young population with a median age of 22.0 years with 35% being under 15 years of age. Health expenditure is 6.0% of total gross domestic product (WHO, 2015). Nepal has a high infant mortality rate (46 per 1000 live births) and neonatal mortality rate (33 per 1000 live births) (Ministry of Health and Population (MOHP) [Nepal] et al., 2012). The country has been successful in reducing infant and under-five mortality since 1990 (*Figure 1*).



**Figure 1 Reduction in the rates of deaths of neonates, infants and children in Nepal during 1990-2013**

mortality reported as per 1000 live birth. Source: (Government of Nepal & National Planning Commission, 2013; Khatri, Mishra, Khanal, Gelal, & Neupane, 2016).# data for neonatal mortality is not available for 2013)

**Table 1 Improvement in maternal health indicators during 1990-2013 in Nepal**

Indicator	1990	2000	2005 <sup>c</sup>	2010	2013
Maternal mortality ratio (per 100,000 live births)	850 <sup>a</sup>	415 <sup>b</sup>	281	229 <sup>d</sup>	170 <sup>e</sup>
Proportion of births attended by skilled birth attendant (%)	7 <sup>f</sup>	11 <sup>g</sup>	19	36 <sup>h</sup>	50 <sup>i</sup>

\*adapted from the MDG Progress report 2013 (Government of Nepal & National Planning Commission, 2013) Note: original sources of data: <sup>a</sup> United Nations Development Program(1992), <sup>b</sup> National Planning Commission (2002), <sup>c</sup> MoHP, New Era, & Macro International Inc. (2006), <sup>d</sup> Family Health Division (FHD) (2009), <sup>e</sup> WHO, United Nations Children's Fund (UNICEF), United Nations Population Fund (UNFPA), & The World Bank (2012), <sup>f</sup> Nepal Family Health Programme (NFHP) (1995). <sup>g</sup> Ministry of Health and Population (MoHP), New Era & Macro International Inc. (2001), <sup>h</sup> MoHP, New Era & ICF International (2011), <sup>i</sup> Family Health Department (FHD) (2013).

Maternal health has remained a major priority of the country. Table 1 shows an unacceptably high level of maternal mortality during the 1990s, of 850 per 100,000 live births, which was reduced to 170 per 100,000 live births by 2013. The proportion of mothers who delivered with the assistance of skilled birth attendants also improved over 1990-2013 increasing from 7% to 50%. Despite improvements in these indicators, the proportion of mothers attending the recommended four or more antenatal visits (50.1%), delivering in a health facility (36.1%); and attending postnatal care visits (46.5%) remains low (Ministry of Health and Population (MOHP) [Nepal] et al., 2012).

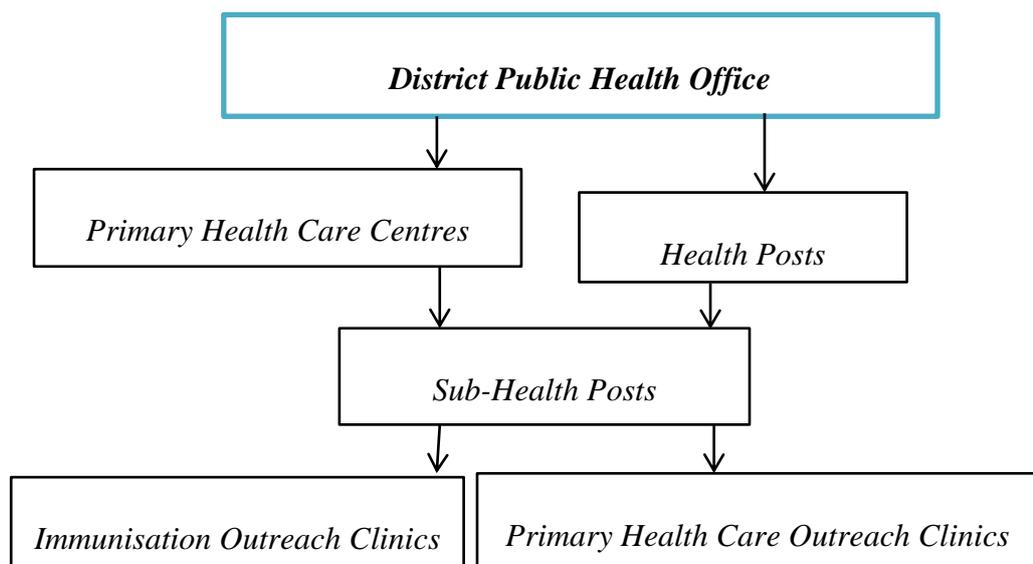
Undernutrition is a major problem in Nepal. The Nepal Demographic and Health Survey 2011 reported that the proportion of children under five years of age who are stunted (short height for age: 41%) and wasted (low weight for age: 29%) was still unacceptably high (Ministry of Health and Population (MOHP) [Nepal] et al., 2012). Nepal has gone through decades of severe political unrest since 1996, due to an armed Maoist rebellion that ended in 2006. Further turmoil started after 2007 where many interest groups came forward with numerous demands with familiar scenes of violent protests that included demonstrations, transport strikes, torching, burning tyres and vehicles, and the destruction of public property. These strikes affected education and social sectors adversely. It has also affected the mobilisation of resources in the health sector. However, despite the continuing political unrest and fragile economic situation, Nepal has achieved continuing success in increasing life expectancy, maternity care and child health. This progress has shown that improvements in maternal and child health are possible despite political unrest and low economic growth rates. Nevertheless, the challenges to reducing the existing burden of undernutrition, infant mortality and maternal mortality still persist.

Despite these challenges, Nepal was one of the few countries that achieved the health-related Millennium Development Goals (MDG) by 2015 (National Planning Commission, 2015). Child mortality was reduced by two thirds and maternal mortality by three quarters from the level of 1990. The epidemic of HIV/AIDS has started to decline. Tuberculosis incidence has declined significantly, and malaria is on the way to being eliminated. For a country with a background of armed conflict, political unrest, unstable government, weak management capacity, low economic

growth rate (4% on average), and inadequate basic health care, the progress made during the MDG period is regarded as impressive (National Planning Commission, 2015).

The current structure of the Nepalese health system is based on the National Health Policy developed in 1991 which includes levels of services starting from the community up to tertiary level (Department of Health Services & Ministry of Health and Population, 2014). Following a pattern of decentralised services, district public health offices are responsible for services that are delivered as part of the public health system. The health system of Nepal is designed on the philosophy of 'health for all' following the principles of the Alma-Ata Declaration (Lawn et al., 2008).

Figure 2 shows the structural representation of health system at the district level. Starting from the lowest rank of health facility, there are sub-health posts then health post and primary health care centres. Below sub-health posts, there are two outreach services: expanded program on immunisation and primary health care clinics. The expanded program on immunisation provides essential immunisation services to mothers and children in village development committees and municipalities in their own communities. Primary health care outreach clinics provide family planning services in the rural areas. At the community level, a network of female community health volunteers, immunisation clinics and outreach clinics have a strong presence and provide services to mothers and children.



**Figure 2 Organisation of public health services at district level in Nepal**

*Adapted from Annual report (Department of Health Services & Ministry of Health and Population, 2013, 2014)*

The services provided by these health institutions vary according to their level and are provided free of cost at all the primary health care levels. All the preventive health services and the treatment of minor illnesses provided from public facilities are free of cost. Mothers who deliver in health facilities are also reimbursed for their transportation costs (Karkee, Lee, & Binns, 2013a; Karkee, Lee, & Binns, 2013b). In addition, health workers and health facilities are also given financial incentives for providing maternity services on a per person served basis.

For secondary levels of curative health areas, district hospitals are the first point of referral followed by the higher levels of services in zonal/regional hospitals and central level hospitals. District hospitals are staffed by general practitioners whereas zonal hospitals and higher level hospitals have specialised doctors who provide specialist services. While this structured referral system exists on paper, it is almost non-functioning and there is no active 'gatekeeper system'. The non-functioning referral system has left tertiary health facilities overcrowded and poorly managed (Karkee et al., 2013b).

Nepal has expressed committed to build on the achievements made during the MDG period and has adopted the recent Sustainable Development Goals 2016-2030(National Planning Commission, 2015). The following targets set by the country, as part of the commitment to the Sustainable Development Goals (2016-2030), are closely related to infant and child health:(1) reduce the prevalence of undernourishment; (2) reduce the prevalence of underweight children under-five years of age; (3) reduce preventable deaths of newborns and children to less than 1 percent; (4) raise the proportion of births attended by skilled birth attendants to 90 percent; and (5) increase institutional deliveries to 90 percent and provide post-natal care for 90 percent of mothers. In conclusion, Nepal is taking further steps towards better health condition for mothers and children.

### **1.3 Study design**

This is a community-based prospective cohort study conducted in the Rupandehi district of Western Nepal during January, 2014 – October, 2014. Data collected from communities of the district were from interviews conducted by trained female enumerators. Community-based sampling was used to obtain a representative sample of the study area as most of the births do not occur in hospital. Therefore, the use of a community-based sample is more desirable than a hospital-based sample owing to reduced selection bias in the former.

### **1.4 Aim and objectives**

#### **1.4.1 Aim of the study**

The aim of this study was to document the rate and identify the determinants of exclusive breastfeeding, and identify problems associated with breastfeeding in the community settings of Rupandehi district of Western Nepal.

#### **1.4.2 Objectives of the study**

The specific objectives of this study were;

1. To document the rate of any and exclusive breastfeeding during one, four and six months postpartum.
2. To report the practice of early initiation of breastfeeding among the mothers
3. To report the proportion of the mothers providing prelacteal feeds to their infants.
4. To document the duration of exclusive breastfeeding among mothers who received postpartum breastfeeding promotion and those who did not.
5. To analyse the factors associated with early initiation of breastfeeding.
6. To analyse the factors associated with the introduction of prelacteal feeds.
7. To examine the association of postpartum breastfeeding promotion and exclusive breastfeeding up to six months among mothers whose delivery was attended by skilled birth attendants.
8. To report the incidence of mastitis among mothers during breastfeeding

9. To evaluate the factors associated with mastitis.
10. To evaluate the effect of mastitis on ‘any’, and ‘exclusive’ breastfeeding at four and six months.

### **1.5 Limitations of previous studies**

The current evidence for breastfeeding in Nepal is usually generated from the Nepal Demographic and Health Surveys (Ministry of Health and Population (MOHP) [Nepal] et al., 2012; Ministry of Health and Population (MOHP) [Nepal], New ERA, & Macro International Inc, 2007). These studies are retrospective surveys that collected information on early initiation feeding and prelacteal feeding in the previous five years, and therefore, recall bias can be a major issue. Similarly, the exclusive breastfeeding information provided by those surveys is based on the 24-hour-recall method, and the exclusive breastfeeding rate is reported for infants who were aged <6 months at the time of survey. This is a “period prevalence” rate and not the rate at a specific point in time. Due to lack of focus on studies in breastfeeding, the Demographic and Health Surveys are the only available sources of national data. However, the 24-hour recall method is not the “gold standard” measure and the measure of <6 months is not the correct denominator if the exclusive breastfeeding rate ‘up to (or for) six months’ is to be reported (Binns, Lee, Sauer, & Hewitt, 2012; Labbok & Krasovec, 1990). For accurate reporting of breastfeeding rates, a longitudinal study of breastfeeding based on repeated measures and recall-since-birth is required (Binns & Lee, 2013). None of the studies prior to the commencement of this present study reported on exclusive breastfeeding based on a prospective cohort study, and only one study was published since then from the Kaski district of Nepal using a prospective cohort design that included questions on prelacteal feeds (Karkee et al., 2014a; Karkee, Lee, Khanal, & Binns, 2014b). The Kaski district is one of the most developed areas in the country with access to hospitals and better transport links for the referral. The findings from that study, therefore, may not be representative of other areas of Nepal.

The majority of births in Nepal still occur at home attended by traditional attendants or senior women and only recently, are mothers increasingly giving childbirth in health facilities (Ministry of Health and Population (MOHP) [Nepal] et al., 2012). It

is not clear whether the presence of health workers and breastfeeding promotion immediately after postpartum has any effect on breastfeeding outcomes in Nepal. There was no study that reported the incidence of and factors associated with mastitis and its impact on breastfeeding outcomes in South Asia.

## **1.6 Significance of current study**

The current study reports the rate of exclusive breastfeeding based on the WHO recommended methodology using a cohort study design and repeated measures, which will provide a more accurate estimation of exclusive breastfeeding in Western Nepal (Binns et al., 2012; WHO, 2007). The current study provides information about the factors associated with early initiation and the introduction of prelacteal feeds in Nepal. It also reports the incidence of mastitis during breastfeeding and its association with breastfeeding outcomes. This is the first published study from South Asia reporting on the topic. The results also include information on the association between postpartum breastfeeding promotion and exclusive breastfeeding. The findings of this study will contribute to the development of health promotion strategies for child survival and the improvement in the nutrition status of infants (Debes, Kohli, Walker, Edmond, & Mullany, 2013). Specific to Nepal, a National Safe Motherhood and Newborn Health-Long term plan (2006-2017) is in place that outlines targets and programmes for maternal and newborn survival (Family Health Division & Ministry of Health and Population, 2006). However, it fails to acknowledge the role of breastfeeding, factors influencing the initiation of breastfeeding, promoting exclusive breastfeeding for six months and continuation of breastfeeding as key child survival interventions. None of the targets in the plan mentioned any breastfeeding related indicators to be achieved by 2017 or after. The findings from this current study will help policy makers develop breastfeeding strategies and targets for Nepal.

## **1.7 Scope of study**

This study covers urban and rural areas of the Rupandehi district of Nepal located in the plain (Terai) area of southern Nepal. The southern plain of Nepal has unique cultural characteristics distinct from the rest of the country. It has a heterogeneous

population that includes the local Tharu indigenous community, people of hilly origin, and the Madhesi community. The study was designed and conducted to report exclusive breastfeeding rates as the main outcome variable; it did not include other areas of child health such as neonatal mortality and its determinants. Due to limited resources and time constraints, the study followed up mothers and children from childbirth through to their sixth month.

## **1.8 Outline of thesis**

Chapter one describes the background of the study including existing gaps in the literature from Nepal. It also presents the aim and objectives of the study and elaborates the significance of the study.

Chapter two presents a critical summary of the literature review. This chapter is presented to address the objectives of the study and organised according to infant feeding outcomes.

Chapter three presents the methodology included in this cohort study. It briefly presents the settings of the study, sample size, sampling process and data collection procedures adopted.

Chapter four includes the results and discussion section of this thesis and presents a combination of descriptive findings and published papers. The results are organised to address the objectives and the outcomes related to those objectives.

Chapter five, the final section, presents the major findings and summarises the limitations related to this study. Finally, it elaborates on recommendations that can be made from the current study.

A STROBE statement and checklist is presented to adhere to international standard of reporting Cohort studies (Appendix 1).

## 1.9 Definitions

### 1.9.1 Outcome variables

**Exclusive breastfeeding:** only 'breast milk (including expressed milk or from a wet nurse), vitamin or mineral syrups, medicine and oral rehydration salt, and no other liquid or solid food items(WHO, 2007). A list of common food items was read to mothers to help them remember their infant feeding practices. The questionnaire to collect this information is provided in appendix.

This study defined exclusive breastfeeding within the last 24-hours as: mother did not introduce any food item besides her breastmilk or other women's milk. A mother was classified as exclusive breastfeeding during the first month using recall-since-birth if (1) she did not introduce any prelacteal feeds (2) responded that she had been feeding only breastmilk since birth and (3) was exclusively breastfeeding based on 24-h recall. A mothers was classified as exclusively breastfeeding during the fourth month using recall-since-birth if (1) she had exclusively breastfed during the first month, (2) did not introduce any complementary food since the last interview (confirmed reading list) and (3) did not introduce any complementary food in the last 24-hr (confirmed reading list). Similarly, a mothers would be classified as exclusive breastfeeding during the sixth month based on recall-since-birth if (1) she had been exclusively breastfeeding during the fourth month, (2) did not introduce any complementary food since last interview (confirmed reading list) and (3) did not introduce any complementary food in the last 24-hr (confirmed reading list). Any mother who was not breastfeeding at the time of interview was classified as not exclusively breastfeeding.

**Predominant breastfeeding:** breast milk (including milk expressed or from a wet nurse) as the predominant source of nourishment; including certain liquids (water and water-based drinks, fruit juice), ritual fluids and oral rehydration salt, drops or syrups (vitamins, minerals, medicines) and does not allow anything else (in particular, non-human milk, food-based fluids) (Labbok & Krasovec, 1990). Similar to exclusive breastfeeding, a list of common food items was read to mothers to help them remember their infant feeding practices.

**Prelacteal feeding:** any food provided prior to the initiation of breastfeeding but excluding medicine, oral rehydration solution, vitamin syrup, and other mother's milk (Szajewska, Horvath, Koletzko, & Kalisz, 2006). A list of common food items was read to mothers to help them remember their infant feeding practices. The questionnaire to collect this information is provided in appendix.

**Early initiation of breastfeeding:** initiation of breastfeeding within one hour of childbirth (WHO, 2007). The variable related to the timing of breastfeeding initiation was initially recorded in hours and days and further recoded as a binary variable: 'early initiation' when the newborn infant was breastfed within the first hour of birth; and 'delayed initiation' when breastfed after one hour.

**Mastitis:** at least two breast symptoms (pain, redness or lump) and at least one of the 'flu-like symptoms' (fever, shivering/chills, and headache) (Amir, Forster, McLachlan, & Lumley, 2004). The breastfeeding problems experienced during the neonatal period were recorded as 'yes' or 'no' responses to prompted questions. Information on mastitis used in this analysis was collected at the baseline interview.

### 1.9.2 Independent variables

**Maternal age:** was collected in years and was categorised into: '15-19', '20-29', and '30 and above' years.

**Maternal education:** was collected as 'no formal education', 'primary or lower secondary' (up to Grade 8), 'secondary' (Grade 9-10), and 'higher' (Grade 11 and above).

**Maternal occupation:** maternal occupations were recorded based on maternal response and was further categorised as 'employed' (salaried job), 'semi-employed' (daily wage, small business), and 'unemployed' (household chores, agriculture work).

**Paternal occupation:** occupations were recorded based on maternal response and was further classified as 'employed' (salaried job), 'semi-employed' (daily wage, small business, foreign migrant labour), and 'unemployed' (household chores, agriculture work).

**Place of delivery:** place of delivery was recorded as: government hospital, private hospital, private clinic, primary health care centre/ health post, birthing centre, and home. It was recoded as ‘home’ or ‘health facility’ to facilitative analysis.

**Assistance during delivery:** referred to ‘unskilled/traditional workers’ (relatives, mother-in-law, neighbours, family members, female community health volunteers, traditional birth attendants, none), and ‘skilled health workers’ (doctor, nurse, auxiliary nurse midwife, health assistant, auxiliary health workers).

**Postpartum breastfeeding promotion:** The eight variables that composed ‘breastfeeding promotion’ were receiving advice to ‘initiate breastfeeding within one hour of childbirth’, ‘skills on breastfeeding’, ‘not to provide food other than breastmilk’, ‘to keep mother and baby together’, ‘breastfeeding on demand’, ‘not to provide pacifier or teats’, ‘where to get support on breastfeeding when needed’, and ‘exclusively breastfeed for six months’. These messages and supports were part of the Baby Friendly Hospital Initiative’s recommendation given together by health workers. They were subsequently recoded into: ‘high intensity’ (6-8 messages), and ‘low to medium intensity’ (0-5 messages) to facilitate analysis. The cut-off points were arbitrary to facilitative analysis as there is no clear cut-off point.

**Mode of delivery:** was either ‘vaginal’ or ‘caesarean’.

**Ethnicity:** was defined by the Ministry of Health and Population Nepal, and was then recoded by amalgamating similar groups into: ‘advantaged’ (Brahmin, Chhetri, Newar, Magar, Gurung, Jogi, Thakuri), ‘disadvantaged’ (Janjati, non-Janjati, Muslim), and ‘dalit-highly disadvantaged’ (Bishwakarma, Dhawal, Kami, Pariyar, Pasi, Sunar). The classification of these ethnic groups is based on the economic and traditional caste-based system in the country. In the caste-based system, the dalit, highly disadvantaged groups, is the occupational caste and traditionally were most deprived of human dignity, access to temples, access to education and equal status in society. These groups were once treated as ‘untouchables’. For the caste group called ‘indigenous groups’ by Western scholars, the native equivalent terms are ‘adivasi, janajati, mulvasi and bhumiputra’ (Sharma SR, Upreti BR, Manandhar P, & Sapkota M, 2014). However, direct interpretation of the Western term ‘indigenous’ may not be applicable in Nepal as almost all of the population has a history of migration to

the country. Therefore, these terms have to be understood in the Nepalese context that includes the complexities of the economic and caste –based system in the country (Sharma SR et al., 2014).

**Wealth status:** was determined based on assets possessed by the household in terms of quintiles and recoded as ‘poor’ (lower 40%), ‘average’ (middle 40%), and ‘rich’ (upper 20%). This method of asset based categorisation of the wealth status of family has been used in several national demographic and health surveys and other studies in Nepal (Ministry of Health and Population (MOHP) [Nepal] et al., 2012; Ministry of Health and Population (MOHP) [Nepal] et al., 2007). The asset components included creating this composite variable were: source of drinking water, toilet facility at home, shared toilet with other households, types of cooking fuel, separate kitchen for cooking, type of floor, and asset possession (electricity, radio, television, mobile phone, sofa, and cupboard).

**Birthweight:** was originally recorded in grams and categorised into: ‘low’ (< 2500 grams) and ‘average or more’ ( $\geq$  2500 grams).

**Birth order:** was initially recorded as number and further categorised into ‘first birth’, ‘second or third’, and ‘four or more’.

**Place of residence:** was recorded as ‘rural’ (village development committees) or ‘urban’ (municipalities and suburbs). The names of communities were recorded and researcher coded this variable as rural or urban.

## **CHAPTER 2 LITERATURE REVIEW**

The literature review for this thesis provides a summary of evidence related to infant feeding practices and lactation problems. Literature in infant feeding is abundant and context specific as it is related to culture and society. Therefore, this literature review focuses mainly on breastfeeding practices in South Asian countries where the cultures are comparable to Nepal. When available, evidence from prospective cohort studies, randomised controlled trials, and systematic reviews are used as primary sources. In some cases, if the findings from these studies were not sufficient, cross-sectional studies were also included. If literature from South Asia was not available, other Asian countries and developing countries were also included. Unlike other countries, for example China, where breastfeeding has been studied extensively, there have been only a few studies from Nepal and these are included in this review. The literature is organised into time periods after childbirth and covers the initiation of breastfeeding, prelacteal feeding, exclusive breastfeeding and problems experienced by mothers during lactation. At the end of the literature review, an overview of national policies and programmes that support breastfeeding in Nepal is also provided.

### **2.1 Initiation of breastfeeding**

#### **2.1.1 Benefits of early initiation**

Several benefits of early initiation of breastfeeding have been documented in developing countries including protection from infections, establishment of breastfeeding, establishment of gut microbiome, and avoidance of potentially harmful food items that could lead to necrotising enterocolitis and food allergy. According to the WHO collaborative study team, these benefits of breastfeeding are not limited to the early infancy phase but are extended beyond infancy (WHO Collaborative Study Team, 2000). Clemens et al.(1999) conducted a cohort study in rural Egypt and reported a 26% reduction in the incidence of childhood diarrhoea among the infants who were breastfed within the first two days. Debes et al. (2013) conducted a meta-analysis and found that there was also a decreased risk of neonatal mortality (relative risk (RR): 0.56; 95% confidence interval (CI): 0.40, 0.79)

among those who were breastfed within 24 hours of birth. The benefit of initiation of breastfeeding within 24 hours of birth was significant for infection-related mortality (RR: 0.55; 95% CI: 0.27, 0.84). The meta-analysis provided moderate strength evidence from three high-quality cohort studies (Edmond et al., 2006; Garcia et al., 2011; Mullany et al., 2008) and a low-quality case-control study (Bamji, Murthy, Williams, & Rao, 2008).

A number of potential mechanisms for the observed reduction in mortality have been suggested (Debes et al., 2013; Edmond et al., 2006) and include the early stimulation of the immune system through exposure to the high levels of immunoglobulins and lymphocytes found in colostrum which prime the immune system. Early initiation of breastfeeding also displaces the prelacteal feeds (Hossain, Radwan, Arafa, Habib, & DuPont, 1992). Prelacteal feeds may be vehicles for infectious pathogens and also disrupt normal gut maturation, resulting in increased permeability to infectious pathogens. Therefore, early initiation of breastfeeding is likely to foster healthy microbiome establishment in an infant's digestive system (Gordon, Dewey, Mills, & Medzhitov, 2012) providing further protection against infection, including diarrhoea (Clemens et al., 1999; Debes et al., 2013).

Early initiation of breastfeeding is an integral component of Kangaroo mother care and essential newborn care. Skin-to-skin contact protects the newborn from heat loss and also stimulates the lymphatic system (Debes et al., 2013). A prospective cohort study (N=202) from North Carolina, USA found that early breastfeeding was also associated with lower risk of necrotising enterocolitis that affects 3-10% of infants with very low birth weight ( $\leq 1500$  g) increasing the risk of mortality and poor growth and neurodevelopment outcomes (Sisk, Lovelady, Dillard, Gruber, & O'shea, 2007).

Early initiation of breastfeeding has been linked to successful bonding between the mother-infant pair (Jansen, Weerth, & Riksen-Walraven, 2008). Mothers who initiated breastfeeding earlier, were more likely to establish breastfeeding easily and breastfeed longer (Hossain et al., 1992; Murray, Ricketts, & Dellaport, 2007).

### **2.1.2 Rates of early initiation**

Early initiation is defined by the WHO as breastfeeding within one hour of birth (WHO, 2007) and unless specified otherwise this definition of early breastfeeding is used for the remainder of the literature review and in this study. Prevalence of early initiation, that is, within one-hour of birth, varies between the countries of South Asia. In this region, Sri Lanka has the highest rate of early initiation of breastfeeding (83.3%) (Senarath et al., 2012) whereas it was much lower in Bangladesh (24%) (Haider et al., 2010), India (36.4%) (Patel, Banerjee, & Kaletwad, 2013) and Pakistan (27.2%) (Hanif, 2011).

Two major issues gain attention while reviewing early initiation rates in the South Asian region: recall period and representativeness. For instance, the Sri-Lankan study (Senarath et al., 2012) while based on the nationally representative Demographic and Health Survey, used cross-sectional data based on recall of up to two years since childbirth. Similarly, the cross-sectional study from Bangladesh (N=356) also had a recall period of up to two years in the study (Haider et al., 2010). The Indian study (Patel et al., 2013) included hospital-based cross-sectional study design (N=500) and interviewed mothers on the same day of childbirth, showing less likelihood of recall bias. However, that Indian study had less representativeness due to its hospital-based sample.

Besides those two issues, a further important matter to consider is use of the term 'early initiation'. While most of the articles published from the South Asian countries used the WHO recommended definitions of initiation of breastfeeding within one-hour (Adhikari, Khanal, Karkee, & Gavidia, 2014; Haider et al., 2010; Hanif, 2011; Senarath et al., 2012), one study from Egypt (Clemens et al., 1999) defined early initiation as 'initiation of breastfeeding within first two days'. It is important that research uses comparable and standard definitions to ensure that monitoring of breastfeeding outcomes is consistent and useful to policy makers.

Nepali cultures have traditionally strongly supported breastfeeding. Despite such positive societal support, the rates of early initiation have been lower in Nepal. Traditionally, mothers used to initiate breastfeeding only after bathing the newborn infants to avoid the possibility of skin infections (Khanal, Gavidia, Adhikari, Mishra,

& Karkee, 2014; Osrin et al., 2002). The rates of initiation of breastfeeding within one-hour of birth were 22% in 1991, 31.1% in 2001, 35.4% in 2006, and 44.5% in 2011 according to the Nepal Demographic and Health Surveys that are conducted every five years (Ministry of Health and Population (MOHP) [Nepal] et al., 2012; Ministry of Health and Population (MOHP) [Nepal] et al., 2007). As these surveys record the information based on the recall period of up to three years, they are, therefore, subject to some recall bias. However, these are the best nationally representative data available to date. More recently, a cohort study (N=639) reported a higher prevalence of early initiation (67%) from the Kaski district of Nepal (Karkee et al., 2014b). It should be noted that the Kaski district is one of the most developed districts in Nepal with better education and health service indicators and ranks among the top five districts based on the human development index (Karkee et al., 2013b).

A summary of studies reporting early initiation of breastfeeding in Nepal are outlined in Table 2. The review of literature from Nepal suggests two issues to be taken into account. First, there is an issue in the definition of 'early initiation'. Some of the authors defined 'early initiation' as per their data availability. For instance, Mullany et al. (2008) defined early initiation as 'initiation of breastfeeding within first two days' whereas others tended to follow the WHO definition 'initiation of breastfeeding within one hour of birth' (Adhikari et al., 2014; Karkee et al., 2014b; Pandey, Tiwari, Senarath, Agho, & Dibley, 2010). The second issue is that of recall period. For instance, the rates reported in the Nepal Demographic and Health Surveys (Ministry of Health and Population (MOHP) [Nepal] et al., 2012; Ministry of Health and Population (MOHP) [Nepal] et al., 2007) were more likely to suffer from recall bias than those reported in other studies with a much shorter recall period (Karkee et al., 2014b; Sreeramareddy, Joshi, Sreekumaran, Giri, & Chuni, 2006).

**Table 2 Independent studies on early initiation of breastfeeding in Nepal**

<b>Author, Year</b>	<b>Study design and sample size</b>	<b>Incidence</b>	<b>Definition and recall period</b>
Nepal Demographic and Health Survey 2006 (2007)#	Cross-sectional study (N=4,020)	35.4%	Initiation of breastfeeding within one hour of birth. Recall period: up to five years
Mullany et al. (2008)	Cohort study (N=23,662 )	3.7% were breastfed before one-hour	Initiation breastfeeding within 24-hour. Recall period: data collected soon after birth and had follow-up at 1-4, 6, 8, 10, 12, 14, 21, and 28 days
Nepal Demographic and Health Survey 2011 (2012)#	Cross-sectional study (N=2,030)	44.5%	Initiation of breastfeeding within one hour of birth. Recall period: up to two years
Sreeramareddy et al. (2006)	Cross-sectional study (N=240)	57.9%	Not defined as “early initiation” but reported as “initiation within one hour”. Recall period: not detailed.
Karkee et al.(2014b)	Cohort study (N=639 )	67%	Introduction of breastfeeding within one hour. Recall period: within 45-days of childbirth.

*#Two further analyses excluded as they reported on NDHS 2011, and 2006.*

### **2.1.3 Factors associated with early initiation of breastfeeding**

#### **2.1.3.1 Socio-demographic factors**

##### **2.1.3.1.1 Maternal education**

A number of studies have reported maternal education as an important factor associated with early initiation of breastfeeding. Studies from Nepal and India reported that a higher maternal education was associated with a higher likelihood of

early initiation of breastfeeding (Acharya & Khanal, 2015; Adhikari et al., 2014; Patel et al., 2013). A study from India reported that education and counselling of mothers was helpful in the early initiation of breastfeeding even in a difficult situation such as caesarean delivery (Banapurmath, Ramachandrappa, Guruprasad, & Biradar, 2013). Educated mothers are more likely to have their childbirth in a health facility or assisted by skilled birth attendants. Health workers in Nepal are encouraged to promote and help initiate breastfeeding immediately after childbirth leading to higher rates of early initiation (Ministry of Health and Population & Child Health Division [Nutrition Section], 2004).

#### **2.1.3.1.2 Maternal age**

Maternal age is one of the most frequently studied sociodemographic factors. Maternal age was not found to be associated with early initiation of breastfeeding in previous studies from Bangladesh, Brazil and Sri Lanka (El Gilany, Sarraf, & Al Wehady, 2012; Miharshahi et al., 2010; Senarath et al., 2012; Vieira et al., 2010). A pooled analysis included 12, 845 last born child-infant pairs using Nepal Demographic and Health Surveys 2001, 2006 and 2011 and reported that there was no significant association of maternal age with early initiation of breastfeeding (Acharya & Khanal, 2015). Only one study from Bangladesh (N=143) reported that younger mothers were more likely to start breastfeeding earlier (Holman & Grimes, 2001).

#### **2.1.3.1.3 Maternal occupation**

Only one previous cross-sectional study based on the data from the Nepal Demographic and Health Survey 2011 has reported that mothers in an agrarian occupation had a higher likelihood of early initiation of breastfeeding (Adhikari et al., 2014). Maternal occupation in South-Asia is determined by their levels of education and empowerment status when it comes to professional jobs. Those who are less educated and are not allowed to go outside home to work are likely to be involved in the agrarian workforce. It is however, not clear how maternal occupation influences the time of initiation of breastfeeding.

#### **2.1.3.1.4 Ethnicity**

Ethnicity has been reported to be one of the influential factors that define infant feeding practices as it determines cultural practices related to birth, infant feeding and other health care practices. Ethnicity is complex to explain and define as it is a combination of local setting, religion, cultural and historical contexts. In some places, such as in the United States, skin colour has widely been used as ethnic groups whereas in India, it is mostly a caste and religion based system. In other parts of Asia ethnicity may be related to poorer economic status and rural (agricultural) occupations, which are also associated with breastfeeding. In Nepal, ethnicity is based on caste and socio-economic status. While the further analysis of Nepal Demographic and Health Survey 2006 (Pandey et al., 2010) did not report on ethnicity, the further analysis of Nepal Demographic and Health 2011 data (Adhikari et al., 2014) reported that the disadvantaged Janjati (middle caste indigenous group) were more likely to initiate breastfeeding within an hour compared to those from advantaged ethnic groups or Dalit caste groups.

#### **2.1.3.1.5 Economic status**

While economic status has been studied in Asian countries as a determinant of breastfeeding, only a few studies have reported the association of early initiation (Perera, Ranathunga, Fernando, Sampath, & Samaranayake, 2012). Senarath et al. (2012) reported that mothers from the highest wealth quintile were more likely to initiate breastfeeding within one hour of childbirth. The association was not significant in the Nepali study reported by Adhikari et al. (2014) based on further analysis of Nepal Demographic and Health Survey 2011. Conversely, in a recent Chinese study, Tang et al. (2013) reported that the association was inverse when monthly income was used as an indicator of wealth (Odds Ratio (OR): 0.31; 95% Confidence Interval (CI): 0.11, 0.86).

#### **2.1.3.1.6 Rural-urban residence**

Place of residence is an important consideration as it determines mothers' access to health services, health workers and supplementary foods. A study from Saudi Arabia (N=906) showed that the mothers from rural areas were more likely to initiate

breastfeeding in the first hour of childbirth (OR: 4.2; 95% CI: 2.6, 6.8) (El Gilany et al., 2012). However, a previous Nepali study (N=4,079) did not find a significant rural-urban difference in the time of initiation of first breastfeeding (Chi-square test: p-value: 0.816) (Adhikari et al., 2014). The large pooled analysis of 12, 845 participants from Nepal Demographic and Health Surveys 2001, 2006, and 2011 also did not find a significant difference in the rates of early initiation of breastfeeding among mothers living in rural and urban areas (Acharya & Khanal, 2015).

### **2.1.3.2 Bio-medical factors**

#### **2.1.3.2.1 Modes of delivery**

A large study from Vietnam (N=10,834) reported that a caesarean delivery was associated with a significantly lower likelihood of early initiation of breastfeeding (OR: 28.95; 95% CI: 20.1, 44.7) (Tuan, Nguyen, Hajeebhoy, & Frongillo, 2014). Similarly, studies in Nepal, India and Brazil have also reported an association between caesarean delivery and delayed initiation of breastfeeding (Pandey et al., 2010; Patel et al., 2013; Vieira et al., 2010). There are two major ways that the time of initiation of breastfeeding is affected by caesarean delivery. First, mothers are still under the influence of anaesthesia and they are not able to move themselves in the first hours of surgery. In Western countries, the mother remains conscious under epidural or spinal anaesthesia and can breastfeed immediately but this is not always the case in Asia. Second, newborn infants born via caesarean section have been found to be less responsive to hunger, and have lower frequency of movement and suckling response (Baumgardner, Muehl, Fischer, & Pribbenow, 2003; Beilin et al., 2005; Ransjö-Arvidson et al., 2001). A recent review published as part of the Lancet breastfeeding series noted that “in the presence of adequate support”, caesarean section is not necessarily a barrier to timely initiation of breastfeeding (RR: 0.95; 95% CI: 0.84, 1.07) (Rollins et al., 2016). However, the finding has to be interpreted with a caution that ‘adequate support’ is yet to be part of routine postpartum care and immediately after caesarean section, especially in the countries where health facilities are overstretched and understaffed.

#### **2.1.3.2.2 Birth weight**

Low birth weight was a risk factor for delayed initiation in an Indian cross-sectional study (N=500) (Patel et al., 2013). The authors asserted that a full term and normal birth weight baby can suckle breasts compared to those who are small for gestational age and are pre-term (Patel et al., 2013). In a previous study from Nepal (N=4,079), children with higher birth weight had higher likelihood of early initiation of breastfeeding compared to low birth weight (Adhikari et al., 2014). Similarly, in Brazil, and Saudi Arabia the full-term babies had more likelihood of breastfeeding within one hour compared to their pre-term counterparts (El Gilany et al., 2012; Vieira et al., 2010). The preterm and low birth weight infants are often found to have some illness when they are born, and most are taken away to the neonatal intensive care unit for further care. In addition, premature newborn are mostly sleepy, and mothers might find it difficult to see the signs of hunger (Vieira et al., 2014). These issues might delay the initiation of breastfeeding.

#### **2.1.3.2.3 Place of delivery**

Place of delivery is an important consideration as early infant feeding practices are dependent on the support mothers receive immediately after birth. A further analysis of Nepal Demographic and Health Survey 2011 (N=4,079) also reported a significant association between health facility delivery and early initiation of breastfeeding (OR: 1.67; 95% CI: 1.25, 2.23) (Adhikari et al., 2014). Across-sectional study (N=2,735) from Sri Lanka reported that having had childbirth in a health facility reduced the likelihood of delayed initiation of breastfeeding (Senarath et al., 2012). A Vietnamese study (N=10,834) also reported that having breastfeeding support from health workers either during pregnancy or childbirth was associated with increased practice of early initiation of breastfeeding (Tuan et al., 2014). When a mother delivers in a health facility, there is an opportunity for health workers to support and encourage mothers to start breastfeeding. If mothers have any problem in breastfeeding, health workers can provide immediate support and help them for proper latching (Tuan et al., 2014). In the South Asia region, the WHO is the major driving force to design and accelerate government policies and guidelines. In general, the South Asian countries follow the Baby Friendly Hospital principles and support

‘initiation of breastfeeding within the first hour of birth’ as part of ten steps to successful breastfeeding. While, there is widespread agreement on the priority given to breastfeeding, the continuous effort to achieve universal availability of Baby Friendly accredited hospitals has lost its momentum.

#### **2.1.3.2.4 Antenatal care**

Antenatal care is a part of maternal health care services that enables and encourages mothers to seek further services and helps them to achieve good health throughout pregnancy and childbirth. A further analysis of the Demographic and Health Survey of Sri Lanka (N=2,735) reported that having three to six antenatal visits was associated with a lesser likelihood of delayed initiation of breastfeeding (OR:0.60; 95% CI:0.41, 0.90) (Senarath et al., 2012). Patel et al. (2013) also reported that counselling on breastfeeding during antenatal care was associated with a higher likelihood of early initiation in India (N=500).

## **2.2 Prelacteal feeding**

### **2.2.1 Disadvantages of prelacteal feeding**

Prelacteal feeds are any feeds (for example water, sweetened and flavoured water, teas, infusion) provided before the initiation of breastmilk (Qiu, Xie, Lee, & Binns, 2007; Szajewska et al., 2006). Although prelacteal feeding is not recommended by the WHO (WHO & UNICEF, 2010) or any national authorities; it is a common practice in many Asian cultures. These feeds are mostly used for non-nutritional reasons such as improving hydration, clearing throat, settling infants, and clearing abdomen (Schwartz et al., 2002). In some cultures, it is also a ritual to introduce prelacteal feeds first, then followed by breastfeeding (Laroia & Sharma, 2006).

Prelacteal feeding has no benefit except for specific clinical indications. The introduction of prelacteal feeding has been found to affect initiation and continuation of breastfeeding. Early suckling of breasts is important for breastmilk production which is reduced by the introduction of prelacteal feeding. It also delays the time of initiation of breastfeeding (Khanal & Sauer, 2013). Martin-Calama et al. (1997) reported that exposure to prelacteal feeds and other substitutes significantly reduced the duration of breastfeeding. A Vietnamese study reported that introduction of prelacteal feeding was associated with childhood diarrhoea among young infants aged 0-5 months (Tuan et al., 2014). In addition, a Chinese cohort study reported that the introduction of prelacteal feeding was associated with low rates of 'any breastfeeding' at hospital discharge (Qiu et al., 2007). Based on 26 studies from India, China, and Australia, the recent Infant Feeding Guideline of Australia concluded that prelacteal feeding is associated with a shorter duration of breastfeeding (National Health and Medical Research Council, 2012).

Concern about the introduction of prelacteal feeds is related to sub-optimal breastfeeding outcomes and the development of the infant's gastro-intestinal microbiome and immunological development. Prelacteal feeds may delay the secretion of colostrum, which contains useful quantities of protein, vitamin A,

vitamin B<sub>12</sub>, lactoferrin, immunoglobulins, antibodies and living cells, including macrophages and bacteria (Qiu et al., 2007).

The harmful effects of prelacteal feeding also depend on the types of food provided. Honey is commonly used and may contain *Clostridium botulinum*. This may cause severe food poisoning in neonates (McKenna & Shankar, 2009). Plain water may be harmful to a newborn if it is contaminated or simply reduces breastmilk intake.

Animal milk is also commonly used as a prelacteal feed. Cow's milk has a low iron content, and a higher concentration of sodium, potassium, and protein that overloads the infant renal system and increases the likelihood of blood loss from the intestine (Binns, Graham, Scott, & Oddy, 2007). Ghee (clarified butter) and honey have high osmolarity that affects intestinal epithelial tissues. Other fluids such as sugar and glucose solutions may also modify the intestinal gut microbiome. In developing countries, poor sanitation often impairs the carer's ability to hygienically prepare and safely administer prelacteal feeds, which increases the risk of infections, especially of gastroenteritis.

### **2.2.2 Prevalence and factors associated with prelacteal feeding**

The prevalence of prelacteal feeding differs between countries and cultures. The prevalence of prelacteal feeding in South Asia is variable but generally high. It was reported to be 16.9% in India (N=500) (Patel et al., 2013), 92% (N=1,100) in the Dhaka region of Bangladesh (Haider, Kabir, & Ashworth, 1999), 23% (N=458) in Maldives (Raheem, Binns, Chih, & Sauer, 2014), and 44.8% (N=387) in Pakistan (Fikree, Ali, Durocher, & Rahbar, 2005). The prevalence of prelacteal feeding is also high in many other Asian countries. For example, it was 26%-93% in some areas of China (Qiu et al., 2007; Tang, Binns, et al., 2013), 12.3% (N= 4,821) in Timor-Leste (Khanal, Lee, da Cruz, & Karkee, 2014), and 73.3% (N=6,068) in Vietnam (Nguyen et al., 2013).

Table 3 summarises the independent studies that have reported on prelacteal feeding in Nepal. This shows that the prevalence of prelacteal feeding varies in Nepal and depends on the setting, the sample and the methodology. A national cross-sectional survey reported that its prevalence was 28.1% (Ministry of Health and Population

(MOHP) [Nepal] et al., 2012); while two other studies reported a slight variation ranging from 9.1% - 15.2% in the Kaski district (Karkee et al., 2014b; Sreeramareddy et al., 2006), 15% in the Makawanpur district of central Nepal (Osrin et al., 2002) and 39% in Kapilvastu district of Western Nepal (Khanal & Sauer, 2013). As many of these studies used a recall period of one year or more, they are likely to suffer from recall bias. In such instances there is likelihood of under reporting if the exposure to prelacteal feeds was brief and the infant was switched to breastfeeding after the initial few days postpartum.

**Table 3 Independent studies on prelacteal feeding in Nepal**

<b>Author, Year</b>	<b>Study design and sample size</b>	<b>Incidence</b>	<b>Recall period</b>
Osrin et al. (2002)	Cross-sectional study (N=5,411)	15.0%	Upto one year
Sreeramareddy et al. (2006)	Cross-sectional study (N= 240)	15.4%	Not detailed
Nepal Demographic and Health Survey 2006 (2007)	Cross-sectional study (N= 4,020)	36.5%	Up to five years
Nepal Demographic and Health Survey 2011 (2012)	Cross-sectional study (N= 2,030)	28.1%	Up to two years
Khanal & Sauer(2013)	Cross-sectional study (N=190)	39.0%	12-24 months
Karkee et al. (2014b)	Cohort study (N=639)	9.1%	≤ 45 days postpartum

### **2.2.3 Types of prelacteal feeds given**

Types of prelacteal feeds also vary based on the local cultural practices. In India, honey, sugar water, sugar water and tamarind juice, jaggery water, ajwain, jaggery and ghee combination, and other milk such as animal milk have been reported to be common prelacteal feeds (Patel et al., 2013; Singh, Haldiya, & Lakshminarayana, 1997). In the Maldives, glucose water, infant formula, honey and dates were reported

to be common (Raheem et al., 2014). In Muslim communities of South Asia, softened dates were reported to be major prelacteal feeds (McKenna & Shankar, 2009). Previous studies from Nepal reported plain water, sugar or glucose, gripe water, sugar or salt solution, fruit juice, infant formula, tea, animal milk (Khanal, Adhikari, Sauer, & Zhao, 2013); and sugarcane juice (Khanal & Sauer, 2013) as common prelacteal feeds. More recently, infant formula appears to be a common prelacteal feed (Karkee et al., 2014b). None of the previous studies elaborated on or offered reasons for the introduction of prelacteal feeds in Nepalese communities.

South Asia has a strong cultural basis of the introduction of prelacteal feeds, predominantly due to regional cultures shaped by the Hindu and Muslim beliefs (Fikree et al., 2005; Laroia & Sharma, 2006). Laroria and Sharma (2006) explained that honey and butter are taken as cleansing agents to clear meconium from the infant's throat and gut before starting breastfeeding. The practice of delaying breastfeeding in the first two weeks of birth, and providing prelacteals as described in the Hindu Scripture dates back thousands of year before the birth of Christ (Laroia & Sharma, 2006). In Hindu society, *Jatkarma* or naming ceremony occurs in the first two week of child birth, and the father provides supplementary feeds (honey, ghee) to his newborn infant. In the early 1980s, Paneru (1981) noted a similar phenomenon in Nepal, and this is probably the first published scientific article on breastfeeding practice including prelacteal feeding in Nepal. In this article, he reported that while breastfeeding was strongly preferred in traditional Nepali society, prelacteal feeds was also an integral part of early infant feeding practices. This practice is still common in all cultures in Nepal irrespective of the religion.

## **2.2.4 Factors associated with the introduction of prelacteal feeding**

### **2.2.4.1 Sociodemographic factors**

#### **2.2.4.1.1 Maternal education**

Maternal education has been reported to be one of the determinants of infant feeding practices. A further analysis of the Nepal Demographic and Health Survey 2011(N=4,079) showed that lower maternal education was associated with prelacteal

feeding in Nepal (Khanal, Adhikari, et al., 2013). A Chinese cohort study including 658 mother-infant pairs reported that mothers with higher education (grade 12 or more) were less likely (OR: 0.61; 95% CI: 0.38, 0.98) to provide prelacteal feeds to their newborn infants (Qiu et al., 2007).

#### **2.2.4.1.2 Economic factors**

Household wealth has frequently been reported as one of the factors affecting prelacteal practices. A further analysis of the Nepal Demographic and Health Survey found that middle-class families were more likely (OR: 1.63; 95% CI: 1.18, 2.26) to introduce prelacteal feeds compared to those from poor households; the difference was marginal for rich families (OR: 1.30; 95% CI: 0.90, 2.14) (Khanal, Adhikari, et al., 2013). A further analysis of the Demographic and Health Survey of Timor-Leste reported that the mothers from middle (OR : 1.43; 95% CI: 1.12, 1.82) and upper socio-economic families (OR: 1.66; 95% CI: 1.21, 2.27) had a higher likelihood of introducing prelacteal feeding (Khanal, Lee, et al., 2014). The findings of these studies are comparable as both used similar methodology and very similar generic questionnaires to collect the data. It has to be noted that despite being larger studies and representative of the countries, those studies collected information based on a recall period of as long as five years. Similarly, a Vietnamese cross-sectional study reported that being from the highest wealth quartile was associated with a higher likelihood of prelacteal feeding (OR: 1.98; 95%CI: 1.60, 2.46) (Nguyen et al., 2013).

#### **2.2.4.1.3 Place of residence**

Place of residence has an influence on the availability of supplementary food items. Being from urban areas was associated with a higher likelihood of introduction of prelacteal feeding in Vietnam (OR: 1.72; 95% CI: 1.44, 2.06) (Nguyen et al., 2013). Further analysis of the Timor-Leste Demographic and Health Survey (Khanal, Lee, et al., 2014) found that mothers who lived in urban areas were more likely to introduce prelacteal feeds to their newborn infants than their rural counterparts.

Geographical differences were also documented based on the ecological and administrative regions of Nepal. Nepal is divided into five administrative regions from north to south in vertical sections called development regions. Similarly, the

country is divided into to three horizontal sections by altitude: Terai (plain) regions, hilly (middle hilly belt), and mountainous regions (Himalayas) in the north. In a former study, it was reported that, compared to the far-western region of Nepal, one of the poorest region in the country, other administrative regions that are comparatively better in socioeconomic indicators had higher rates of prelacteal feeding (Khanal, Adhikari, et al., 2013). One study from the Kaski district of the central region reported that infants from urban areas were significantly more likely to be provided with prelacteal feeds as their first feed (Karkee et al., 2014b). Such geographical difference could be due to the different cultures in these regions. For instance, culture in the southern plains of Nepal is significantly different from hilly regions and the far-western areas. In the southern plains, the commercially available fluids such as ‘gripe water’ and ‘janm ghunti’ (a herbal syrup commercially available and common in Indian sub-continent) are provided for use as prelacteal feeds, but in the far-western region and the hilly and mountainous areas of Nepal, these products are not used probably due to these commercial products not being available. Culture and accessibility might be the major contributing factors to such regional and geographical variation.

#### **2.2.4.1.4 Maternal occupation or employment status**

The association between maternal employment status and prelacteal feeding has been studied less frequently. A further analysis of the Nepal Demographic and Health Survey 2011 reported that mothers who were not in a paid occupation (OR: 1.43; 95% CI: 1.06, 2.03) were more likely to introduce prelacteal feeds to their infants (Khanal, Adhikari, et al., 2013). However, the Timor-Leste Demographic and Health Survey reported that there was no association between maternal occupation and prelacteal feeding (Khanal, Lee, et al., 2014). Other studies from Nepal and Vietnam also did not report such a relationship (Karkee et al., 2014b; Nguyen et al., 2013).

## **2.2.4.2 Bio-medical factors**

### **2.2.4.2.1 Antenatal care visits**

Maternal health care services are available for mothers during the antenatal period, and it often encourages mothers to use the child health services after the delivery. Frequent visits during the antenatal period provide health workers with the opportunity to educate mothers and help them with any health and emotional difficulties during pregnancy (Karkee et al., 2013a). Health workers also have an opportunity to help mothers plan the place of delivery and encourage breastfeeding as early as possible, and continue exclusive breastfeeding for six months (Nguyen et al., 2013).

Not attending antenatal care visits has been reported to be associated with higher likelihood of prelacteal feeding. Having no antenatal care visits was associated with increased odds of prelacteal feeds in Nepal (OR: 1.23; 95% CI: 0.81, 1.87) (Khanal, Adhikari, et al., 2013). The study from the central region (N=639) of Nepal did not investigate this association (Karkee et al., 2014b). However, such an association was not significant in a hospital-based study in India (Patel et al., 2013). Birth preparedness counselling is provided in Nepal as part of antenatal care, and it has been found to be effective for preparedness behaviour and successive childbirth in a health facility (Karkee et al., 2013a). It has been found that birth preparedness was also associated with a lower likelihood of prelacteal feeding in the Kapilvastu district of Nepal (Khanal & Sauer, 2013).

### **2.2.4.2.2 Parity**

One hospital-based study from India did not find any association between parity and prelacteal feeding practice (Patel et al., 2013). However, parity has been reported to be associated with prelacteal feeding in two community-based studies in Nepal with both of the studies reporting a higher likelihood of introduction of prelacteal feeds among first time mothers (Karkee et al., 2014b; Khanal, Adhikari, et al., 2013). This could be related to mother's inexperience in infant feeding practices and inadequate skills to establish early breastfeeding.

#### **2.2.4.2.3 Facility-based childbirth**

The place of delivery, whether at home or a facility, was not a significant factor in determining the practice of prelacteal feeding in a number of South Asian studies (Karkee et al., 2014b; Khanal, Adhikari, et al., 2013; Patel et al., 2013). It is an expectation of the health system that health workers educate mothers and family, actively support mothers to breastfeed immediately after childbirth and discourage any harmful cultural practices (Ministry of Health and Population & Child Health Division [Nutrition Section], 2004).

#### **2.2.4.2.4 Mode of delivery**

Caesarean delivery has been found to be associated with higher odds of the introduction of prelacteal feeds (OR: 5.64; 95% CI: 4.69, 6.78) (Nguyen et al., 2013). Caesarean section was associated (OR: 10.10; 95% CI: 5.47, 18.67) with an increased rate of prelacteal feeding in Nepal (Karkee et al., 2014b). Two other studies that were based on the Nepal Demographic and Health Survey 2011 and the community-based study in the Kapilvastu district did not report on the mode of delivery (Khanal, Adhikari, et al., 2013; Khanal & Sauer, 2013). Two major reasons can be linked to such an association. Firstly, the mothers who undergo caesarean delivery may not be able to initiate breastfeeding in the first hours or day after delivery due to the effects of anaesthesia and find the introduction of animal milk or formula feeding more practical. Secondly, hospital staff might not have strongly supported and encouraged mothers to initiate colostrum feeding.

#### **2.2.4.2.5 Birth weight**

Birth weight is an important consideration concerning infant feeding. Few studies have reported on the association of birthweight of infant with prelacteal feeding practices. A study from India did not find any association (Patel et al., 2013). Two further analyses of Demographic and Health Surveys reported that having lower birthweight infants was associated with a higher likelihood of the introduction of prelacteal feeds in Timor-Leste (Khanal, Lee, et al., 2014) and Nepal (OR: 1.24; 95% CI: 0.94, 1.64) (Khanal, Adhikari, et al., 2013). It is postulated that small infants might not be developed enough to start suckling, that mothers may not feel confident

to manage these infants, and that these infants are more likely to be sick and separated from their mothers and cared for in a neonatal intensive care unit (Khanal, Lee, et al., 2014). Mothers of smaller infants might also feel that the newborn needs extra feeds before the mother's milk "comes in".

## **2.3 Exclusive breastfeeding**

### **2.3.1 Benefits of any and exclusive breastfeeding**

#### **2.3.1.1 Benefits to child**

##### **2.3.1.1.1 Short-term benefits of breastfeeding**

The WHO collaborative study conducted a pooled analysis and reported that breastfeeding protected against infant mortality and contributed to a reduction in deaths related to acute respiratory infections (WHO Collaborative Study Team, 2000). Many reviews followed this pioneering study. Recently, Khan et al. (Khan, Vesel, Bahl, & Martines, 2015) conducted a meta-analysis on the effects of 'exclusive breastfeeding' on infection-related neonatal mortality in developing countries. They found that partially breastfed neonates had a higher risk of mortality (pooled OR: 3.81; 95% CI: 2.19, 6.64) compared to those exclusively breastfed. Similarly, the partially breastfed neonates had a higher risk of sepsis or other infections (pooled RR: 3.46; 95% CI: 2.41, 4.98) compared to those exclusively breastfed. They were also at higher risk of neonatal diarrhoea (pooled RR: 2.97; 95% CI: 1.38, 6.41) and acute respiratory infections (pooled RR: 2.97; 95% CI: 1.38, 6.41).

In a recent systematic analysis and meta-analysis Sankar et al. (2015) reported that there was an inverse dose-response relationship between the risk of death and breastfeeding practice. When the analysis was restricted to the 0-5 months group, there was also an increased risk of mortality among predominantly breastfed infants (RR: 1.48; 95% CI: 1.14, 1.92), partially breastfed infants (RR: 2.84; 95% CI: 1.63, 4.97) and not breastfed infants (RR: 14.4; 95% CI: 6.13, 33.9), compared to exclusively breastfed infants. Furthermore, any breastfeeding in the 6-23 months age group had a significant benefit, reducing child mortality in the 12-23 months age group, compared to their non-breastfed counterparts (RR: 1.97; 95% CI: 1.45, 2.67). The authors infer that while exclusive breastfeeding is always the best infant feeding practice, any type of breastfeeding practices are beneficial when compared to non-breastfeeding.

Bowatte et al.(2015) conducted a systematic review and meta-analysis to investigate if breastfeeding has any protective effect against acute otitis media. Twenty-four studies from the USA and Europe met the inclusion criteria. Among these, the meta-analysis of five studies including 17,735 samples reported that exclusive breastfeeding for first the six months was protective against acute otitis media during the first two years of childhood (OR: 0.57; 95% CI: 0.44, 0.75). Any breastfeeding (total studies=5, N=19,650) also has a protective effect against otitis media during the first two years of childhood compared to never breastfed categories (OR: 0.67; 95% CI: 0.56, 0.80). The plausible explanation for such a protective effect may be linked to the oropharyngeal microbiome growth related to breastfeeding. *Corynebacterium* bacteria is found to be well colonised in the pharynx when infants are breastfed and are found to be protective against the risk of ear infection (Bowatte et al., 2015). However, studies to verify such association are limited and need further investigation to justify the authors' hypothesis.

There is a growing interest in the association of breastfeeding with the development of allergies including asthma. A recent systematic analysis and meta-analysis (Lodge et al., 2015) reported on the association of asthma and allergies with breastfeeding. Their pooled analysis showed that there was no significant association between 'exclusive breastfeeding' for 3-4 months and asthma during the ages of 5-18 years compared to the less breastfeeding category. But, there was a significant protective effect of ever breastfed [odds ratio among high-income countries: 0.90; 95% CI: 0.83, 0.97) and odds ratio among low-income countries: 0.79; 95% CI: 0.70, 0.88)] compared to the never breastfed. In terms of other outcomes such as allergic rhinitis, breastfeeding (more versus less) was protective among children under five years of age (OR: 0.79; 95% CI: 0.63, 0.98), however, the finding was not significant after five years of age (OR: 1.05; 95% CI: 0.99, 1.12). Pooled analysis of cohort studies included in that study reported a lower risk of eczema among the infants who were breastfed upto one year. Exclusive breastfeeding for 3-4 months was also associated with lower risk of eczema (OR: 0.74; 95%CI: 0.57, 0.97).

### **2.3.1.1.2 Long-term benefits of breastfeeding**

Breastfeeding has also been reported to provide long-term benefits to children. Kramer et al. (2008) reported on 6.5 years follow up of 17,046 children; of which only 81.5% could be followed-up. They found those children who received exclusive breastfeeding for three or more months have higher Intelligent Quotient (IQ) scores. It is postulated that human milk contains biological peptides and polysaturated fatty acids that help brain growth although maternal intimacy has to be considered an important factor while interpreting these findings (Angelsen, Vik, Jacobsen, & Bakketeig, 2001).

A recent interesting study by Cesar et al. (2015) has provided a 30-year follow-up on a relatively large (n=3,493) Brazilian cohort study showing the impact of breastfeeding on IQ. They found that participants who were predominantly breastfed for 12 months or more had higher IQ scores (mean difference: 3.76 points, 95% CI: 2.20, 5.33). Buturovic and Ignjatovic (2015) questioned the relevance of this historic association and asserted that the currently available improved milk formulas which mimic the properties of breast milk, may have similar benefits in terms of IQ. However Buturovic and Ignjatovic's viewpoint is unsubstantiated and the argument is not relevant to low and middle-income countries, because such premium modern day formulas that have 'n3 fatty acids' are unlikely to be affordable to families. In addition, in high-income countries, as Horta replies (Horta & Victora, 2015), with advances in science, new information on myelination and the microbiome property of breast milk are better understood. Therefore, such 'mimic' formula milks are less likely to match the benefits of breastmilk.

In addition, a recent systematic review and meta-analysis (Horta, Loret de Mola, & Victora, 2015) also reported an association of IQ and breastfeeding with an increased mean IQ level (3.44 points; 95% CI: 2.30, 4.58). Former arguments against similar findings were that maternal IQ impacts on a child's outcome, therefore; it should not be treated as a benefit of breastfeeding. However, in the current meta-analysis, the author adjusted for maternal IQ and the findings were still significant (pooled OR: 2.62; 95% CI: 1.25; 3.98) confirming the benefits to infant IQ (Horta et al., 2015).

Owen et al.(2008) conducted a review that included 17 studies reporting on 17,498 children and investigated the association of breastfeeding and blood cholesterol level in individuals aged 16 years and above. They found the mean blood cholesterol level was lower among the breastfed group compared to the formula-fed group after controlling for key sociodemographic variables. Breastfeeding has been shown to have positive effect in protecting from obesity. A large Japanese study that included 43,367 children who were followed-up from 2001 till 2009 reported a decreased risk of obesity (RR: 0.44; 95% CI: 0.31, 0.63) at the age of eight years among those children who were exclusively breastfed for 6-7 months compared to their formula-fed counterparts (Yamakawa, Yorifuji, Inoue, Kato, & Doi, 2013). Connolly and Tracewell (2012) discussed three possible pathways of the protective effects of breastfeeding on obesity: first, there is decreased insulin level among breastfed infant that leads to fewer adipocytes; second, breastfeeding leads to self-regulation of energy level among these children, and finally, protein content in breastmilk is less than that of formula milk. The higher protein content in infant formulas is a risk factor for obesity.

One of the important long-term benefits of breastfeeding is protection against type 2 diabetes. An Australian study of 3,595 infants born between 1981 and 1983 followed- up for 21 years and investigated the protective effect of breastfeeding against diabetes (Mamun et al., 2014). The information on breastfeeding was collected at six months postpartum. The findings showed that there was a decreased risk of diabetes among those who were exclusively breastfed for at least four months (RR: 0.24; 95%CI: 0.13, 0.63) (Mamun et al., 2014). The association was significant even after adjusting for maternal age, smoking during pregnancy, maternal education, parity, birth weight z-score for gestation, maternal pre-pregnancy body mass index and hypertensive disorder in pregnancy (Mamun et al., 2014).

Nepal traditionally had a burden communicable disease, but with a transition in life style and dietary patterns, non-communicable diseases are on the rise. A recent review highlighted the prevalence of hypertension (defined as systolic blood pressure > 140 mm Hg and diastolic blood pressure > 90 mm Hg) at 22.7% in urban areas (Mishra, Neupane, Shakya, Adhikari, & Kallestrup, 2015). The burden of diabetes was also high in urban areas (14.6%) compared to rural areas (2.5%) (Mishra et al.,

2015). At population level, about 5.7% have cardiovascular disease (Vaidya et al., 2009). With such increase in non-communicable diseases, which were previously uncommon, exclusive breastfeeding and particularly avoiding infant formula would offer some protection from such morbidities.

### **2.3.1.2 Benefits to mother**

The benefits of breastfeeding are not limited to infants and children. Studies have reported that there are many benefits to mothers. Zhou et al. (2015) conducted a systematic review and meta-analysis of 24 articles published between 2008 and 2014 and reported that 'ever' breastfeeding was protective (RR: 0.61; 95% CI: 0.44, 0.85) against breast cancer compared to 'never breastfed' group. Ip et al. (2009) summarised the findings from 45 studies and reported that each year of breastfeeding reduces risk of breast cancer by 4.3%.

Ovarian cancer is another outcome of interest that is linked to breastfeeding. Ip et al. (2009) found that there was a significantly lower risk of ovarian cancer among those mothers who breastfed for one year or more (OR: 0.72; 95% CI: 0.54, 0.97). More recently Luan and colleagues (2013) conducted a meta-analysis of five observational studies and 30 case-control studies to investigate the association between breastfeeding and ovarian cancer (epithelial ovarian cancer). They reported a reduction of risk of ovarian cancer by 34% among those mothers who ever breastfed (OR: 0.76; 95% CI: 0.69, 0.83) compared to those who never breastfed. The most recent meta-analysis by Chowdhury et al. (2015) found that the risk of ovarian carcinoma was reduced by 28% if mothers breastfed for 6-12 months. The protective effect increased to 37% if mothers breastfed for more than 12 months showing a dose-response relationship between duration of breastfeeding and ovarian carcinoma.

Postpartum depression is common and has adverse consequences to the health outcomes of mothers and newborns (Dennis & McQueen, 2009). Breastfeeding practice has been found to be protective against maternal postpartum depression (Ip et al., 2009). Based on longitudinal data, Watkins, Meltzer-Brody, Zolnoun, & Stuebe (2011) also reported that mothers who had breastfeeding difficulties in the early infant feeding period were more at risk of having postpartum depression at two

months postpartum. One of the most important considerations in such an association is reverse causality as many studies also reported that maternal depression would lead to early cessation of breastfeeding and exclusive breastfeeding (Dennis & McQueen, 2009; Gagliardi, Petrozzi, & Rusconi, 2012).

### **2.3.1.3 Benefits to the environment**

More recently there has been increasing interest in how breastfeeding may contribute towards sustainable development goals and save the environment. The use of breastmilk substitutes requires resources for the production of infant formula, storage, packaging, and a massive amount of waste materials are generated as a result of consumption. While studies in this area are limited, a recent breastfeeding series in Lancet reported that about 4,000 litres of water is consumed to produce one kilogram of infant formula; reducing the use of infant formula, it is argued, will save a large amount of water (Rollins et al., 2016). In addition, this study further reported that a total of 550 million cans of infant formula, 86,000 tonnes of metal and 364,000 tonnes of paper are the result of the annual production of infant formula in the United States (Rollins et al., 2016). Given that many cities in the developing world, such as Kathmandu (Nepal), Dhaka (Bangladesh) and New Delhi (India), are well behind the developed world in terms of waste disposal, a greater benefit to the environment and waste disposal systems can be expected.

### **2.3.2 Measurement and reported rates of exclusive breastfeeding in South Asia**

South Asian countries have a high rate of breastfeeding and a comprehensive search of exclusive breastfeeding research published during 2000-2015 found 29 studies in the region. Appendix 2 provides a summary of exclusive breastfeeding rates in Nepal, India, Bangladesh, and Pakistan which have similar cultures. The summary highlights the study designs, the definition used for exclusive breastfeeding, age of infant when the infant feeding information was obtained, and method of recall. The following paragraphs will provide a brief summary of the rates of exclusive breastfeeding in the individual South Asian countries.

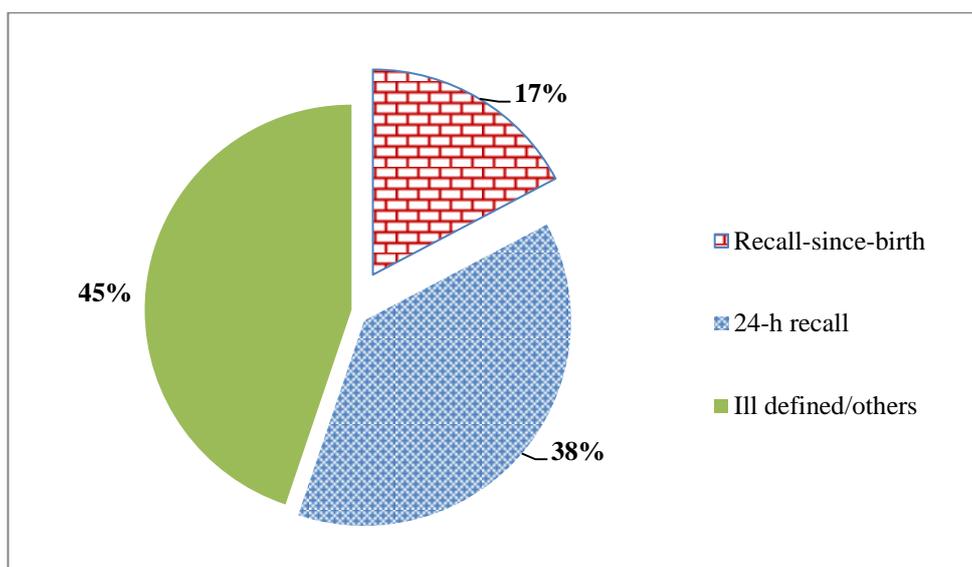
Bangladesh has made a unique contribution to lactation research. In 2000, Haider et al.(2000) reported a contrasting difference in exclusive breastfeeding rates in the fifth month among those who receive breastfeeding promotion intervention (70%) and those who did not (6%). In 2012, Zongrone, Winskell & Menon (2012) reported a 24-hour prevalence of exclusive breastfeeding of 36.05% among infants aged 0-5 months. A cross-sectional study used a similar measurement method and reported 36% prevalence rate among infants aged 0-5 months (Joshi et al., 2014).

Studies from India also reported exclusive breastfeeding practices comparable to those in Bangladesh. According to the national survey conducted in 2005-2006, the 24- hour exclusive breastfeeding prevalence among 0-5 month infant was 42% (Chowdhury, Henderson, & Watson, 2013). Although a higher rate of 69.5% at 6<sup>th</sup> month was reported by Suresh et al. (2014), the study did not provide details on the data collection method. The reported exclusive breastfeeding rate in infants aged <6 months in Pakistan was similar to that of India, with 37.1% during 2005-2006 (Hanif, 2011).

Only a few studies reported exclusive breastfeeding rates and prevalence in Nepal (see appendix: 3, manuscript under review). Chandrashekhar et al. (2007) reported exclusive breastfeeding of 82% among infants aged two month. Pandey et al.(2010) reported a national rate of exclusive breastfeeding of 53% among infants aged <6 months during 2006-2007, a rate that was found to be higher (69%) in the 2011 Nepal Demographic and Health survey (Khanal, Sauer, et al., 2013). More recently, Karkee et al.(2014a) used a prospective cohort study, recruited mothers during pregnancy, collected information in the first, fourth and sixth months, and reported exclusive breastfeeding rates of 84.4%, 67.2% and 29.7%, respectively. This is the only cohort study that reported on exclusive breastfeeding.

A few issues appear relating to accurate measurement, and interpretation of exclusive breastfeeding data in South Asia are notable. First, most of the studies used cross-sectional study designs (24 out of 29 retrieved studies); and only three were cohort studies. The rates reported by cross-sectional studies are likely to fluctuate with infant age. The cross-sectional study design is also not able to capture intermittent introduction of complementary feedings. Second, two studies reported exclusive

breastfeeding at a very young age (<3 months) (Chandrashekhar et al., 2007; Miharshahi et al., 2007). These studies are likely to reflect better results for exclusive breastfeeding due to infants being more likely to be exclusively breastfed in the first few months of their life. On the other hand, other studies reported exclusive breastfeeding using retrospective recall as they were recruiting infants aged 6-12 months (Islam, Rahman, Kamruzzaman, Islam, & Samad, 2013; Roy, de Groot, Shafique, & Afroz, 2002; Subedi, Paudel, Rana, & Poudyal, 2012) and this is likely to introduce recall bias. Finally, in many of the studies that are based on demographic and health surveys, multiple indicator cluster surveys or similar studies, mothers are read a list of common food items to prompt recall of the complementary food items provided to their infants. The WHO recommends reading a list of common food items so that mothers do not miss any food or fluid provided to their infants. In some publications, this information is missing, and it was not clear whether it was based on the list of food items or based on a question such as, ‘how long did you exclusively breastfeed your infant?’



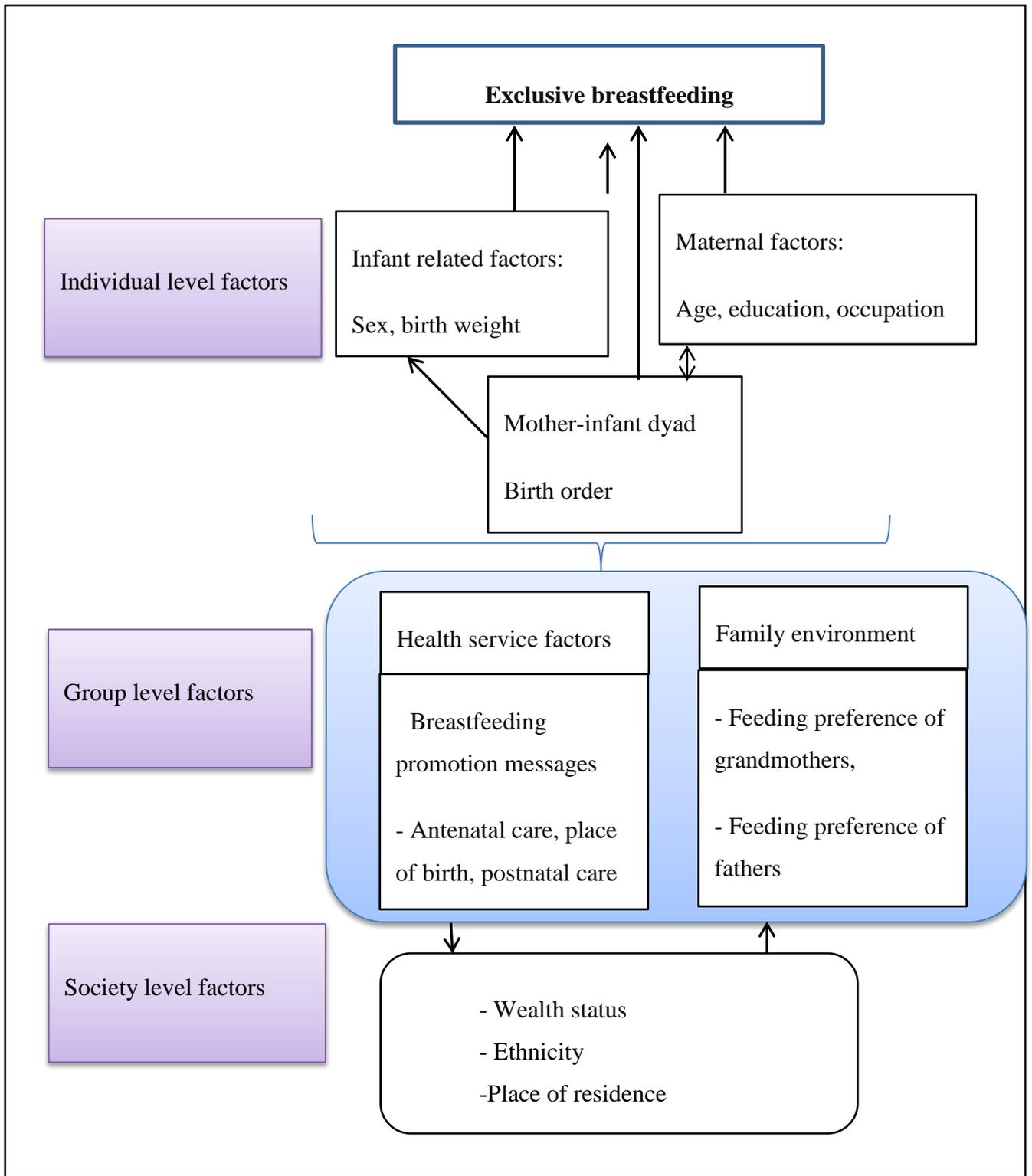
**Figure 3 Measurement methods used in breastfeeding studies in South Asia (N=29)**

Another identified issue was the measurement methods of exclusive breastfeeding in South Asia. There are two widely used methods to collect data in South Asian countries: 24-hour recall, and recall-since-birth (Figure3). The Demographic and Health Surveys, the major source of data in these countries, use 24-

hour-recall method. Based on this method, these surveys report a 24-hour prevalence of exclusive breastfeeding among infants aged 0-5 months. However, these prevalence rates are often misinterpreted as 'exclusive breastfeeding for six months' (Pullum, 2014). The second commonly used method was recall-since-birth (Haider et al., 2000) which is appropriate for reporting "exclusive breastfeeding for six months". It is noted that a number of studies depended on retrospective recall after six months from birth and might be subject to recall bias (Karande & Perkar, 2012; Ulak, Chandyo, Mellander, Shrestha, & Strand, 2012). Slightly less than half (45%) of the studies did not report or used different methods than these two (Bagul & Supare, 2012; Meshram, Laxmaiah, Venkaiah, & Brahman, 2012; Suresh et al., 2014). A lack of information on measurement methods makes comparability of reported rates difficult.

### **2.3.3 Factors associated with exclusive breastfeeding**

A number of factors affect breastfeeding practices in developed and developing countries. The demarcation between causation and association also remains ill-defined when it comes to explaining the factors associated with exclusive breastfeeding. For the same reason, none of the previous publications presented a well-defined conceptual framework to show the inter-linkage of factors with exclusive breastfeeding. One conceptual framework developed by Hector, King and Webb (2013) is adapted for this review (Figure 4).



**Figure 4 Conceptual framework of factors associated with exclusive breastfeeding (Source: Hector, King, & Webb, 2013)**

### **2.3.3.1 Individual factors**

#### **2.3.3.1.1 Maternal age**

Three previous studies reported on the factors associated with exclusive breastfeeding in Nepal (Khanal, Sauer, et al., 2013; Pandey et al., 2010). None of those studies found a significant association between maternal age and exclusive breastfeeding practices. Similarly, Senarath et al. (2012) did not find any significant association between maternal age and exclusive breastfeeding. On the other hand, a cohort study of 220 Brazilian mothers reported that maternal age was significantly associated with cessation of breastfeeding before six months (Santo, De Oliveira, & Giugliani, 2007). In that study, adolescent mothers were more likely to cease exclusive breastfeeding prematurely (Hazard Ratio (HR): 1.48; 95% CI: 1.01, 2.17). A number of reasons could be attributable to this practice. The older mother in developing countries is likely to be grand multipara, and, if she suffers ill-health condition, is less able to take care of herself and the infant (Akter & Rahman, 2010).

#### **2.3.3.1.2 Maternal education**

Education is one of the important factors that influence breastfeeding practices. Being literate was associated with a lower likelihood of cessation of exclusive breastfeeding (OR: 0.64; 95% CI: 0.43, 0.96) amongst Pakistani women (Hazir et al., 2013). Conversely, a lower education level (<8 years) was associated with a higher likelihood of cessation of exclusive breastfeeding in Brazil (HR: 1.34, 95% CI: 1.17, 1.53) (Vieira et al., 2014). Previous studies from Nepal did not find any association of maternal education and exclusive breastfeeding (Khanal, Sauer, et al., 2013).

#### **2.3.3.1.3 Maternal employment**

Employment of mothers affects a mother's ability to breastfeed in a number of ways. In a nationally representative cross-sectional study in Pakistan, employed mothers were more likely to discontinue exclusive breastfeeding (OR: 1.76; 95% CI: 1.13, 2.75) (Hazir et al., 2013). Xu et al. (2009) reviewed the findings of cohort studies from China and concluded that mothers who needed to return to their work earlier

were prone to discontinue breastfeeding. Inadequate maternity leave was a major barrier to sustain exclusive breastfeeding. A three-month paid maternity leave is provided in China. After three months, mothers have little support at the workplace to continue breastfeeding. The Taiwan Birth Cohort Study (Chuang et al., 2010) of 24,200 mothers reported that “returning to work” was one of the most common reasons for early cessation of breastfeeding. Similarly, mothers working outside the home as paid workers was a risk factor for early cessation of exclusive breastfeeding in a Brazilian cohort study (HR: 1.73, 95%CI: 1.53, 1.95) (Vieira et al., 2014).

#### **2.3.3.1.4 Gender of infant**

Gender of infants has major role in child health in Asian societies, where males are treated in a superior way to females. Such gender-based disparity has been witnessed in health care seeking with the male child being taken to hospital earlier than their female counterparts (Victora et al., 2003). Gender of infants, therefore, has been one of the frequently included variables of interest in breastfeeding studies. A cohort study in Sri Lanka enrolled mother after childbirth and followed up at two, four and six months to report the rates of exclusive breastfeeding (Perera et al., 2012). In that study, there was no significant association between infant’s gender and exclusive breastfeeding practice. A recent cohort study from Brazil included 1,265 mother-infant pairs and followed up through the first six months of infants age (Vieira et al., 2014). That study also did not find a significant association between infant’s gender and the duration of exclusive breastfeeding. A further analysis of Nepal Demographic and Health Surveys 2006 and 2011 data also did not report any significant association between exclusive breastfeeding practice and gender of an infant (Khanal, Sauer, et al., 2013). In summary, these studies suggest gender has no significant impact on exclusive breastfeeding.

#### **2.3.3.1.5 Birth weight**

In developing countries, especially in South Asia, the incidence of low birth weight is 14 % (95% CI: 11.4, 18.2) (De Wilde, van Buuren, & Middelkoop, 2013). Further analysis of Nepal Demographic and Health Survey 2006 and 2011 did not find any association between the infant size at birth- a proxy measure to report the birth

weight of infant when birth weight was not taken, and exclusive breastfeeding (Khanal, Sauer, et al., 2013). Similarly, Senarath et al. (2012) did not find any association of birth weight with exclusive breastfeeding in Sri Lanka. However, a Chinese cohort study reported a significantly higher risk of cessation of exclusive breastfeeding among low birth weight infants (HR: 1.87, 95% CI: 1.10, 3.18) (Xu, Binns, Zhang, Yang, & Zhao, 2010). Conversely, findings from Timor-Leste reported that it was infants with larger birth size who were at risk of non-exclusive breastfeeding (Khanal, da Cruz, Karkee, & Lee, 2014).

#### **2.3.3.1.6 Birth order**

A previous cohort study from Nepal (Karkee et al., 2014a) and a large cross-sectional study from Sri-Lanka did not find any association between birth order and exclusive breastfeeding (Senarath et al., 2012). Conversely, a further analysis of Nepal Demographic and Health Survey 2006 reported that second or third order infants were more likely to be exclusively breastfed compared to their first order counterparts (OR: 1.79; 95% CI: 1.08, 2.99) (Khanal, Sauer, et al., 2013). It is assumed that first-time mothers might not have the confidence to establish and continue breastfeeding. This lack of experience might reduce the likelihood of exclusive breastfeeding among the first-time mothers.

#### **2.3.3.2 Group factors**

##### **2.3.3.2.1 Health service factors**

###### **2.3.3.2.1.1 Health service utilisation**

The use of antenatal care, intra-partum care in a health facility and postnatal services are important and are the continuum of maternal and newborn health care. A mother who attends antenatal checks is more likely to be prepared for childbirth in health facility with the assistance of skilled birth attendants (Karkee et al., 2013a). Similarly, a mother delivering in a health facility is more likely to have postnatal visits (Khanal, Adhikari, Karkee, & Gavidia, 2014). These connected services

strengthen the potential for health workers to educate mothers on breastfeeding, assist with establishing breastfeeding and motivate continuation of breastfeeding after discharge from the health facility.

Further, a previous study that utilised the data from Nepal Demographic and Health Survey 2006 and 2011 found that infants who were born at home were more likely to be exclusively breastfed (OR: 1.89, 95%CI: 1.04, 3.41) compared to their health facility-born counterparts (Khanal, Sauer, et al., 2013). Having no postnatal visit was associated with cessation of exclusive breastfeeding in Sri-Lanka (OR: 1.17, 95%CI: 3.05, 0.01) (Senarath et al., 2012). These findings show that there is a strong link between contact with health workers, skilled birth attendants and continuation of exclusive breastfeeding. Having breastfeeding problems was another reason for discontinuing breastfeeding in Nepal (HR: 2.07; 95%CI: 1.66, 2.57) (Karkee et al., 2014a). Health workers can support mothers to manage these problems and continue breastfeeding. The support mothers get during this period is important and might be one of the major reasons for continuation of exclusive breastfeeding. Further elaboration on postpartum breastfeeding support and impact on exclusive breastfeeding and maternal problems during breastfeeding are presented in respective sections below.

#### **2.3.3.2.1.2 Caesarean section**

Caesarean delivery is one of the factors that have been reported to influence exclusive breastfeeding. In Nepal, early cessation of exclusive breastfeeding is more common among mothers who delivered their babies via caesarean section (HR: 1.88; 95% CI: 1.36, 2.62) (Karkee et al., 2014a). Leung et al.(2002) conducted a large cohort study in Hong Kong enrolling 7,825 mother-infant pairs and followed-up through nine months since birth. They found that caesarean section was a significant risk factor for cessation of breastfeeding <1 months (OR: 1.25; 95%CI: 1.00, 1.56), and was associated with lower breastfeeding duration (HR: 1.16, 95%CI: 1.04, 1.30). The further analyses of the Nepal Demographic Surveys 2006 and 2011 did not find any association between exclusive breastfeeding and caesarean sections (Khanal, Sauer, et al., 2013; Pandey et al., 2010). The findings from these two studies need to be interpreted with caution as the studies used 24-hour recall methods to collect the

data among infants aged <6 months. This method of data collection is less sensitive towards intermittent cessation of exclusive breastfeeding and short-term introduction of other complementary food.

### **2.3.3.2.2 Family level factor**

#### **2.3.3.2.2.1 Decision making**

Decision making on health is an important factor. Timorese mothers who could decide about their health on their own were more likely to exclusively breastfed (OR: 2.02; 95%CI: 1.11, 3.67) compared to women whose health decisions were made by husband or other family members (Khanal, da Cruz, et al., 2014) and comparable findings were reported from Sri Lanka (OR: 1.58, 95% CI: 0.96, 2.59) (Senarath et al., 2012). A previous qualitative study conducted in central Nepal reported that the mothers-in-law of the Tamang ethnic group considered themselves as important decision makers and supporter of their daughters-in-laws during postpartum (Masvie, 2006).

### **2.3.3.3 Society level factors**

#### **2.3.3.3.1 Wealth status**

Pakistani women in the highest wealth quintile had high likelihood of cessation of exclusive breastfeeding among infants aged 0-5 months (OR: 2.31; 95% CI: 1.22, 4.36) (Hazir et al., 2013). The difference was not significant in Nepal when Pandey et al.(2010) reported on Nepal Demographic and Health Survey 2006 data. The effect of wealth status has not been consistently associated with exclusive breastfeeding in South Asia. This could be due to the fact that cultural practices are more influential than wealth status.

#### **2.3.3.3.2 Place of residence**

Rural-urban differences in breastfeeding are well known. In developing countries, mothers from urban areas are likely to interrupt breastfeeding in favour of complementary feeding. Being from an urban area was one of the factors associated with non-exclusive breastfeeding among infants aged 0-5 months in Sri Lanka (OR:

1.72, 95% CI: 1.02, 2.89) (Senarath et al., 2012). A cohort study from central Nepal reported significantly shorter duration of exclusive breastfeeding among urban mothers (mean: 104.5; 95% CI: 95.8, 113.1 days) compared to rural mothers (mean: 144.7; 95% CI: 132.3 to 157.1 days) (Karkee et al., 2014a). A number of reasons have been postulated to explain this phenomenon. Urban women are more likely to be exposed to advertisements for breastmilk substitutes leading to an early introduction of complementary foods. They are also more likely to be employed, making them unable to meet exclusive breastfeeding recommendations due to time constraints.

### **2.3.4 Postpartum breastfeeding promotion and Baby Friendly Hospital Initiative**

#### **2.3.4.1 Baby Friendly Hospital Initiative**

The Baby Friendly Hospital Initiative (BFHI) was promoted by the WHO since 1991 and its ‘ten steps to successful breastfeeding’ has been used to promote and protect exclusive breastfeeding (WHO & UNICEF, 2009). The 10 steps to successful breastfeeding include:

1. Have a written breastfeeding policy that is routinely communicated to all health care staff.
2. Train all health care staff in skills necessary to implement this policy
3. Inform all pregnant women about the benefits and management of breastfeeding.
4. Help mothers initiate breastfeeding within a half-hour of birth (note: revised as one hour in current infant feeding guidelines).
5. Show mothers how to breastfeed and how to maintain lactation even if they should be separated from their infants.
6. Give newborn infants no food or drink other than breastmilk unless medically indicated.
7. Practice rooming in: allow mothers and infants to remain together-24 hours a day.
8. Encourage breastfeeding on demand.

9. Give no artificial teats or pacifiers (also called dummies or soothers) to breastfeeding infants.
10. Foster the establishment of breastfeeding support groups and refer mothers to them on discharge from the hospital or clinic.

Of the above steps, steps 1-9 focus on institution-based intervention and support for mothers whereas step 10 is community focused. Initially, there was some rapid progress in the BFHI certification and support globally. Later, due to other emerging priorities, momentum has slowed.

In 1998, the WHO published evidence that BFHI has increased breastfeeding rates (WHO, 1998). Recently, Pérez-Escamilla, Martinez, and Segura-Pérez (2016) published a systematic review, including studies from 19 different countries around the world, and reported that there was improvement breastfeeding outcomes (early initiation, exclusive breastfeeding at hospital discharge and duration of exclusive breastfeeding) when the BFHI was implemented. They also report that there was a dose-response relationship between the number of components of BFHI implemented and the improvements of breastfeeding outcomes. While there is ample evidence that BFHI works in developing countries (Abrahams & Labbok, 2009) the coverage of implementation was varied with 31% in developing countries (Labbok, 2012), and 50% in East-Asia (Semenic, Childerhose, Lauziere, & Groleau, 2012). As of 2009-2010, only 26% of 7,448 hospitals in developing countries were designated as BFHI, showing a further need to scale up the initiative (Labbok, 2012). In the same time period, 20,000 hospitals across 156 countries have been certified as BFHI hospitals (WHO & UNICEF, 2009).

In 2009, the WHO and UNICEF reported a major lesson learned from 15 years' experience and recommended that step 10 of the initiative to be scaled up in the NICU and different community settings such as breastfeeding supportive paediatric care, and Baby Friendly physician's office (WHO & UNICEF, 2009). In developing countries, scaling up these ten steps to birthing centres, primary health care centres and rural health centres would be beneficial for increasing breastfeeding rates. Labbok (2012, p.219) further asserted that 'implementation of even some of the steps result in significantly improved exclusive breastfeeding outcomes'.

#### **2.3.4.2 Other postpartum breastfeeding interventions**

Labbok (2012) asserted that the combination of health facility-based and community-based interventions are more beneficial to increase breastfeeding outcomes. A randomized control trial in Kenya enrolled 360 mothers during their 34-36 weeks postpartum and intervention was given at the health facility and home (Ochola, Labadarios, & Nduati, 2013). The control groups received standard health and nutrition education, depending on the availability of staffs' and their work load, and was inconsistent in delivery method. The first intervention group received facility-based counselling whereas the second group received home-based counselling. At six months, the mothers who received home-based counselling were more likely (OR: 3.40, 95% CI: 1.34, 8.80) to exclusive breastfeed than their control counterparts. This intervention suggests that mothers need continuous support while they are breastfeeding.

A systematic review based on 66 intervention studies reported on the effects of educational interventions on lactation promotion (Haroon, Das, Salam, Imdad, & Bhutta, 2013). The 'interventions' of interest were: (1) education or support session, (2) delivered by lay or professional counsellor or health workers, (3) either in group or individual session, (4) delivery period could be prenatal, postnatal or combined. The authors found an increase in exclusive breastfeeding among 1-5 months old infants (RR: 2.88, 95% CI: 2.11, 3.93) in developing countries when educational interventions were given (Haroon et al., 2013).

In conclusion, there is ample evidence that breastfeeding outcomes, including exclusive breastfeeding rates, are likely to improve when breastfeeding promotion programmes including BFHI, are implemented.

## **2.4 Lactation problems**

Lactation problems have been reported to be one of the reasons for the discontinuation of breastfeeding. An extensive search of the literature from South Asia yielded one study that reported lactation problems in Nepal (Karkee et al., 2014a) but it did not report on types of lactation problems, their management, and effect on the duration of exclusive breastfeeding. Therefore, literature from China, Brazil, and other developed countries are also included in this sub-section.

### **2.4.1 Problem magnitude**

A longitudinal study (Amir, 2003) found that inflammation of breast(s) (mastitis), breast pain, and sore nipples were the common problems reported by Australian lactating mothers. A Western Australia based longitudinal study, with a sample of 556 mothers, reported that anxiety over perceived milk insufficiency was the most common problem during breastfeeding, and often led to an early cessation of exclusive breastfeeding (Binns & Scott, 2002). These two Australian studies also documented ‘being unsuccessful previously’, ‘flat or inverted nipples’, ‘being embarrassed’, ‘sore breast(s)’, ‘baby refusing breastmilk’, and ‘baby was not gaining weight’ as the problems experienced by lactating mothers. These difficulties have been consistently reported to be major barriers to continuing exclusive breastfeeding for six months and continuing breastfeeding (Binns & Scott, 2002; Damato, Dowling, Standing, & Schuster, 2005). Only a limited amount of literature is available from developing countries on the problems of breastfeeding among mothers (Karkee et al., 2014a; Tang, Lee, et al., 2013).

Mastitis is an inflammatory condition of the mammary gland and is characterised by a tender, hot, swollen, wedge-shaped area of the breast in conjunction with flu-like symptoms, such as fever and malaise (Tang, Lee, et al., 2013; WHO, 2000). A recent hospital-based cohort study in China reported on the incidence of mastitis among 670 Chinese breastfeeding mothers and found 6.3% of mothers experienced at least one episode of mastitis (Tang, Lee, et al., 2013). The proportion of mothers experiencing mastitis varies by country. For instance, in Australia, it was 20.6% (N=306) during the first three months (Fetherston, 1997), and 20.6% (N=1,075) during the first 6

months (Kinlay, O'Connell, & Kinlay, 2001). In Scotland, it was 18.0% (N=420) during the first six months (Scott et al., 2008).

Mastitis is most common in the first few weeks of postpartum and the rate declines thereafter (Amir, Forster, Lumley, & McLachlan, 2007; Scott et al., 2008; WHO, 2000). In the 2008 Glasgow study, 53% of cases (30 of 57) occurred in the first four weeks (Scott et al., 2008). Similarly, an Australian study (Amir et al., 2007) reported 17.3% (N=1,193) of cumulative incidence in the first six weeks postpartum, of which 53% of cases occurred in the first four weeks.

#### **2.4.2 Risk factors of mastitis**

A number of studies have reported the risk factors for mastitis. Blocked ducts, cracked nipples, started consecutive feeds with same breast, history of mastitis were reported to be risk factors for mastitis in Australia (Kinlay et al., 2001). Maternal stress and cracked or sore nipples were significant risk factors in Chinese cohort study (Tang, Lee, et al., 2013). Cracked nipples (RR: 1.71; 95% CI: 1.14, 2.56) was reported to be a risk factor in an Australian cohort study (Amir et al., 2007). Infection is also reported to be one reason for mastitis (Barbosa-Cesnik, Schwartz, & Foxman, 2003).

The WHO report on mastitis (2000) listed two major causes of mastitis: milk stasis and infection. The factors presented above can be linked to milk stasis because cracked nipple and other problems may delay removal of milk from the breast, leading to engorgement and mastitis. It is also postulated that if mothers have ample milk supply, they are actually at more risk of having mastitis. These mothers may also breastfeed more frequently as a consequences in order to avoid breast encouragements (Barbosa-Cesnik et al., 2003). A recent study also supported the relationship between milk stasis and mastitis. The Spanish case-control study (N=516) reported that factors that could contribute to milk stasis such as: having cracked nipple, topical antifungal medication, previous history of mastitis, separation of mother-child for more than 24-hours and application of cream in the nipple (Mediano, Fernández, Rodríguez, & Marín, 2014). Inappropriate positioning,

latching and inadequate time of breastfeeding are also likely to contribute to milk stasis and have been reported to be risk factors of mastitis (Mediano et al., 2014).

Infection in mastitis is still under-studied. A recent study published by Jimenez et al.(2015) documented findings from bacteriological analysis using the milk of 10 mothers who had lactation mastitis. *Staphylococcus aureus* was the most common bacteria isolated. *Staphylococcus epidermis* was isolated among sub-acute mastitis. Gram-negative bacteria and yeast were not found in the culture. A recent Australian cohort study (N=346) found that 59% of the milk samples from mothers with mastitis were positive for *Staphylococcus aureus* culture (Cullinane et al., 2015). Indeed, this is the most common microorganism consistently found to be associated with mastitis. Nipple fissure, nipple damage, crack, sores and the use of creams are some of the factors that have been reported to be associated with mastitis (Amir et al., 2007; Barbosa-Cesnik et al., 2003) by contributing to infection. The cracked nipple may provide a portal of entry to microorganisms and cream may serve as vehicle for microorganisms and blocking agents for breastmilk (Vogel, Hutchison, & Mitchell, 1999).

### **2.4.3 Management of mastitis**

The management of mastitis and other lactation problems are important consideration during the postpartum period. While the complete pathophysiology of mastitis is not detailed, the WHO recommends four major ways to manage it; (1) supportive counselling, (2) effective milk removal, (3) antibiotic therapy when infection is suspected, and (4) symptomatic treatment (WHO, 2000). The recently published clinical protocol of the Academy of Breastfeeding Medicine also suggest further areas of focus, especially the management of complications; and management of abscess and candida infection (Amir, 2014). The protocol also recommends a number of preventive measures for lactation mastitis: (1) effective management of breast fullness and engorgement, (2) prompt attention to any signs of milk stasis,(3) prompt attention to other difficulties with breastfeeding,(4) rest, and (5) good hygiene (Amir, 2014, p.41).

The point of contact to seek such care and support is important. A Chinese cohort study reported that 70% of the mothers sought help from a health professional on the management of mastitis (Tang, Lee, et al., 2013). It is expected that mothers get correct advice and support from the health workers, however; surprisingly, 10% of the women in a Scottish study were incorrectly advised to stop feeding from the infected breast when they consulted a health worker (Scott et al., 2008). In South Asian society, there is a period of isolation where mothers are not allowed to go outside the home during the immediate postpartum period (Khanal, Adhikari, et al., 2014). If lactation problems occur in this isolation period, it is unlikely that mothers would get prompt support from health workers. In such cases, local senior women and relatives would take care of the postpartum mothers and are likely to be the major source of information. The literature shows a lack of research in this area.

#### **2.4.4 Impact of mastitis on exclusive breastfeeding**

The WHO stated that mastitis has an adverse effect on breastfeeding. The relationship, however, has been found to vary among different studies. In two Australian studies, one (Fetherston, 1997) reported mastitis as a reason for breastfeeding cessation among 18% of the respondents, and the other (Amir et al., 2007) did not find any significant difference. A Norwegian cohort study reported that breastfeeding problems were one of the reasons for breastfeeding cessation (Häggkvist et al., 2010). The Scottish study (Scott et al., 2008) found that the mothers who experienced mastitis were more likely to report breastfeeding at 26<sup>th</sup> weeks postpartum. They hypothesised that mothers who have a higher amount of breastmilk supply had shown the signs of milk stasis leading to mastitis. As a management strategy, mothers might choose to breastfeed more often and longer to avoid milk stasis. Only one study from Nepal has reported that the risk of cessation of exclusive breastfeeding increased significantly when mothers had ‘any breastfeeding problems’ (HR: 2.07; 95% CI: 1.66, 2.57) (Karkee et al., 2014a). However, that study did not report on mastitis in particular.

## **2.5 International policies on exclusive breastfeeding**

Currently, the WHO and UNICEF are the key organisations that lead international policy and program recommendations regarding infant feeding practice. The WHO and UNICEF recommend breastfeeding be initiated within one hour of childbirth and to continue exclusive breastfeeding for six months (WHO, 2007).

In August 1990, the Innocenti Declaration affirmed that infants should be breastfed for 4-6 months, which was later amended to six months by the WHO (Rollins et al., 2016). UNICEF had already changed its recommendation to six months, and the WHO's decision made the recommendation more coherent across the UN. Except for slight changes from 4-6 months for exclusive breastfeeding, the recommendation has remained consistent (Binns & Lee, 2014). For instance, American Academy of Pediatrics also recommends for 'exclusive breastfeeding for about six months' (Eidelman, 2012). In Australia and Europe, exclusive breastfeeding for 'around six months' is adapted (Binns & Lee, 2014) whereas, in South Asia, all of the countries adopted the WHO and UNICEF recommendations of exclusive breastfeeding 'for six months'.

## 2.6 National policy and programmes related to breastfeeding in Nepal

Nepal's current health system is guided by the Nepal Health Policy 1991 which included health prevention and health promotion as major areas of the health system (Department of Health Services & Ministry of Health and Population, 2014). Under-nutrition has remained a significant chronic problem in Nepal. In 2005, the National Nutrition Strategy was adopted. This strategy states: 'protecting, promoting and supporting optimal feeding practice for infants and young children' will be a major aim (Ministry of Health and Population & Child Health Division [Nutrition Section], 2004 p. 20). The 2004 strategy further outlined the following:

1. ensure early initiation of breastfeeding within one hour of birth, avoidance of prelacteal feed and promotion of exclusive breastfeeding for the first six months.
2. ensure continuation of breastfeeding for at least two years and introduction of appropriate complementary feeding after six months.
3. strengthen the capacity of health workers or medical professionals for nutrition and breastfeeding management.
4. protect from commercial promotional practices that undermine optimal breastfeeding practices.
5. empower all mothers, families and care givers to make and carry out fully informed decisions about feeding.
6. support community-based programmes.
7. promote mother and child-friendly working environment.
8. promote the use of appropriate and adequate locally available complementary foods like *jaulo* (porridge) and *sarvottam pitho* (superflour porridge).

The Government of Nepal endorsed a Multi-Sector Nutritional Plan (2013-2017) with a high emphasis on a multi-sectoral approach to reducing undernutrition in the country. This plan also highlights the importance of infant and young child feeding practices which remains one of the priority areas for the improvement of the nutritional status of children.

One of the positive aspects of Nepal's child health programmes is the inclusion of the WHO recommended infant feeding recommendations as part of their community-based program. For instance, the community-based integrated management of childhood illness and the community-based newborn care package (Department of Health Services & Ministry of Health and Population, 2014) both include exclusive breastfeeding for six months as one of the recommendations and the introduction of complementary food after that along with the continuation of breastfeeding. Health workers at the primary health care level are trained according to the child health training module adopted by the Ministry of Health and Population. The development and revision of the child health training module are supported by the WHO, and UNICEF.

Consistent with the National Nutrition Strategy 2004, the current National Nutrition Program includes breastfeeding as one of the strategic areas to reduce undernutrition (Department of Health Services & Ministry of Health and Population, 2014):

1. ensure early initiation of breastfeeding within one hour of birth, avoidance of pre-lacteal feed and promotion of exclusive breastfeeding for the first six months.
2. ensure the continuation of breastfeeding for at least two years and the introduction of appropriate (quantity and quality) complementary feeding after six months.

About 50,000 health volunteers, known as Female Community Health Volunteers, are working in Nepal in their communities, which is considered one of the major strengths of the Nepalese Health System (Department of Health Services & Ministry of Health and Population, 2014). These health volunteers are married local women who are selected by local mothers to be trained in maternal and child health promotion and perform roles as volunteers. After training, they work as local health volunteers and also get involved in public health programmes such as vitamin A supplementation and polio immunisation (Glenton et al., 2010; Schwarz et al., 2014). As part of their responsibilities, these volunteers educate mothers on breastfeeding during the antenatal period, and encourage and support mothers to initiate and

continue exclusive breastfeeding. Nepal also celebrates breastfeeding week on the first week of August every year and conducts various activities in the country to promote breastfeeding (see: Figure 5). The translation of the bullet points is: initiate colostrum feeding within an hour of birth, exclusively breastfeed for six months and adopt proper position and attachment while breastfeeding.



Figure 5 Breastfeeding messages during breastfeeding week, Nepal

## CHAPTER 3 METHODOLOGY

### 3.1 Overview

This chapter describes the methodology used in this cohort study: the study design, instruments used, and data collection methods. In addition, ethical considerations are also detailed.

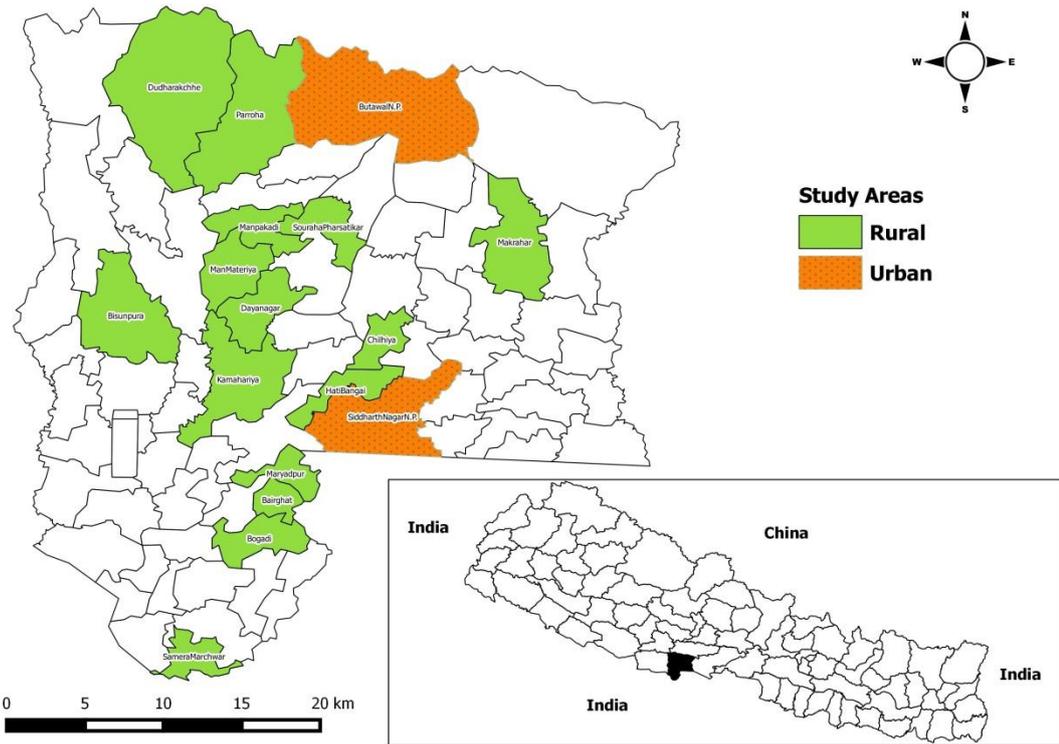
### 3.2 Study setting

The study was conducted in the Rupandehi district, located in the southern plains (Terai) of Western Nepal at an altitude of 100 to 1,229 metres bordering India to the south (Figure 6). The district occupies an area of 1,360 square kilometres. This district is famous for being the birthplace of 'Lord Buddha' and therefore, the name of the district comes from the name of the mother of Lord Buddha, Mayawati, also known as '*Rupidevi*' meaning 'beautiful'. The living place of '*Rupidevi*' initially was called 'Rupindehi' and later known as 'Rupandehi' (District Development Committee, 2013). The district is mainly plains with a few hills to the north. The temperature ranges from 43.7 degree Celsius in summer to 8.75 degree Celsius in winter.

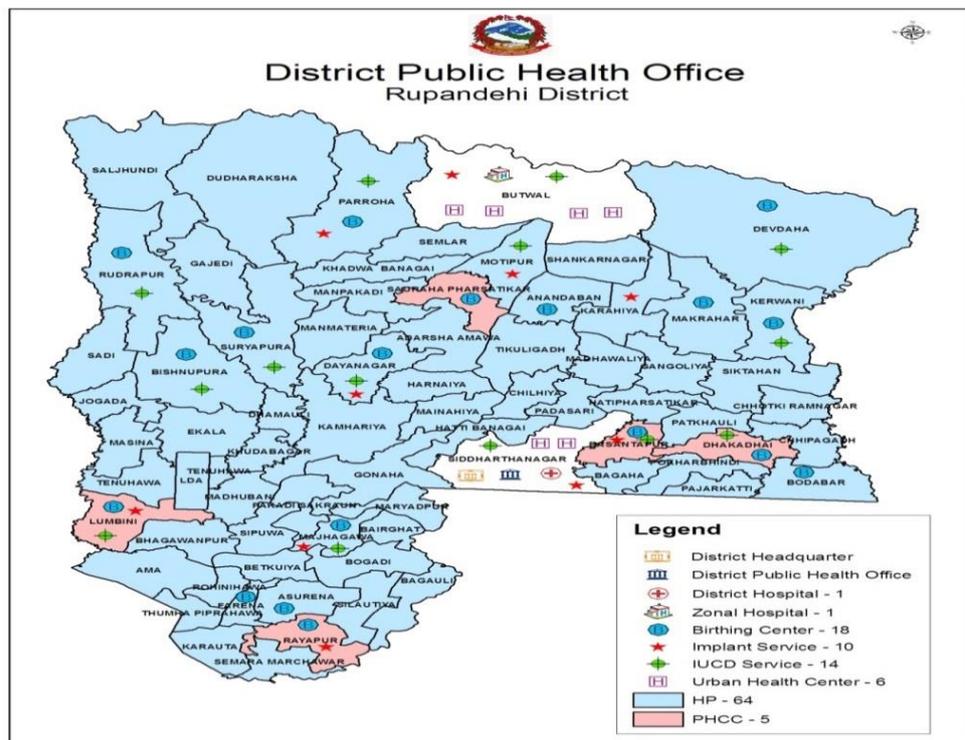
In 2011, the district had a population of 880,196 (males: 432,193; females: 448,003) with 25,070 pregnancies expected annually (Central Bureau of Statistics, 2012). Only 21.1% of the population lived in urban areas. A national survey of 2009 showed that the maternal mortality ratio in this district was 274 per 100,000 live births which was higher than the national mortality ratio of 229 (Suvedi et al., 2009). At the time of commencement of the current study, there were two municipalities and 69 village development committees in Rupandehi district. Municipalities and village development committees are the lowest administrative areas in urban and rural areas of Nepal, respectively.

The public health programmes are implemented through five primary health care centres, six health posts and 58 sub-health posts (District Public Health Office

Rupandehi, 2014). These activities are monitored by the District Public Health Office, which is located in one of the municipalities, Sidharthanagar Municipality (Bhairahawa) (Figure 7 and 8). One referral public (zonal) hospital, one district hospital, two medical colleges, and one children's and women's hospital are located in the urban areas (Clemens et al., 1999). In the rural areas, the majority of the population relies on health posts and sub-health posts staffed with health assistants (with 36 months training), auxiliary medical assistants (with 15 months vocational training), and auxiliary nurse midwives (with 18 months of vocational training). The majority of the rural areas are linked with the cities by gravel roads with little access to regular public transport. The public transport that exists is often irregular and non-functional during the rainy season due to road blockages and, therefore, cannot be relied on for medical emergencies. Bicycles and motorbikes are the common means of transport when public transport is interrupted. Despite these difficulties, the population has better access to health services compared to their counterparts living in the hilly and mountainous areas of Nepal where there is no road access, and people have to walk many hours to reach a health post. The basic health services provided at these rural health facilities (primary health centres, health posts and sub-health posts) are free of cost (District Public Health Office Rupandehi, 2014). Maternal health services are provided either in the community as outreach services or in health facilities are also free of cost. The mothers who have their childbirth in birthing centres located in rural areas receive transportation cost and a small gift known as '*nyano jhola*' that includes warm clothes for their newborn infant.



**Figure 6 Location of the study district in Nepal**  
(coloured area show the selected sites)



**Figure 7 Rupandehi district map**



**Figure 8** A health post located in a rural area, Rupandehi district

*(Women were waiting for health facility to open at 10.00 am in the morning)*

### 3.3 Study design

This study was a community-based prospective cohort study. Mothers who had given birth and were within 30 days postpartum, were recruited into the study and followed up at regular intervals for six months. The field work for the study was conducted between January, 2014 and October 2014 in the rural and urban areas of Rupandehi district of Nepal (Figure 9).

### 3.4 Sample size

Assuming a national exclusive breastfeeding rate of 70% at 4 months power 0.8, alpha 0.05, and loss to follow up 10%, the total required sample was 716 (rural and urban areas 358 for each) (WHO, 2013). This sample is expected to be able to detect a clinically significant difference of 10% between the exclusive breastfeeding rate in the urban and rural areas. To address the possible loss to follow-up, sample size was inflated to 735.

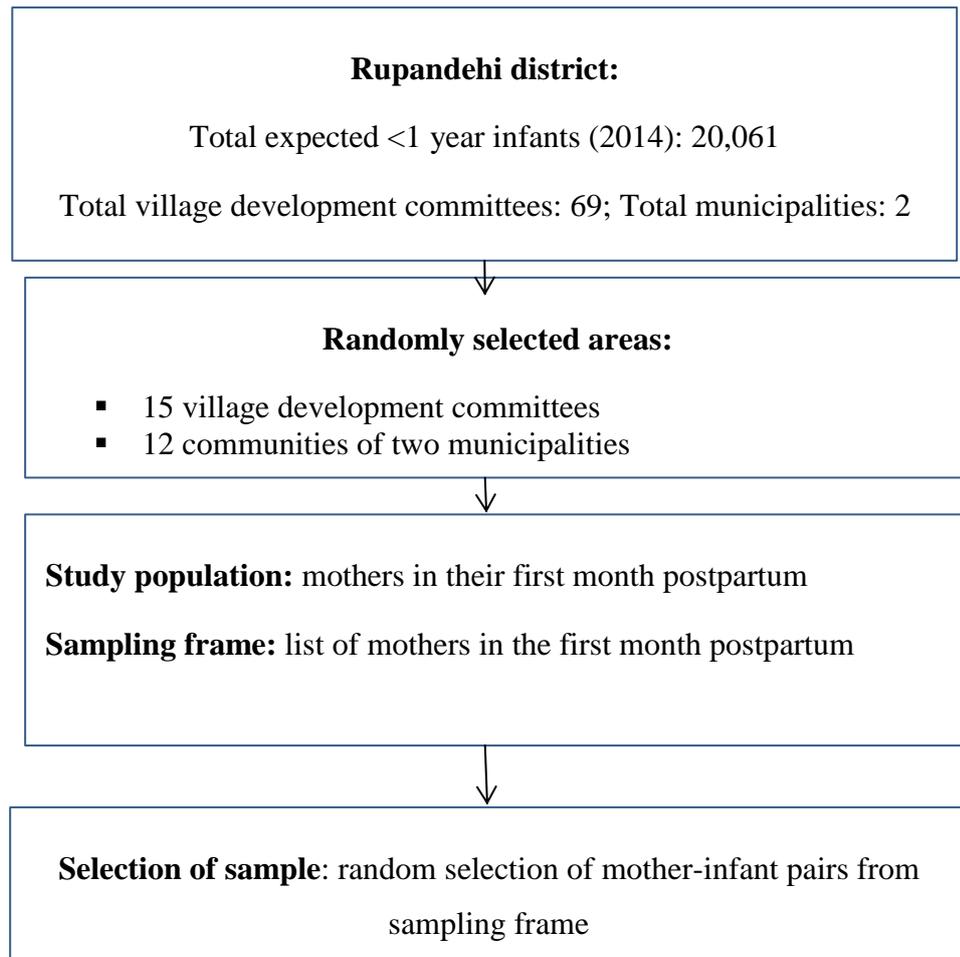
### 3.5 Recruitment

Figure 9 shows the process of recruiting the study sample. Briefly, the total expected district population of infants (< 1 year) was 20,061 in 2014 [Source: District Public Health Office, Rupandehi, Annual Target 2013/2014]. Mother-infant pairs were recruited from randomly selected communities: 15 rural and 12 urban. The source of list for eligible respondents was prepared by enumerators in the selected areas with the help of local female community volunteers and health facilities. The health facilities maintain the records of mothers who give childbirth in these facilities. In part, the maintenance of such records enables mothers to be reimbursed for travel costs via the maternity incentive scheme (known as *Aama* programme). This list was then complemented by the list of local female community health volunteers who are often the gatekeepers of local health services and have knowledge of the recent births in their communities. Including the list from these volunteers assisted the listing of all the home-based childbirths in the community. The female community volunteers are supported by the Ministry of Health and Population to provide health education and iron and vitamin A supplementation in rural communities. They also treat childhood pneumonia and diarrhoea after their training on integrated management of childhood illness (Department of Health Services & Ministry of Health and Population, 2013). Each volunteer serves up to 250 households in their community.

The process for recruiting the study sample is illustrated in the study flow chart (Figure 9). Briefly, the total expected district population of infants (< 1 year) was 20,061 in 2014 [Source: District Public Health Office, Rupandehi, Annual Target 2013/2014]. Mother-infant pairs were recruited from a total of 15 rural and 12 urban, randomly selected communities. The number of mother-infant pairs recruited from each community was proportionate to the population size based on the monthly target of expected numbers of infants aged <30 days. This number was calculated from the annual targets of infants based on the record of the District Public Health Office, Rupandehi [Source: District Public Health Office, Rupandehi, Annual Target 2013/2014].

Mother-infant pairs were included if they met inclusion criteria of: the age of the infant was <30 days, mothers were residents of the community, single birth and the

child was alive at the time of recruitment. Participants were recruited as early as possible after the childbirth but in Nepal, it is a common cultural practice to isolate the mother-newborn pairs after childbirth, and for this reason, recruitment may be delayed by up to four weeks (Karkee, 2013). Mother-infant pairs were excluded if: twin birth, if mothers were not the local residents and if mothers were not able to respond for medical condition.



**Figure 9 Recruitment process of participants**

The participants were followed- up during the fourth (90-120 days) and sixth months (150-180 days) in their own home (Figure 10). Date of follow-up negotiated between mothers and enumerators so that mothers were available to respond. Enumerator collected information based on interview questionnaire.

### **3.6 Instruments for data collection**

The standardised structured questionnaires that were used for data collection had been used in previous studies: a maternal health study in Nepal (Karkee et al., 2013a); Nepal Demographic and Health Survey 2011 (Ministry of Health and Population (MOHP) [Nepal] et al., 2012); mastitis study in China (Tang, Lee, et al., 2013), and a mastitis study in Glasgow (Scott et al., 2008). Most of the questionnaire was adapted from the Nepali version of a former cohort study conducted in Nepal by researchers of the School of Public Health, Curtin University that was adapted from the Nepal Demographic and Health Survey (Karkee et al., 2014a). The additional section of the questionnaire on lactation mastitis was translated into Nepali and then back translated to English to ensure there was no variation in the intended meaning due to translation. The questionnaires were pre-tested using interviews with 30 women to ensure cultural appropriateness, and content validity of the questions; some words were replaced with equivalent local terms, but no significant change was necessary.

#### **Part 1: Interview (first month)**

Background information included socioeconomic details such as age, education, occupation, religion. Breastfeeding information included initiation of breastfeeding, continuation of breastfeeding, prelacteal feeding, and colostrum feeding. Pregnancy and childbirth information included birth weight, use of antenatal care, and breastfeeding promotion information during antenatal care, maternal illnesses and place of birth.

#### **Part 2: Interview 2 (fourth month)**

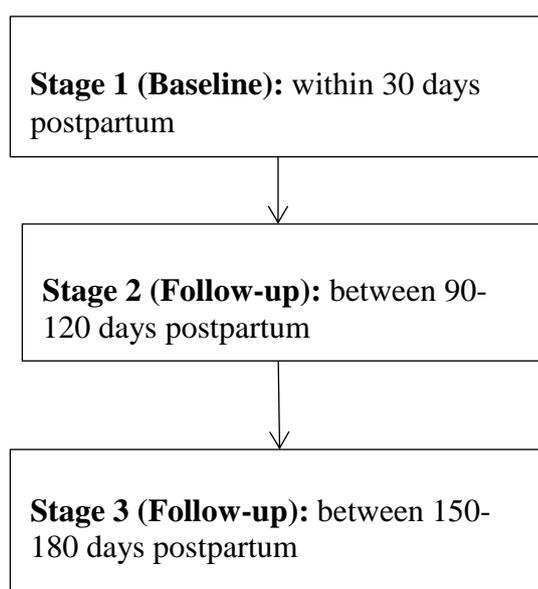
Breastfeeding information included continuation of breastfeeding, the introduction of complementary foods, problems during breastfeeding, and mastitis. Other questions were on postnatal care and information during the postnatal period, problems during the postnatal period, and newborn care.

### Part 3: Interview 3 (sixth month)

Follow up breastfeeding information included continuation of breastfeeding, introduction of complementary food, mother's perceived support from partner, infant feeding information about: the types of complementary food provided to an infant, and the time of introduction of complementary foods.

### 3.7 Data collection

Data were collected using the enumerator administered interviews. Figure 10 describes the data collection process. Mothers were recruited during the first month postpartum and completed the baseline interview; the follow-up interviews were conducted during four months and six months, and were conducted by female enumerators who had vocational training in health science after high school level of education. These enumerators received a one-day orientation on data collection including a data collection exercise in the community and the researcher provided feedback after the pretesting. The enumerators were regularly monitored to ensure the quality of data. During the follow-up interviews, enumerators again received a brief orientation as most of the questions on infant feeding were repeated. The interviews were conducted in the Nepali language.



**Figure 10 Interview flow chart**

### **3.8 Data editing and cleaning**

The completed questionnaires were checked regularly by the researcher and feedback was provided via one-to-one meetings, and telephone. If there was any error in form filling, and it was within the data collection period, enumerators collected data again to correct the error. The questionnaires were collected from the data collectors every 15 days so that errors and missing values could be rectified as early as possible. If it was not possible to recollect the data after errors had been found, it was not included in the analyses. For instance, information on lactation mastitis was also collected in the second interview. It was not included in analysis and reporting because of a number of inconsistencies in the data collection. Once checking was done, the data were entered in the Statistical Package for Social Science (SPSS) by the researcher to minimise errors and check the correctness of data collection.

### **3.9 Data analysis**

All analyses were conducted in SPSS unless otherwise stated. Prevalence of the introduction of prelacteal feeds, any breastfeeding, exclusive breastfeeding, and problems during breastfeeding were reported as proportions at specific time points (objectives 1, 2, 3, and 8). The rate of exclusive breastfeeding was reported during one, four and six months to reflect the change in exclusive breastfeeding pattern with increasing age of infants using survival analysis life table (objectives 1, and 4). For the outcomes reported in this thesis, data analyses were performed according to the outcome variables as below (details are also published in related peer-reviewed publications):

#### **3.9.1 Early initiation**

The associations between early initiation and independent variables were first tested using the Chi-square test. Multiple logistic regression was used to investigate the factors independently associated with early initiation of breastfeeding. All variables were entered in the initial model and the backward stepwise regression method was used to ascertain significant factors (objective 5).

### **3.9.2 Prelacteal feeding**

Factors affecting prelacteal feeding were first assessed using Chi-square tests before entering into a multivariable logistic regression model. The backward stepwise method was adopted in view of the possible collinearity between the socioeconomic variables (objective 6).

### **3.9.3 Postpartum breastfeeding promotion and exclusive breastfeeding**

The median duration of exclusive breastfeeding was estimated using the Kaplan-Meier method (objective 4). In addition to reporting the rate of exclusive breastfeeding during the sixth month using the 'recall since birth' method, associations between exclusive breastfeeding and independent variables were initially assessed via univariate statistics and then confirmed using a multivariable Cox regression model. The backward stepwise method was adopted to account for potential collinearity between variables (objective 7).

### **3.9.4 Mastitis**

Factors associated with mastitis were screened using the Chi-square test and those factors significantly associated with the incidence of mastitis were further investigated using multivariable logistic regression adjusting for the duration of exposure (days since childbirth) using the 'off-set' term in Stata 14. This was deemed necessary to adjust for the unequal duration of exposure since childbirth to recruitment among the participants. The stepwise backward elimination method was performed in the logistic regression (objective: 9).

The association between mastitis and exclusive and predominant breastfeeding at four and six month was determined using multivariable logistic regression after adjusting for other independent variables (maternal education, maternal age, place of residence, mode of delivery, birth weight, time of initiation of breastfeeding, place of delivery) investigated in the study (objective: 10). The duration of exclusive breastfeeding was examined using the Kaplan-Meier method. Statistical analyses were performed using the Stata 14 and Statistical Package for Social Sciences, Version 20 (IBM Corporation).

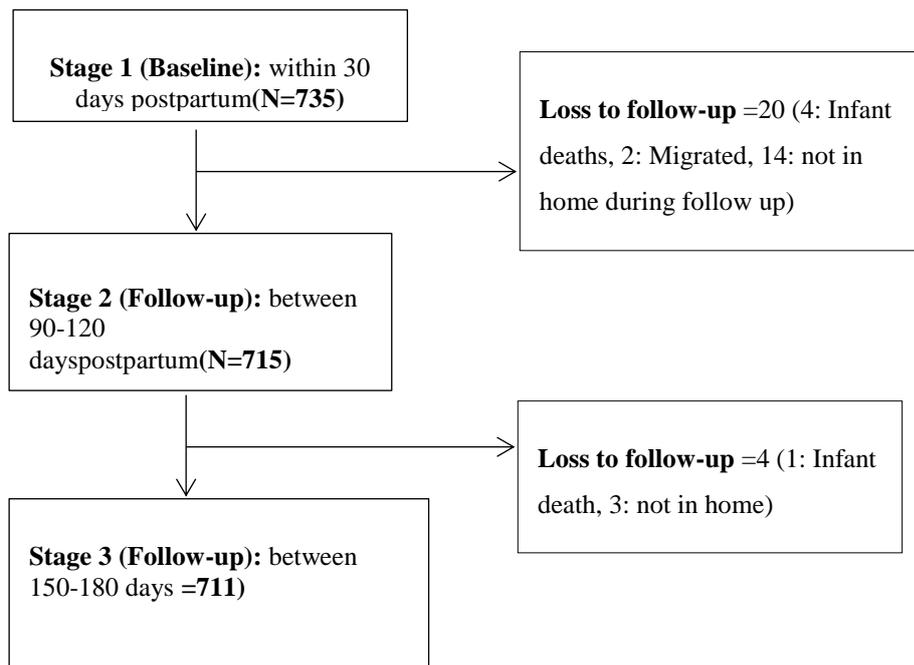
### **3.10 Ethical considerations**

This research project obtained approval from the Curtin University Human Research Ethics Committee, (approval number: HR 184/2013), and the Nepal Health Research Council (approval number: 773/2014) (see Appendices 5 and 6). All participants were read an information sheet in Nepali, which included the aim of the study and their right to participate or not to participate, and to withdraw at any point of during the study (see Appendix 7). The enumerators asked if the participants wanted more information and provided the information on the participant's request. The participants were informed that there would not be any effect on the treatment for the mother, father and the child if they choose not to participate or withdraw from the study. Only those mothers who provided consent for herself and her child were involved in the study. The consent form was signed (or thumb printed or verbal consent given as the last resort) if the participant was willing to participate. The interview was conducted in the home of the participant, preferably alone. It was up to the participant if she or he wanted the presence of a partner or next of kin during the interview. The database was password protected according to Curtin University's policy and is stored at Curtin University. While in Nepal, the questionnaires were stored in a secure locker at the Public Health Office, Rupandehi. Data will be destroyed after seven years according to the Curtin University data safety and security policy. The personal identifiers such as name, family name, addresses were removed before data analysis and not reported.

## CHAPTER 4 RESULTS

### 4.1 Response rate

A total of 735 mother-infant pairs were recruited with a response rate of 97.6% after 18 (2.4%) mothers declined to participate in urban areas due to possible migration(Figure 11). The sample size represents approximately 22% of the total childbirths occurring in the district during the recruitment period. In the second interview during the fourth month postpartum, 20 mothers could not be included because of infant deaths (4), family migration (2) and absence at home during follow-up (14) leaving a sample size of 715. In the third interview during sixth months, a further four mothers were excluded: one infant died and three mothers were not at home during follow-up. The final sample size was 711 giving a completion rate of 96.73%.



**Figure 11 Baseline and loss to follow-up**

### 4.2 Characteristics of participants

Mothers were in the age range 16 to 45 years (mean 24.6, standard deviation: 4.6 years). The age of infants that were included in the study were 1 to 29 days (mean

17.39, standard deviation: 9.13 days) when enrolled. A small portion of mothers was in the adolescent age group (15-19 years; 9.0%). About a quarter (26.1%) had no formal education; with only 22.9% of them having grade 12 or a post-secondary qualification. A total of 378 (51.4%) were from rural areas, and 357 (48.6%) were from urban areas. Only a small proportion of mothers (4.1%) was employed in a salaried job and the proportion was slightly higher for their partners (13.9%). Three-quarters (76.3%) of mothers were involved in household and unpaid agricultural occupations.

Slightly more than three quarters (76.2%) of mothers had reported having four or more antenatal care visits, and a few (2.3%) did not have any visit at all. The majority of childbirths (88.2%) occurred in health facilities, and 88.3% of childbirths were assisted by skilled birth attendants. A small proportion (14.1%) of mothers had their childbirth by caesarean section. Four in 10 (42.8%) mothers were first time mothers, and 14.2% had low birth weight (<2500 g) infants. The relevant details according to the outcome variables of interest are presented in published papers and are included in this thesis. A description of characteristics is also published as the first paper from this project (see published paper 1).

### **4.3 Early initiation and prelacteal feeding**

All of the mothers reported having initiated breastfeeding. Of the 735 mother-infant pairs, 310 (42.2%) reported early initiation (within one hour of birth); followed by breastfeeding initiation after 1- 6hours (39.5%), after 6-24hours (9.8%), after 24hours-3 days (5.3%), more than three days (1.8%), or could not recall the time (1.3%). Factors associated with early initiation are published as paper 1.

Early supplementation with prelacteal feeds is another major practice that affects breastfeeding in Nepal. A total of 225 (30.6%) of mothers reported providing prelacteal feeds to their infants. Types of prelacteal feeds varied with formula feeding being the most prevalent type (94, 41.7%); the others were cow or buffalo milk (60, 26.6%), sugar/glucose water (28, 12.4%), plain water (23, 10.2%), honey (19, 8.4%), ghee or refined butter (9, 4.0%), fruit juice (7, 3.1%), ghee and honey mix (5, 2.2%), and sugar-salt solution (4, 1.7%).The prevalence of prelacteal feeding

by maternal characteristics and the factors associated with prelacteal feeding are published as paper 2. Formula feeding appeared as one of the leading prelacteal feeds in these settings. A peer reviewed article highlighting the magnitude of infant formula use is published (see appendix: 4).

#### **4.4 Any and exclusive breastfeeding at one, four and six months**

All of the mothers were breastfeeding during recruitment. A total of 99.7% (n=715) mothers were breastfeeding during the fourth month, and 99.3% (n=711) were doing so during the sixth month showing universal breastfeeding practice in the setting.

Rates of predominant breastfeeding changed according to infant's age. The predominant breastfeeding rates was higher during the first month 88.6% (95% CI: 88.3, 90.9; N=735) and dropped to 78.2% (95% CI: 75.1, 81.2; n=715) during fourth months and 26.3% (95% CI: 23.1, 29.5; n=711) during sixth months.

The median duration of exclusive breastfeeding was 97.0 days (95% confidence interval (CI): 93.1 to 100.9 days). Table 4 shows the rapid decline of the rates of exclusive breastfeeding from 66.3% during the first month to 8.9% during the sixth month. The table also shows the comparison of breastfeeding prevalence measured using 24 hour recall of exclusive breastfeeding and rates of exclusive breastfeeding using recall-since-birth methods. The difference was statistically significant in each time frame. A manuscript related to difference in the reported rates of breastfeeding in Nepal based on recall-since-birth and 24 hour recall is under review, and a poster was presented at the third international conference on nutrition and growth (see appendices: 3 and 10 ).

**Table 4 Prevalence of exclusive breastfeeding from a cohort study using two measurement indicators, Nepal, 2014**

Infant's age	Exclusive breastfeeding rates	
	24-hour recall (Prevalence; 95 % CI)	Recall-since-birth (Rate; 95 % CI)
1 <sup>st</sup> month (N=735)	617 (83.9%; 81.3, 86.6)*	487 (66.3%; 62.8, 69.7)*
4 <sup>th</sup> month (n=715)	437 (61.1%; 57.5, 64.7)**	280 (39.2%; 35.6, 42.7)**
6 <sup>th</sup> Month (n=711)	133 (18.7%; 15.8, 21.6)***	63 (8.9%; 6.8, 11.1)***

CI: Confidence Interval; \*, \*\*, \*\*\*:statistically significant at  $p < 0.05$ .

Published paper 3 presents the association of postpartum breastfeeding promotion with exclusive breastfeeding among 649 mothers who were assisted by skilled birth attendants during their childbirth. Eight breastfeeding promotion activities were investigated. Specifically, the types of advice received were: 90.3% on initiation of breastfeeding within one hour of birth, 80.9% on exclusive breastfeeding for six months, 79.5% on breastfeeding on demand, 66.4% on not to provide other food or drinks, 62.7% on where to go when breastfeeding support was needed, and 48.4% on not to give pacifier or teats. Furthermore, 84.1% mothers were kept with their infants, and 70.4% percent were taught breastfeeding skills. Overall, 35% received all eight types of advice. Further, these variables were subsequently recoded into: 'high intensity' (6-8 messages), and 'low to medium intensity' (0-5 messages) to facilitate analysis. A total of 383 (59.0%) reported receiving 'high intensity' breastfeeding promotion messages while the others reported 'low to medium intensity'.

Among the 649 mothers who received birth supervision by skilled attendants, the median duration was 100.0 days (95% CI: 95.5 to 104.5 days). The median duration of exclusive breastfeeding among mothers who received 'high intensity' breastfeeding promotion message (median: 108.0, 95% CI: 100.8 to 115.2 days) was significantly higher (log-rank test,  $p$ -value= 0.017) than those receiving 'low to medium intensity' support (median: 94.0; 95% CI: 90.1 to 97.9 days).Paper 3 reports

an association between postpartum breastfeeding promotion and significantly higher exclusive breastfeeding practices. There was a dose-response relationship between the number of these messages or support provided and cessation of exclusive breastfeeding (HR: 0.94; 95% CI: 0.90, 0.97).

#### **4.5 Mastitis and its management**

A total of 27 mothers (8.0%; 95% confidence interval: 5.1, 10.8) reported having at least one episode of mastitis within the neonatal period (0 to 29 days). In addition, 9.8% reported cracked nipples and 8.9% reported breast abscess. Mastitis did not appear to be associated with a lower likelihood of exclusive and predominant breastfeeding at fourth months. Further details on the factors associated with mastitis and association of breastfeeding practices with the occurrence of mastitis are presented in paper 4.

#### **4.6 Published papers**

The followings are the published papers according to the outcome variables.

**Paper -1:** Factors associated with early initiation of breastfeeding in Western Nepal (Khanal, Scott, Lee, Karkee, & Binns, 2015)

**Paper -2:** Prevalence and factors associated with prelacteal feeding in Western Nepal (Khanal, Lee, Karkee, & Binns, 2015b)

**Paper -3:** Postpartum breastfeeding promotion and duration of exclusive breastfeeding Western Nepal (Khanal, Lee, Karkee, & Binns, 2015a)

**Paper -4:** Incidence of mastitis in the neonatal period in a traditional breastfeeding society: Results of a cohort study (Khanal, Scott, Lee, & Binns, 2015)

Due to copy right requirements, the accepted final version of papers are included in the next section, and a link to full text is also provided for each paper

#### **4.6.1 Paper -1: Factors associated with early initiation of breastfeeding in Western Nepal**

Link to full text: <http://www.mdpi.com/1660-4601/12/8/9562/htm>

**Journal:** International Journal of Environmental Research and Public Health

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**Abstract:**

The initiation of breastfeeding within one hour of birth has numerous nutritional and immunological benefits and been found to reduce neonatal mortality. This study aimed to report the rate of, and factors associated with, early initiation of breastfeeding in Western Nepal. A community-based prospective cohort study was conducted in Western Nepal. The rate of early initiation of breastfeeding was reported, and associations between early initiation and independent variables were tested by Chi-square test, followed by multiple logistic regression. Of the 735 mother-infant pairs, a total of 310 (42.2%) reported early initiation. Mothers who were assisted by traditional attendants during childbirth, delivered by caesarean section, from ethnically disadvantaged families and had delivered low birth weight infants, were less likely to initiate breastfeeding early whereas the mothers who were from the poorest families and did not introduce prelacteal feeds to their infants had higher likelihood. Skills-training to support breastfeeding as part of the training of skilled birth attendants and other health workers is likely to promote recommended infant feeding practices.

**Keywords:** Breastfeeding; Cohort study; Early initiation; Nepal; Initiation of breastfeeding

**1. Introduction**

Global commitment to Millennium Development Goals has brought significant progress in child survival with an average of 3.4% annual rate of reduction globally in child mortality (1-59 months) since 1990 [1]. The progress in the reduction of neonatal mortality; however, was much slower globally (2.0% annual rate since 1990) [1]. Recent estimates show that a total of 71% of neonatal mortality could be prevented using existing antenatal, intra-partum and postnatal interventions [1]. Immediate care of the newborn which includes the nutrition of neonates (early initiation within 1 hour of birth and exclusive breastfeeding), is a major area of intervention for newborn survival during the perinatal period [1]. A recent meta-analysis [2] reported that the initiation of breastfeeding in less than 24 hours of birth

was significantly associated with reduction in ‘all-cause neonatal mortality’, ‘low birth weight related neonatal mortality’ and ‘infection related neonatal mortality’ among all live births. A number of potential mechanisms for the observed reduction in mortality have been suggested [2,3] and include the early stimulation of the immune system through exposure to the high levels of immunoglobulins and lymphocytes found in colostrum, along with the displacement of prelacteal feeds which may be vehicles for infectious pathogens and also disrupt normal gut microbiome, resulting in increased permeability to infectious pathogens. Furthermore, early initiation of breastfeeding is recommended as one of several steps that should be taken to prevent hypothermia in the newborn [4].

Besides reducing neonatal mortality, early initiation of breastfeeding has benefits for the mother as early suckling stimulus is linked with secretion of oxytocin which reduces the risk of postpartum haemorrhage in the mother [5]. Despite these recognised benefits of early initiation of breastfeeding, the rates in South Asia are well below universality, ranging for example from 45% [6] to 72.7% in Nepal [7], 36.4% in India [8], and 83.3% in Sri Lanka [9].

In Nepal, there has been significant progress in the reduction of the child mortality rate (162 per 1,000 live births in 1990 to 54 in 2011) and infant mortality rate (108 per 1,000 live births in 1990 to 46 in 2011) [10]. While the neonatal mortality rate decreased significantly between 2001 and 2006 from 43 to 33 per 1,000 live births, it remained unchanged between 2006 and 2011 [10], and the current burden of neonatal mortality is well above Nepal’s target of reducing the neonatal mortality rate to 15 per 1,000 live births by 2017 [11]. While, the universal adoption of early initiation of breastfeeding is likely to have a positive impact on newborn survival [12], the rates of early initiation of breastfeeding were 35 % and 45 % in 2006 and 2011, respectively [6].

To date, few studies have reported factors associated with the early initiation of breastfeeding in Nepal [7,13]. The most recent study showed that mothers with higher education, involved in agricultural occupations, and delivering in health facilities were more likely to initiate breastfeeding within the first hour of birth [13].

This study; however, was based on a long recall period of up to three years indicating likelihood of recall bias.

Nepal is diverse in its population composition, and culture with more than 100 caste groups [14]. The people in the upper Himalayan region resemble the Tibetan culture whereas people in the Southern plain are culturally similar to those from India. With this heterogeneity in population and culture, infant feeding practices may vary significantly in the Western plain compared to those reported in earlier studies in central Nepal [15] or based on the 2011 Nepal Demographic and Health Survey [13] which did not include a sample from this study setting. Furthermore, appropriate infant feeding is the one of the major priorities of child health programs in Nepal [16,17]; hence continuous monitoring of infant feeding practices is necessary to inform these programs. The objective of this study was to report the incidence of, and factors associated, with early initiation of breastfeeding in Western Nepal.

## **2. Experimental Section**

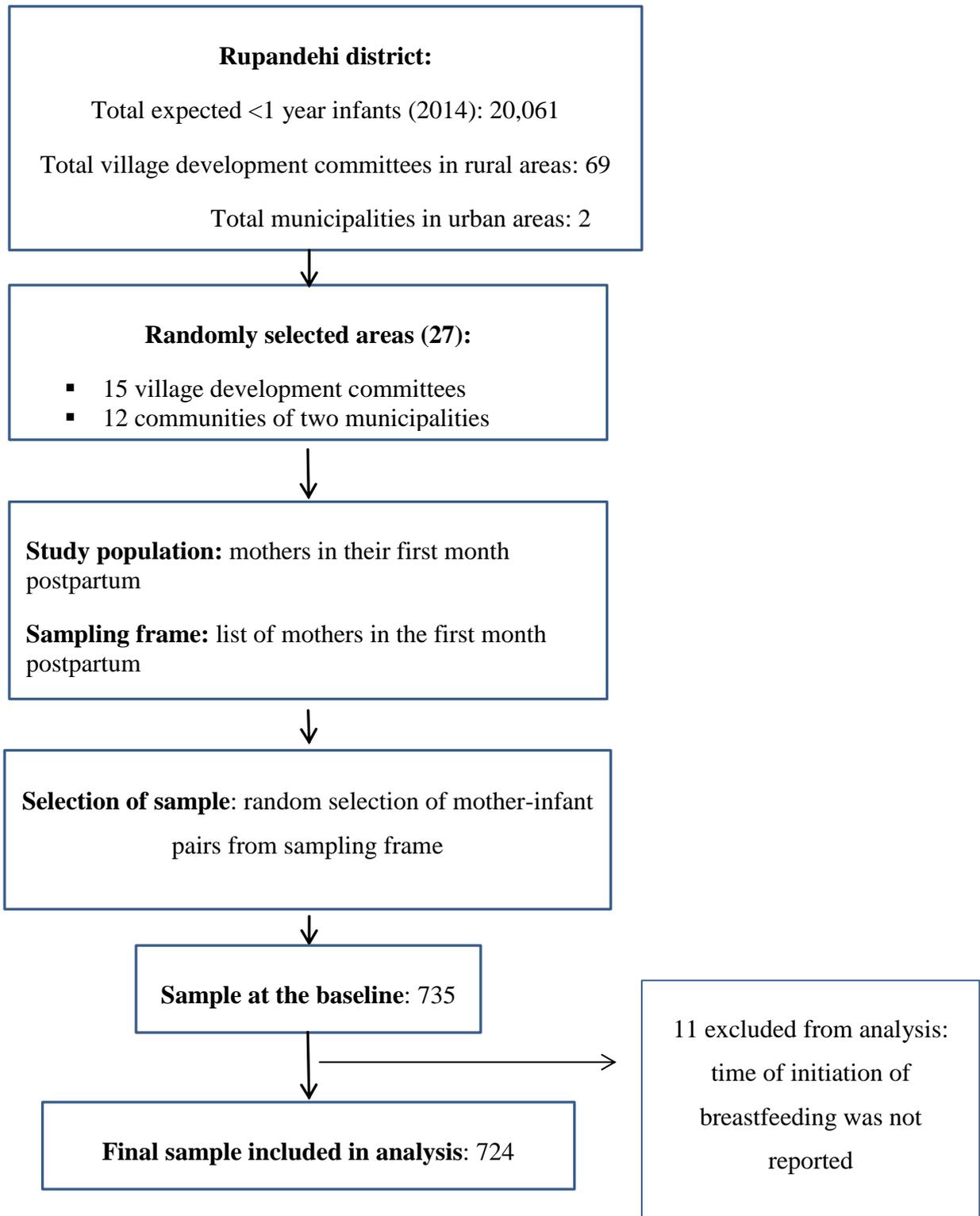
A community-based cohort study was conducted in the Rupandehi district of Nepal during January-October, 2014. The Rupandehi district is located in the Western plain area of Nepal bordering India to the South. This district has 69 village development committees in rural areas and 2 municipalities in urban areas. The village development committee and municipalities are the lowest administrative units with locally elected representatives in Nepal. The district has hospitals in the urban areas that serve as referral hospitals, and rural health facilities (primary health care centres, health posts or sub-health posts) in rural areas. Due to its plain terrain, available local area health services are relatively accessible. Nevertheless, the district had a relatively high maternal mortality rate of 274 per 100,000 live births compared to the national average of 229 per 100,000 live births for 2008/9 [18].

The process for recruiting the study sample is illustrated in the study flow chart (Figure 1). Briefly, the total expected district population of infants (< 1 year) was 20,061 in 2014 [Source: District Public Health Office, Rupandehi, Annual Target 2013/2014]. Mother-infant pairs were recruited from a total of 15 rural and 12 urban, randomly selected communities. Lists of eligible mothers were prepared in the selected areas with the help of local female community volunteers, and health

facilities. The required numbers of mothers were selected randomly from the lists. The number of mother-infant pairs recruited from each community was proportionate to population size based on the monthly target of expected numbers of infants aged <30 days. This number was calculated from the annual targets of infants based on the record of the District Public Health Office, Rupandehi [Source: District Public Health Office, Rupandehi, Annual Target 2013/2014]. Mother-infant pairs were included if: age of the child was <30 days, mothers were residents of the community, and the child was alive at the time of recruitment.

Trained, experienced female enumerators used standardised questionnaires to collect data using interviews in the participant's home. We adapted the Nepali version of the questionnaire that was used in the Kaski district of Nepal [15] and which was based on questionnaires previously used in similarly designed studies of Australian women [19,20]. These questionnaires have been translated subsequently into a variety of languages for use in studies of women in Vietnam [21], China, [22,23], the Maldives [24], as well as Nepal [15]. Although the questionnaire used in the Kaski district [15] was in Nepali language which is the language spoken in our study setting, the questionnaires were pre-tested using interview with 30 women. Some words were replaced with equivalent local terms; however, no significant change was necessary. Baseline information and infant feeding practices were collected in the first interview.

**Figure 1. Study flow chart**



The outcome variable for this study was ‘early initiation of breastfeeding’ which was defined as ‘initiation of breastfeeding within the first hour of childbirth’ based on the definition provided by the World Health Organization [25]. The variable related to the timing of breastfeeding initiation was recoded as a binary variable: ‘early initiation’ when the newborn infant was breastfed within the first hour of birth; and ‘delayed initiation’ when breastfed after one hour.

Independent variables in this study were those suggested by the literature to be associated with the early initiation of breastfeeding. We categorised ‘assistance during delivery’ as: ‘skilled attendance’ (doctor, health assistant, nurses, auxiliary nurse midwife, auxiliary health workers, maternal and child health workers) and ‘unskilled/traditional attendance’ (village health workers, female community health volunteer, traditional birth attendants, mother-in-law, other family members, relatives, friends, neighbours). Prelacteal feeds were defined as any fluids or foods that were provided before the introduction of first breastfeeding, the response was recorded as ‘yes’ or ‘no’. Birth weight’ was categorised as: ‘low birth weight’ (<2500 grams), and ‘average or greater’ ( $\geq$ 2500 grams or more). We categorised ‘maternal age’ (years) as: 15-19, 20-29, and 30-45; ‘maternal education’ as: ‘no education’, ‘primary/lower secondary’ (up to grade 8), ‘secondary’ (grade 9-10) and ‘higher’ (grade 11-12 and university degree); ‘maternal occupation’ as: ‘employed’ (salaried jobs), ‘semi-employed’ (labour and daily wage jobs), and ‘unemployed’ (household work and subsistence agriculture work); ‘antenatal care visits’ as: ‘no antenatal visit’, ‘1-3 visits’, and ‘4 or more visits’; and mode of delivery as: ‘vaginal’, and ‘caesarean’ Nepal has a unique hierarchical caste-based system which is used by the government of Nepal to classify ‘ethnicity’ [26,27]. We used this system to re-categorise the ethnic groups based on their caste similarities into: ‘advantaged caste groups’ (Brahmin, Chhetri, Newar, Gurung, Jogi, Thakuri), ‘middle caste groups’ (Janjati, non-Janjati and Muslim), and ‘Dalit caste’ (Dalit). ‘Wealth quintiles’ were derived from the scores of principal component analysis of household assets (water source, toilet facility, types of cooking fuel, separate kitchen, floor material, electricity, radio, television, mobile phones and cupboard). The score was further divided into five quintiles as poorest (first quintile), poor (second

quintile), middle (third quintile), rich (fourth quintile) and richest (fifth quintile) [6,28,29].

## **2.1 Statistical analyses**

The rate of early initiation was reported using frequency distribution. The associations between early initiation and independent variables were first tested using the Chi-square test. Multiple logistic regression was used to investigate the factors independently associated with early initiation of breastfeeding. All variables were entered in the initial model and the backward stepwise regression method was used to ascertain significant factors. Analysis was performed using Statistical Package for Social Science Version 20 (IBM Corp. Armonk, NY, USA).

## **2.2 Ethical considerations**

The study protocol was approved by the Nepal Health Research Council (773/2014), and the Human Research and Ethics Committee at Curtin University (HR184/2013). Informed consent was obtained before enrolment. Mothers provided consent for themselves and their infants.

## **3. Results**

A total of 735 mother-infant pairs were recruited with a response rate of 97.6% after 18 (2.4%) mothers declined to participate in urban areas due to possible migration. This represents approximately 22% of the total childbirths occurring in the district during the recruitment period. Characteristics of the 724 participants, who could recall the time of first breastfeeding, are presented in Table 1. Briefly, the median age of mothers was 24.0 years and about one in five had higher education (22.9%). The majority of mothers had their childbirth attended by skilled birth attendants (88.1%), and had a vaginal delivery (86.0%). A total of 96 (14.0%) of newborn infants were born low birth weight.

Of the 735 mother-infant pairs, a total of 310 (42.2%) reported early initiation; followed by breastfeeding initiation after 1h - 6h (39.5%), after 6h-24h (9.8%), after

24h-3 days (5.3%), more than three days (1.8%), or could not recall the time (n=11, 1.3%). Of the 724 included in this analysis, the majority (92.4%) of mothers provided colostrum to their newborn infants; however, nearly one third (30.2%) were provided with prelacteal feeds that included plain water, animal milk, glucose water, honey, ghee, salt water and/or fruit juice. Of the 55 mothers who reported discarding colostrum, the major reasons were: colostrum is difficult to digest (n=23, 41.8%), not clean (n=20, 36.3%), harmful to baby (n=2, 3.6%), and does not look nice (n=3, 5.45%).

### **Factors associated with early initiation of breastfeeding**

The result of the stepwise multivariable logistic regression (Table 2) showed that having traditional attendants at birth were significantly associated with lower likelihood of early initiation of breastfeeding (adjusted odds ratio (aOR): 0.47, 95% confidence interval (CI): 0.22 to 0.99). Infants who were born by caesarean section (aOR: 0.39; 95% CI: 0.239 to 0.67), born to middle caste group (aOR: 0.62; 95% CI: 0.40 to 0.95) and Dalit caste group (aOR: 0.52; 95% CI: 0.28 to 0.94) were less likely to be breastfed within the first hour of their life. In addition, the infants who were born low birth weight (aOR: 0.36; 95% CI: 0.21 to 0.63) and born to mothers of older age i.e. 30-45 years (aOR: 0.45, 95% CI: 0.22 to 0.93) were less likely to be breastfed within one hour of birth. Infants born to the poorest families (aOR: 2.43; 95% CI: 1.36 to 4.37) were more likely to be breastfed within one hour of childbirth. Infants who were not provided prelacteal feeds had higher likelihood of breastfeeding initiation within one hour of birth (aOR: 2.00; 95% CI: 1.35 to 2.98).

**Table 1. Characteristics of participants according to time to first breastfeed in Western Nepal**

Factor	Time to first breastfeed			P value*
	Frequency n (%)	Delayed n(%)	Early n(%)	
<b>Maternal age (in years)<sup>#</sup> (n=723)</b>				0.003
15-19	64 (8.8)	30 (46.9)	34 (53.1)	
20-29	542 (75.0)	301 (55.5)	241 (44.5)	
30-45	117 (16.2)	82 (70.1)	35 (29.9)	
<b>Maternal education (n=724)</b>				0.208
No education	190 (26.2)	119 (62.6)	71 (37.4)	
Primary/Lower secondary	240 (33.2)	129 (53.8)	111 (46.2)	
Secondary	128 (17.7)	68 (53.1)	60 (46.9)	
Higher	166 (22.9)	98 (59.0)	68 (41.0)	
<b>Maternal occupation (n=724)</b>				0.001
Employed	30 (4.2)	17 (56.7)	13 (43.3)	
Semi-employed	140 (19.3)	99 (70.7)	41 (29.3)	
Unemployed	554 (76.5)	298 (53.8)	256 (46.2)	
<b>Antenatal care visits<sup>#</sup> (n=721)</b>				0.669
No antenatal visit	17 (2.4)	11 (64.7)	6 (35.3)	
1-3 visits	155 (21.5)	92 (59.4)	63 (40.6)	
4 or more visits	549 (76.1)	310 (56.5)	239 (43.5)	
<b>Assistance during delivery(n=724)</b>				0.069

Unskilled/Traditional attendants	86 (11.9)	57 (66.3)	29 (33.7)	
Skilled attendants	638 (88.1)	357 (56.0)	281 (44.0)	
<b>Mode of delivery (n=724)</b>				<0.001
Vaginal	623 (86.0)	338 (54.3)	285 (45.7)	
Caesarean	101 (14.0)	76 (75.2)	25 (24.8)	
<b>Ethnicity(n=724)</b>				0.481
Advantaged caste group	270 (37.3)	149 (55.2)	121 (44.8)	
Middle caste groups	366 (50.6)	210 (57.4)	156 (42.6)	
Dalit caste	88 (12.2)	55 (62.5)	33 (37.5)	
<b>Wealth quintile (n=724)</b>				<0.001
1-Poorest	146 (20.2)	61 (41.8)	85 (58.2)	
2-Poor	146 (20.2)	84 (57.5)	62 (42.5)	
3-Middle	145 (20.1)	85 (58.6)	60 (41.4)	
4-Rich	146 (20.2)	98 (67.1)	48 (32.9)	
5-Richest	141 (19.5)	86 (61.0)	55 (39.0)	
<b>Sex of infant (n=724)</b>				0.520
Male	379 (52.3)	221 (58.3)	158 (41.7)	
Female	345 (47.7)	193 (55.9)	152 (44.1)	
<b>Birth order<sup>#</sup> (n=723)</b>				0.062
First	307 (42.5)	170 (55.4)	137 (44.6)	
Second or third	329 (45.5)	184 (55.9)	145 (44.1)	
Fourth or more	87 (12.0)	60 (69.0)	27 (31.0)	
<b>Birth weight<sup>#</sup> (n=668)</b>				<0.001
Low birth weight (<2500 g)	93 (14.0)	72 (77.4)	21 (22.6)	

Average or greater ( $\geq 2500$ g)	573 (86.0)	311 (54.3)	262 (45.7)	
<b>Place of residence (n=724)</b>				0.577
Rural	373 (51.5)	217 (58.2)	156 (41.8)	
Urban	351 (48.5)	197 (56.1)	154 (43.9)	
<b>Prelacteal feeds (n=724)</b>				<0.001
Not provided	505 (69.8)	252 (49.9)	253 (50.1)	
Provided	219 (30.2)	162 (74.0)	57 (26.0)	

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*\*P value: Chi-square test p-value; #the total in each variable varies due to missing responses. Early: initiation of breastfeeding within 1-hour of birth, Delayed: initiation of breastfeeding after one hour of birth.*

**Table 2. Factors associated with early initiation of breastfeeding in Western Nepal**

<b>Factors</b>	<b>Crude odds ratio (95% confidence interval)</b>	<b>p-value</b>	<b>Adjusted odds ratio (95% confidence interval)</b>	<b>p-value</b>
<b>Maternal age (in years)</b>		0.004		0.040
15-19	1.00		1.00	
20-29	0.71 (0.42, 1.19)		0.83 (0.46, 1.50)	
30-45	0.38 (0.20, 0.71)		0.45 (0.22, 0.93)	
<b>Assistance during delivery</b>		0.071		0.048
Unskilled/Traditional attendant	0.65 (0.40, 1.04)		0.47 (0.22, 0.99)	
Skilled attendant	1.00		1.00	
<b>Mode of delivery</b>	P<0.001			0.001
Vaginal	1.00		1.00	
Caesarean	0.39 (0.24, 0.63)		0.39 (0.23, 0.67)	
<b>Ethnicity</b>		0.483		0.038

Advantaged caste group	1.00	1.00	
Middle caste groups	0.91 (0.67, 1.26)	0.62 (0.40, 0.95)	
Dalit caste	0.75 (0.45, 1.21)	0.52 (0.28, 0.94)	
<b>Wealth Quintiles</b>			0.001
1-Poorest	2.18 (1.36, 3.49)	2.43 (1.36, 4.37)	
2-Poor	1.15 (0.72, 1.85)	1.36 (0.77, 2.40)	
3-Middle	1.10 (0.69, 1.77)	1.22 (0.72, 2.06)	
4-Rich	0.77 (0.47, 1.24)	0.69 (0.41, 1.15)	
5-Richest	1.00	1.00	
<b>Birth weight</b>			<0.001
Low birth weight (<2500g)	0.35 (0.21, 0.58)	0.36 (0.21, 0.63)	
Average or greater	1.00	1.00	
<b>Prelacteal feeds</b>			<0.001
Not provided	2.85 (2.01, 4.04)	2.00 (1.35, 2.98)	

Provided

1.00

1.00

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*Variable excluded during backward stepwise regression: maternal education, maternal occupation, antenatal care visits, sex of infant, birth order, place of residence.*

#### 4. Discussion

This study showed that only about four in ten infants were being breastfed within the first hour of birth. The finding is comparable to the recent Nepal Demographic and Health Survey 2011 (45%), but, much lower than that reported for the Kaski district (67%) in central Nepal [15] and higher than that reported by the 2006 Nepal Demographic and Health Survey (35.4%) [29]. Our finding is higher than those reported from neighboring countries Bangladesh (24%) [30], and India (36.4%)[31]. Such variation in the rates of early initiation within Nepal and within the South Asian countries is likely due to differences in the geography, ethnicity, culture and socioeconomic status of populations [13].

A high neonatal mortality rate of 33 per 1,000 live birth is a major bottleneck of child survival in Nepal and neonatal mortality was identified as one of the priority areas of action in the recent Millennium Development Goals country progress report (2013) [10] and the National Safe Motherhood and Newborn Health Long-Term Plan (2006-2017) [11]. Immediate newborn care, including early nutrition interventions such as early initiation and exclusive breastfeeding are some of the proven interventions that reduce neonatal mortality [1]. Debes et al. (2013) have shown that the initiation of breastfeeding within 24 hours of birth can reduce up to 44% of all cause neonatal mortality, and 42% of low birth weight related neonatal mortality. An earlier Nepali study also found that initiation of breastfeeding within 24 hours of birth can prevent about 19.1% of all neonatal deaths [32]. A Ghanaian study further reported an increase in the risk of neonatal mortality with delayed breastfeeding initiation [3] with the highest risks being associated with breastfeeding being initiated after 3 days (aOR:3.64; 95% CI: 1.43, 9.30) compared to those initiated within an hour. Increasing the rate of early initiation of breastfeeding from the current rate of 42.2% to universal practice (near 100%) therefore, is likely to contribute significantly to reducing neonatal mortality in Nepal.

Prelacteal feeding, which in Nepal includes honey, ghee (refined butter), sugar water and animal milk, was associated with delayed initiation of breastfeeding. Just under one third of infants received prelacteal feeds and of these three quarters were not breastfed within the first hour. A similar association between prelacteal feeding and

delayed initiation of breastfeeding was reported also by studies in the southern region of Nepal [33] and India [31]. As this is a cross-sectional analysis, it is not clear whether prelacteal feeding is a cause or consequence of delayed initiation.

The Ministry of Health and Population in Nepal trains health workers to become skilled birth attendants. As part of the curriculum, skilled birth attendants are trained in 'supporting successful breastfeeding' that includes 'education', and 'skill' components on encouraging and supporting mothers to breastfeed as part of immediate newborn care [34]. Our findings showed that being assisted by skilled attendants during childbirth increased the likelihood of a woman initiating breastfeeding within one hour of childbirth, which is consistent with the skilled attendants' training. Previous findings from Nepal [13] and Sri Lanka [9] have also reported that the mothers who had their childbirth in a health facility, attended by health workers, were more likely to initiate breastfeeding within the first hour of birth.

This study found that low birth weight newborn infants were more at risk of delayed breastfeeding. This finding is similar to those from Sri Lanka [35] where low birthweight newborns had less likelihood of being breastfed within the first hour of birth. This could be due to poor suckling capacity or associated illness among the low birth weight infants [8]. A high prevalence of low birth weight is one of the challenges to neonatal survival in Nepal [16]. Indeed, low birth weight infants need immediate breastfeeding [36], which is helpful in reducing hypothermia [16,37] as their bodies are less able to self-regulate body temperature [38]. Low birth weight infants have greater benefits from early initiation of breastfeeding as breast milk protects from necrotising enterocolitis, milk intolerance, and early onset of sepsis among these groups [36]. Therefore, future breastfeeding promotion programs should focus on immediate breastfeeding of low birth infants. In addition, small newborns need support for feeding; therefore, nurses and health workers must receive training in the care and support of low birth weight newborns [38].

Caesarean delivery has been reported to be a major risk factor of lower duration of exclusive breastfeeding, delayed initiation of breastfeeding [8] and increased risk of prelacteal feeding [15]. Our study also found that the infants who were delivered by

caesarean section were also at risk of not being breastfed within the first hour of birth. The effect of anaesthesia, caesarean procedure, maternal tiredness, reduced maternal alertness and inadequate maternal skills to initiate breastfeeding are some of the reasons for delayed breastfeeding among caesarean births [8].

Maternal socio-demographic factors have been reported to be important factors that determine infant feeding behaviour. In our study, two socio-demographic factors were also found to be significantly associated with time of initiation of breastfeeding. Mothers who were from the poorest wealth quintile were most likely to initiate breastfeeding in the first hour of childbirth, similar to those reported from Sri Lanka [35] and is opposite to those from developed countries. Mothers from the poorest socioeconomic group might not have access to infant formula or have less capacity to buy expensive breast milk substitutes such as honey and ghee (refined butter), that could leave breastfeeding as the only choice. On the other hand, the mothers from the richest wealth quintile may have higher caesarean deliveries, leading to delayed initiation of breastfeeding. However, further study is needed to explore more on why the mothers from richest wealth quintile tended to delay initiation of breastfeeding. Nevertheless, our findings suggested that the mothers in the rich and riches quintiles need more focus while implementing breastfeeding promotion programs.

Surprisingly, mothers who identified themselves as marginalised Dalit caste group [39] were more likely to delay initiation of breastfeeding. Nepal has unique caste-based ethnic groups in which the Dalit caste constitutes the lowest rank in the caste hierarchy of Nepali society. While there is no overt government discrimination restricting this caste group's access to health care and other services, members of this caste traditionally have been socially excluded and for example, restricted from entering temples and water sources, resulting in a subordinate social hierarchy and poor health status [27,39]. While there is limited literature on infant feeding practices related to disadvantaged ethnic groups of Nepal, our findings suggest that infants born to these families are vulnerable for delayed initiation of breastfeeding. Further study is necessary to explore the cultural reasons for why the Dalit ethnic group has higher risk of delayed initiation independent of socio-economic status.

This study is one of the few studies that report on early initiation of breastfeeding in the plain areas of Western Nepal. The recall period for this study is short compared

to previously published studies [13,15]; therefore, recall bias is minimal and the measurement of early initiation is more accurate. A limitation of this study is the small number of mothers (n=11) who could not report the time of initiation of breastfeeding; however, this is unlikely to change our result. This study reports only from the South-western plain area of Nepal therefore, the findings may not be generalizable to the entire country due to cultural and ethnic difference in other parts of the country. Nevertheless, the findings of this study are generally consistent with those of studies in other regions in Nepal and countries in the region. Hence the results may be used to inform both local and national infant nutrition programs as the findings provide useful insights into those groups most at risk of delayed breastfeeding initiation, as well as potentially modifiable risk factors for this practice. Further research is warranted to explore why the mothers whose childbirth was assisted by an unskilled birth attendant, and those from middle and Dalit cast groups, were at higher risk of delayed initiation, despite Nepali society being supportive of breastfeeding.

## **5. Conclusions**

This study demonstrates that delayed initiation of breastfeeding continues to be a problem in Nepal as only four in ten newborn infants received breast milk within the first hour of birth. Given the protective association of early breastfeeding and neonatal mortality, promoting early initiation of breastfeeding at a universal level will contribute to significant progress in newborn survival in the post Millennium Development Goal period in Nepal. The results show that receiving assistance from skilled birth attendants during childbirth had a positive impact on early infant feeding practices. The skilled attendance at childbirth is increasing in Nepal; therefore, including lactation support skills as part of the training of skilled birth attendants and other health workers, who provide support during childbirth, is likely to promote recommended infant feeding practices. Those mothers who are from richest quintile, disadvantaged ethnic groups and deliver low birth weight infants should be targeted when implementing breastfeeding promotion programs.

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## **Author Contributions**

VK contributed to study design, literature review, data collection, data analysis and interpretation, and writing the first draft. CB, JS and AL supervised the project, contributed to study design, data interpretation and revised the manuscript. AL and RK contributed in data analysis and interpretation of findings. All authors revised and agreed on the views expressed in the manuscript.

## **Conflicts of Interest**

“The authors declare no conflict of interest”.

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#### **4.6.2 Paper-2: Prevalence and factors associated with prelacteal feeding in Western Nepal**

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**Short title:** Prelacteal feeding in Nepal

**Journal:** Women and Birth

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**Well established**

Prelacteal feeding is a common practice in Nepal. Honey and ghee have been the main traditional prelacteal foods given to Nepalese infants.

**Newly expressed**

Infant formula has emerged as a popular prelacteal food in Nepal. Half of the mothers received advice from their mother/mother-in-law on prelacteal feeding. Women from a wealthy family, with high parity, and those who delivered by caesarean section, tended to give non-breastmilk as the first feed. Newborns with a low birthweight were also at risk of receiving a prelacteal feed.

## **Abstract**

### **Background**

Newborn infants are often given prelacteal feeds in Nepal despite government policies encouraging exclusive breastfeeding for the first six months of life.

### **Aim**

This study investigated the prevalence, reasons, types and factors associated with prelacteal feeding in the south-western region of Nepal.

### **Methods**

Information on prelacteal feeding was obtained from 735 recently delivered women who were recruited for a prospective community-based cohort study conducted during 2014 in the Rupandehi district of Nepal. Factors associated with prelacteal feeding were assessed using logistic regression analysis.

### **Findings**

A total of 225 (30.6%) mothers reported giving prelacteal feeds to their infants. The most popular prelacteal food was formula milk (41.7%), followed by cow or buffalo milk (26.6%), and sugar/glucose water (12.4%). Caesarean delivery (17.3%), cultural preference (16.4%) and being tired after childbirth (10.6%) were the most commonly cited reasons. Almost half (48%) of the mothers were advised by their mother/mother-in-law on prelacteal feeding method. Higher parity (adjusted odds ratio (OR) 2.05; 95% confidence interval (CI) 1.18 to 3.54), low birthweight (OR 1.97; 95% CI 1.23 to 3.16), caesarean delivery (OR 3.70; 95% CI 2.37 to 5.80) and wealthy status (OR 2.49; 95% CI 1.52 to 4.06) were associated with prelacteal feeding.

### **Conclusion**

Nearly one-third of the infants in this study were given prelacteal feeds. Future breastfeeding promotion programs should focus on the mothers with low birthweight infants, of high parity, from a wealthy family and those who had caesarean delivery.

**Key Words:** Breastfeeding, Cohort study, Infant feeding, Nepal, Prelacteal feeds

## Introduction

Prelacteal feeding interferes with the establishment of ‘any breastfeeding’ and a healthy gut microbiome<sup>1</sup>. Prelacteal feeding may also delay the initiation of breastfeeding and reduce the benefits of colostrum. In addition, it has no immunological benefit, contains potentially harmful and contaminated ingredients, and may contain solid or semi-solid food items which cannot be digested by infants<sup>2</sup>. Prelacteal feeds include any food items, primarily liquid other than breastmilk, that are provided to newborn infants before the initiation of breastfeeding. Sugar-water, tea, formula milk, animal milk, honey, and butter have been used as prelacteal foods in different cultures<sup>3-5</sup>.

The practice of prelacteal feeding is a cultural part of infant feeding in Nepal<sup>6</sup>, India<sup>7</sup>, Vietnam<sup>4</sup>, China<sup>8</sup> and other developing countries<sup>2,3</sup>. It has been reported to be as high as 53.1% in rural China<sup>9</sup>, 73% in Vietnam<sup>4</sup> and 16.9%-34.9% in India<sup>7,10,11</sup>. Mothers with a low level of education<sup>5</sup>, living in urban areas<sup>3</sup>, and having a caesarean delivery,<sup>4,7</sup> are at risk of providing prelacteal feeds to their newborns.

Breastfeeding has been universally adopted in Nepali society<sup>12</sup>, though prelacteal feeding remains a common infant feeding practice. Similar to other countries, variations in prelacteal feeding rates have been reported in Nepal, with 26.5% at national level<sup>13</sup>, 39% in Kapilvastu district<sup>6</sup>, and 9.1% in Kaski district<sup>14</sup>, yet these estimates share a common limitation of being retrospective and having a long recall time. The rate of initiation of breastfeeding within the first hour was 44.5% nationally<sup>15</sup>, 54.7% in Kapilvastu district<sup>6</sup> and 67% in Kaski district<sup>14</sup>. While the 24-h prevalence of exclusive breastfeeding among 0-5 month infants was 70% nationally<sup>15</sup>, a much lower rate of exclusivity (29.7%) was reported at six month in the Kaski district<sup>14</sup>. Nepal is diverse in its topography ranging from the Himalayas highland to the Southern Plains, with different cultures scattering across the country. There are more than 100 different castes that define the ethnic groups<sup>16</sup>. The population living in the Northern Himalayas resembles closely to the Tibetan culture<sup>2</sup>, while those residing in the Southern Plains (Terai) are culturally similar to Indians. However, changes in transportation and living standard, the influence of media, and migration from hilly and mountain regions to the plains and urban areas, have made

the populations in different regions of Nepal heterogeneous in nature. Early infant feeding practices in the Southern Plains, including prelacteal feeds, are different from those in the north.

In the literature, there have been no reports as to whether mothers are aware of the risks associated with prelacteal feeds, such as increased rates of infection, especially gastroenteritis. The National Nutrition Strategy (2004) of Nepal <sup>17</sup> strongly recommends exclusive breastfeeding for the first six months of life including colostrum feeding. However, specific recommendations to avoid prelacteal feeding have not been made, which may be due to inadequate evidence available for the country. Studies to address this knowledge gap are important towards the design and implementation of effective breastfeeding education programs.

The present study aimed to investigate the prevalence, reasons, types and factors associated with prelacteal feeding in south-western Nepal. The findings should provide useful information for the development of breastfeeding promotion strategies to curtail the prelacteal feeding practice.

## **Methods**

### **Study setting**

While Nepal is mainly a mountainous country, it has plain areas in the Southern part that shares an open border with India. This study was conducted in the Rupandehi district of Nepal located in the Southern Plains (Terai) of Western Nepal. The Rupandehi district was chosen because it has one of the highest maternal mortality ratios in the country, with a heterogeneous population that includes 'hill people' (*Pahadi*), local indigenous groups (*Tharu*) and *Madhesi* caste groups. Their infant feeding practices are quite different from the Central regions, such as the Kaski district <sup>14</sup>. The Rupandehi district is the major economic centre for the western region. The population of this district in 2011 was 880,196 (Male: 432,193; Female: 448,003) according to the most recent census <sup>18</sup>. The district is primarily rural with only 21.1% of the population living in urban areas. There were two municipalities and 69 village development committees in the district at the time of the survey. The public health programs in rural areas are implemented through five primary health

care centres, six health posts, and 58 sub-health posts<sup>19</sup>. These programs are monitored by the District Public Health Office. One referral public hospital (zonal hospital), one district hospital, two medical colleges, and one maternal children hospital are located in the urban areas<sup>19</sup>, whereas the majority of the rural population have to rely on health posts and sub-health posts staffed with health assistants (with 36 months of training), auxiliary medical assistants (with 15 months of vocational training), and auxiliary nurse midwives (with 18 months of vocational training). Most rural areas are linked to the cities by unpaved roads with little access to public transport. The existing public transport is irregular and non-functional during the rainy season due to river flooding and consequently cannot be relied upon medical emergencies.

### **Study design and participants**

A community-based prospective cohort study was conducted between January and October 2014. Mother-infant pairs were recruited within the first month of delivery and followed up through fourth and sixth months postpartum. Fifteen rural village development committees and two urban municipalities were randomly selected for the survey, encompassing 15 rural and 12 urban locations within the district. For each location, proportionate sampling was implemented in the recruitment process until the desired number of participants was met. Adjacent village development committees or wards (in municipalities) were also used whenever insufficient subjects were available from the selected areas.

A total of 735 mother-infant pairs (rural 378, urban 357) were recruited. In the urban areas, 18 (4.8%) mothers declined to participate; the most common reason given was possible migration to another district. In the rural areas, all mothers gave their informed consent to participate. The calculation of sample size was based on the following assumptions. Given the total number of <1 year old infants for the target year 2013/2014 was 20,061 [Source: District Public Health Office, Rupandehi, Annual Target 2013/2014], the sample required for detecting a clinically significant difference of 10% in prelacteal feeding between the Rupandehi district and the neighbouring Kapilvastu district<sup>6</sup> with similar demographic profile would be 645 with 80% power at 5% level of significance, and a loss to follow up rate of 10%<sup>20</sup>.

Our final sample size comprised 22% of all births (n = 3,343) that occurred during the two months of recruitment. Only mothers residing in the enumeration areas who gave birth to a singleton living baby at the time of recruitment were eligible for the study.

### **Data collection**

Personal interviews were conducted by trained data enumerators using a standardised structured questionnaire, with questions taken from the Nepal Demographic and Health Survey 2011<sup>15</sup> and another cohort study of maternal health<sup>14</sup>. The Nepali version of the questionnaire was pretested to ensure cultural appropriateness and content validity. The study was reviewed and approved by the Human Research Ethics Committee of Curtin University (HR 184/2013) and the Nepal Health Research Council (773/2014). The study protocol was also accepted by the District Public Health Office, Ministry of Health. Mothers provided consent for themselves and their infants after being briefed verbally about the study purpose and through an information sheet distributed to all potential participants.

### **Definition of variables**

The outcome variable was “prelacteal feeding”, defined as “any food provided prior to the initiation of breastfeeding”<sup>5</sup>. This definition excluded “medicine, oral rehydration solution, vitamin syrup, and other mother’s milk” from being defined as prelacteal foods. Sugar-water, tea, formula milk, animal milk, honey, and butter have been used as prelacteal foods in different cultures<sup>3-5</sup>.

The explanatory variables considered were based on an extensive literature review. ‘Maternal age’ was categorised into: ‘15-19’, ‘20-29’, and ‘30 and above’ years; ‘maternal education’ as: ‘no formal education’, ‘primary or lower secondary’ (up to Grade 8), ‘secondary’ (Grade 9-10), and ‘higher’ (Grade 11 and above)<sup>15</sup>; ‘maternal occupation’ as: ‘employed’ (salaried job), ‘semi-employed’ (daily wage, small business), and ‘unemployed’ (household chores, agriculture work)<sup>14</sup>. ‘Paternal occupation’ was classified by: ‘employed’ (salaried job), ‘semi-employed’ (daily wage, small business, foreign migrant labour), and ‘unemployed’ (household chores, agriculture work). ‘Place of delivery’ was either ‘home’ or ‘health facility’, whereas

‘assistance during delivery’ referred to: ‘unskilled/traditional workers’ (relatives, mother-in-law, neighbours, family members, female community health volunteers, traditional birth attendants, none), and ‘skilled health workers’ (doctor, nurse, auxiliary nurse midwife, health assistant, auxiliary health workers) <sup>15,21</sup>. ‘Mode of delivery’ was either ‘vaginal’ or ‘caesarean’. ‘Ethnicity’ was defined by the Ministry of Health and Population Nepal, which was then recoded by amalgamating similar groups into: ‘advantaged’ (Brahmin, Chhetri, Newar, Magar, Gurung, Jogi, Thakuri), ‘disadvantaged’ (Janjati, non-Janjati, Muslim), and ‘dalit-highly disadvantaged’ (Bishwakarma, Dhawal, Kami, Pariyar, Pasi, Sunar) <sup>13,16</sup>. ‘Wealth status’ was determined based on assets possessed by the household in terms of quintiles and recoded as: <sup>21,22</sup> ‘poor’ (lower 40%), ‘average’ (middle 40%), and ‘rich’ (upper 20%) <sup>23</sup>. ‘Birthweight’ was originally recorded in grams and categorised into: ‘low’ (< 2500 grams) and ‘average or more’ ( $\geq$  2500 grams) <sup>24</sup>. ‘Birth order’ has three categories: ‘first birth’, ‘second or third’, and ‘four or more’ <sup>3</sup>. ‘Place of residence’ was reported as either ‘rural’ (village development committees) or ‘urban’ (municipalities and suburbs).

### **Statistical analysis**

The binary outcome variable ‘prelacteal feeding’ was coded as 1 (provided) or 0 (not provided). The prevalence of prelacteal feeding and information on the types, reasons and effects of prelacteal feeds were reported using frequency distributions. Factors affecting prelacteal feeding were first assessed using chi-square tests before entering into a multivariable logistic regression model. The backward stepwise method was adopted in view of the apparent collinearity between the socioeconomic variables. All statistical analyses were performed using the Statistical Package for Social Sciences (SPSS, IBM statistics, Version 20).

### **Findings**

#### **Characteristics of participants**

Table 1 presents the characteristics of the 735 participants, who ranged from 16 to 45 years in age (mean 24.6, SD 4.6). More than a quarter (26.1%) of mothers did not have formal education, while a small proportion (4.1%) was employed in salaried

occupations, and only 13.9% of their partners were employed in salaried occupations. The majority (88.2%) of child births occurred at health facilities, with 85.9% being vaginal delivery, and 40.1% were born to poor families. About four in ten (42.8%) births were first order, yet 14.2% of babies had a low birthweight.

### **Prevalence, types, and reasons for prelacteal feeding**

A total of 225 (30.6%) of mothers reported providing prelacteal feeds to their infants. Among them, formula milk (94, 41.7%), cow or buffalo milk (60, 26.6%), sugar/glucose water (28, 12.4%), plain water (23, 10.2%), honey (19, 8.4%), ghee or refined butter (9, 4.0%), fruit juice (7, 3.1%), ghee and honey mix (5, 2.2%), and sugar-salt solution (4, 1.7%) were common prelacteal foods. The main reasons for giving prelacteal feeds were: having caesarean delivery (39, 17.3%), a common cultural practice (37, 16.4%), and being tired after child birth (24, 10.6%). Besides, various other reasons were collected from the open ended responses:

- Baby could not suckle breasts
- Baby will be lucky to start feeding with ghee/honey
- Breastmilk not secreted/not enough
- Medical condition of newborn (ill, low birthweight)
- Can make infant urinate
- Baby was very hungry
- Child will be clever if fed with honey
- Clears throat
- Easier to start feeding
- Breast problems: no nipple/retracted nipple/wound in breast

Upon asking those 225 mothers “*Is there any adverse effect of prelacteal feeds?*” the responses were: ‘no effect’ (131, 58.2%), ‘increase infection’ (32, 14.2%), ‘cause diarrhoea’ (22, 9.7%), and ‘difficult to breastfeed’ (8, 3.5%). It is interesting to find that almost half of them (108, 58%) were advised by their mother/mother-in-law to administer prelacteal feeds, followed by doctor/health assistant/community medical assistant (43, 19.1%), nurse/auxiliary nurse midwives (28, 12.4%), senior women of community (11, 4.8%), female community health volunteers (9, 4%), other persons

(8, 3.5%), and traditional birth attendants (4, 1.7%). A few mothers (26, 11.5%) introduced prelacteal feeds to their newborn without obtaining advice from anyone.

### **Factors associated with prelacteal feeding**

According to chi-square tests (Table 1), several explanatory variables appeared to be significantly associated with prelacteal feeding. Results of stepwise logistic regression analysis, shown in Table 2, further confirmed the impact of mode of delivery, wealth status, birth order and birthweight. Specifically, mothers who delivered by caesarean section (adjusted odds ratio (AOR): 3.70; 95% confidence interval (CI): 2.37 to 5.80), with a higher wealth status (AOR: 2.49; 95% CI: 1.52 to 4.06), and of higher birth order (AOR: 2.05; 95% CI: 1.18 to 3.54), tended to provide prelacteal foods to their newborn infant. In addition, mothers who reported their babies as low birthweight were twice more likely to introduce prelacteal feeds.

### **Discussion**

This study found that nearly one-third of infants were provided with prelacteal feeds in south-western Nepal. This prevalence is higher than previously reported rates of 26.5% at a national level<sup>13</sup> and 9.1% in a hilly district in central Nepal<sup>14</sup>, but comparable with the observed rate of 39% in a neighbouring district<sup>6</sup>. Similar geographical variations have been reported in other countries. For example, a review from China found an overall prevalence of 48.8% (urban 38.8%, rural 53.1%)<sup>9</sup>, while the proportion of mothers introducing prelacteal feeds in India varied from 22.76% in the north to 34.9% in the south<sup>7,10,11</sup>.

Traditionally, honey and ghee (refined butter) were popular prelacteal foods in Nepal, India and Pakistan which have similar cultures<sup>12</sup>. However, with the widespread marketing of baby foods in recent years, formula milk has become the main substitute. This is alarming especially in the context of Nepal where mothers are less educated, sanitation is poor, and access to safe drinking water is limited. Any unhygienic way of preparation will contaminate formula milk which can lead to gastroenteritis<sup>25,26</sup>. Despite these adverse consequences, only a few mothers in our study were aware of the risks posed to their infant. In the decision making process,

advice from grandmothers of infants appeared to be the most influential on prelacteal feeding. This finding suggests a need to educate senior women of the family.

Babies who were born by caesarean section tended to be at risk of receiving prelacteal feeds. In caesarean deliveries, mothers are not allowed to move their body and head under anaesthesia. Consequently, the family may resort to formula milk or animal milk as the only alternative to feed the newborn<sup>3</sup>. Anecdotal evidence has shown that nurses do advise mothers to breastfeed. However, mothers are rarely demonstrated how to breastfeed when they are still recovering from pain, immobilisation and tiredness after caesarean section. Our finding indicates that some nursing staff may not be equipped with the appropriate skills to support mothers under such circumstances.

Similar to a recent study in Timor-Leste<sup>3</sup>, low birthweight infants were more likely to be given prelacteal feeds. In fact, such infants may be taken to the Intensive Care Unit or other care units where they are fed with formula by nurses. Moreover, they may be perceived by the family as cannot suckle breast or have less suckling capacity<sup>27</sup>. In developed countries such as Australia, efforts are made to give breastmilk or expressed breastmilk to all low birthweight infants, which has the additional benefit of reducing the rate of necrotising enterocolitis<sup>28,29</sup>.

Our finding concerning wealth status is consistent with previous studies<sup>4,13</sup>, which reported that mothers of higher socioeconomic status often provide prelacteal feeds. In Nepal, those without economic constraints have access to a variety of prelacteal food items such as formula milk, cow milk and honey. Unlike their poorer counterparts, the high wealth status would place them at a higher risk of giving prelacteal feeds instead of initiate and continue breastfeeding after delivery.

Despite a number of education materials have been used by the Nepal Ministry of Health and Population to promote exclusive breastfeeding (Figure 1), the practice of prelacteal feeding is not explicitly discouraged. Findings of the present study have important implications for both community and health facility settings. In the community where home births still occur, senior women and mothers with higher parity should be discouraged from prelacteal feeding but provided with breastfeeding initiation skills early in the pregnancy. In the health facility, particular attention

should be paid to mothers with low birthweight infants and those who have undergone caesarean delivery, by assisting them to initiate and establish breastfeeding appropriately. Furthermore, advanced training of nursing staff is needed to ensure they possess the necessary skill base to educate and support these high risk individuals.

There are some limitations when interpreting the results. Firstly, this study recruited participants from the Rupandehi district in the lowland area of south-western Nepal. Although the sample size was deemed adequate, our postpartum mothers might not be representative of the whole country because of the reported variations in prelacteal feeding rate. Secondly, all data were collected from the participants retrospectively, which might incur recall bias to some extent. However, unlike previously conducted studies<sup>3,6,14,30</sup>, our participants were recruited within their first month of postpartum to minimise recall errors. Another strength of this study was the face-to-face interviews being conducted by qualified data enumerators who had been trained by the first author to ensure consistency in the data collection process.

### **Conclusion**

This study found that nearly one-third of newborn infants were given prelacteal feeds in western Nepal. Those delivered by caesarean section, with a low birthweight, and born into a wealthy family were particularly susceptible to prelacteal feeding. With increasing rates of health facility delivery in Nepal, it is important that breastfeeding promotion should be part of the maternity and newborn care service to curtail prelacteal feeding. Further education programs should focus on grandmothers and senior women of the family so that exclusive breastfeeding is practised as a universal norm.

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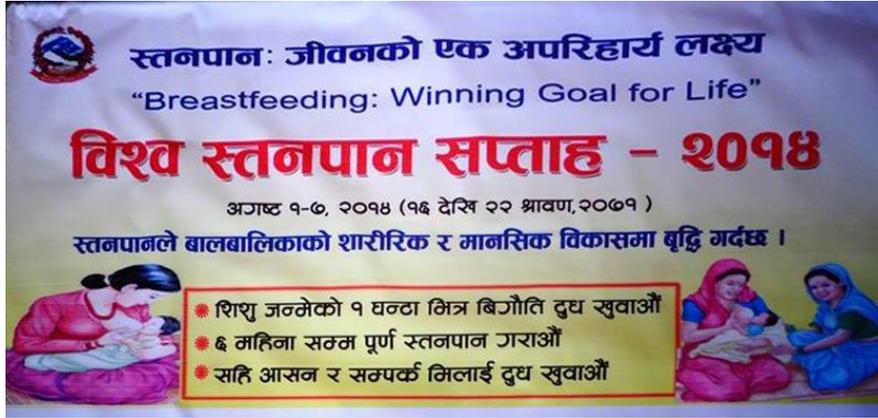
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Figure 1



Message in bullet points: initiate colostrum feeding within an hour of birth, exclusively breastfeed for six months, and adopt proper position and attachment while breastfeeding.

(Photo source: Ministry of Health and Population)

## Tables

**Table 1. Characteristics of participants (n = 735)**

<b>Factor</b>	<b>Frequency</b>	<b>Percent</b>	<b>Prelacteal feeding n (%)</b>	<b>P value *</b>
<b>Parental factors</b>				
<b>Maternal age (years)#</b>				0.165
15-19	66	9.0	16 (24.2)	
20-29	549	74.8	165 (30.1)	
30-45	119	16.2	44 (27.0)	
<b>Maternal education</b>				0.005
No education	192	26.1	64 (33.3)	
Primary or lower secondary	243	33.0	61 (25.1)	
Secondary	132	18.0	33 (25.0)	
Higher	168	22.9	67 (39.9)	
<b>Maternal occupation</b>				0.044
Employed	30	4.1	13 (43.3)	
Semi-employed	144	19.6	53 (36.8)	
Unemployed	561	76.3	159 (28.3)	
<b>Paternal occupation</b>				0.714
Employed	102	13.9	34 (33.3)	
Semi-employed	516	70.2	158 (30.6)	
Unemployed	117	15.9	33 (28.2)	
<b>Antenatal care (frequency)#</b>				0.776
No visit	17	2.3	4 (23.5)	

1-3 visits	157	21.4	50 (31.8)	
4 or more visits	558	76.3	171 (30.6)	
<b>Place of delivery</b>				0.404
Home	87	11.8	30 (34.5)	
Health facility	648	88.2	195 (30.1)	
<b>Assistance during delivery</b>				0.360
Unskilled/traditional workers	86	11.7	30 (34.9)	
Skilled health workers	649	88.3	195 (30.0)	
<b>Mode of delivery</b>				<0.001
Vaginal	631	85.9	165 (26.1)	
Caesarean	104	14.1	60 (57.7)	
<b>Sociodemographic factors</b>				
<b>Ethnicity</b>				0.500
Advantaged	274	37.3	90 (32.8)	
Disadvantaged	371	50.5	111 (29.9)	
Dalit-highly disadvantaged	90	12.2	24 (26.7)	
<b>Wealth status</b>				<0.001
Poor	295	40.1	65 (22.0)	
Middle	295	40.1	107 (36.3)	
Rich	145	19.8	53 (36.6)	
<b>Child related factors</b>				
<b>Sex of child</b>				0.779
Male	383	52.1	119 (31.1)	
Female	352	47.9	106 (30.1)	

<b>Birth order#</b>				0.001
First	314	42.8	104 (33.1)	
Second or third	332	45.2	82 (24.7)	
Fourth or more	88	12.0	39 (44.3)	
<b>Birthweight</b>				0.009
Low	96	14.2	40 (41.7)	
Average or more	581	85.8	581 (28.4)	
Weight not reported	58			
<b>Contextual factors</b>				
<b>Place of residence</b>				0.493
Rural	378	51.4	120 (31.7)	
Urban	357	48.6	105 (29.4)	
<b>Type of family</b>				0.172
Joint/extended	530	72.5	171 (32.3)	
Nuclear	201	27.5	52 (25.9)	

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*\* From chi-square test of association between prelacteal feeding and each factor. # missing data present*

**Table 2. Factors associated with prelacteal feeding, western Nepal (n = 735)**

<b>Factor</b>	<b>Adjusted odds ratio (95% confidence interval)</b>	<b>P value *</b>
<b>Mode of delivery</b>		<0.001
Vaginal	1.0	
Caesarean	3.70 (2.37, 5.80)	
<b>Wealth status</b>		<0.001
Poor	1.0	
Middle	2.27 (1.49, 3.45)	
Rich	2.49 (1.52, 4.06)	
<b>Birth order</b>		0.001
First	1.0	
Second or third	0.68 (0.47, 1.00)	
Fourth or more	2.05 (1.18, 3.54)	
<b>Birthweight</b>		0.005
Average or more	1.00	
Low	1.97 (1.23, 3.16)	

\* *From stepwise logistic regression model after excluding maternal education and maternal occupation*

### **4.6.3 Paper -3: Postpartum breastfeeding promotion and duration of exclusive breastfeeding Western Nepal**

Link to full text: <http://onlinelibrary.wiley.com/doi/10.1111/birt.12184/full>

Journal: Birth

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## **ABSTRACT**

### **Background**

Encouragement and skills provided to mothers during the postpartum period has been found successful to increase exclusive breastfeeding rates. However, evidence from developing countries is limited. This study aimed to ascertain whether education and skill support provided by health workers during the postpartum period was associated with increased duration of exclusive breastfeeding in Western Nepal.

### **Methods**

A community-based prospective cohort study was conducted between January and October, 2014, in the Rupandehi district of Nepal. Information on breastfeeding promotion, provided by health workers after birth, was collected from 649 mothers. The association between breastfeeding promotion and exclusive breastfeeding was investigated using multivariable Cox regression analysis.

### **Results**

Of the 649 mothers, 35% received all eight breastfeeding promotion advices, and 60% received six or more such advices. Breastfeeding promotion, such as 'breastfeeding on demand' (hazard ratio (HR) 0.74; 95% confidence interval (CI) 0.59 to 0.92) and 'not to provide pacifier or teats' (HR 0.82; 95% CI 0.68 to 0.97), were significantly associated with a lower risk of exclusive breastfeeding cessation. The dose-response relationship was also significant for the number of advices received (HR 0.94; 95% CI 0.90 to 0.97).

### **Conclusions**

This study provides evidence that breastfeeding education and support immediately after childbirth could increase the duration of breastfeeding. The results suggest further attention to breastfeeding promotion in all maternity hospitals and birthing centres through skilled birth attendants.

**Keywords:** Breastfeeding duration, Cohort study, Exclusivebreastfeeding, Infant feeding, Nepal

## **Introduction**

The benefits of exclusive breastfeeding for six months after birth are well documented. Black et al. (1) estimated that 11.6% of all child deaths in low and middle income countries were due to suboptimal breastfeeding. Exclusive breastfeeding is associated with a lower risk of gastrointestinal infection, enhanced motor development, and improved nutritional status (2). Despite the proven benefits of exclusive breastfeeding, it still has a relatively low prevalence worldwide (3). Cai et al. (4) reported that only 39% infants were exclusively breastfed in 2010; whereas a slightly higher rate of 45% had been reported in South Asia. These figures referred to the 0-5 month infant group. As such, they are likely to be much lower if measured for exclusive breastfeeding for six months, as recommended by the World Health Organization (WHO) (5).

Encouragement and skill education provided to mothers during the antenatal and post-partum periods have been found useful to enhance exclusive breastfeeding rates. The PROBIT study, the largest published cluster randomized trial in human lactation, also provided evidence that professional support, in the form of the baby friendly hospital initiative, was successful to increase breastfeeding rates (6). While a number of strategies for breastfeeding promotion have been outlined by Hannula et al. (7) in a systematic review, structured content in breastfeeding promotion was more likely to deliver positive outcomes. In England, when mothers were provided with practical skills on lactation position and latching, the likelihood of breastfeeding up to six months increased (8). However, there was no apparent improvement in breastfeeding when sessions were delivered via education methods only (9; 10). Despite encouraging results of breastfeeding promotion have been demonstrated in developed countries (7), evidence from developing countries remains limited.

Nepal is located in South Asia with a population of 26.5 million, of which only 17% live in urban areas. The reported prevalence of exclusive breastfeeding in Nepal was 69.9 % in 2011 from a national survey (11); but varied between regions and was only 29.7% at sixth months of age in Central Nepal (12). Variations in reported rates may be due to the different definitions of exclusive breastfeeding, survey methodology,

sample selection and the period of measurement of exclusivity. Several studies have also suggested the impact of maternal and socio-demographic factors (13-16).

The baby friendly hospital initiative commenced in Nepal in 1991 after training health workers from 22 hospitals throughout the country. However, not all of the recommended ten steps had been practised regularly (17). The main reasons were low priority given to the initiative and the hospitals being reluctant to adopt the changes, yet the Ministry of Health and Population has included most of the contents of baby friendly hospital initiative into community-based programs, including integrated management of childhood illness, community-based newborn care package and skilled birth attendant training (18). These programs educate health workers on immediate and exclusive breastfeeding of infants, avoiding infant formula, and restricting the use of bottle or pacifiers in hospitals. Since 2006, the rate of facility-based childbirth has increased from 19% in 2006 to 35% in 2011. In some areas of Nepal, this rate was as high as 80% (12). Consequently, health workers have more opportunity to educate and support mothers on breastfeeding. Nevertheless, the effectiveness of such breastfeeding promotion has never been evaluated in Nepal. The present study aimed to ascertain whether education and support provided by health workers during the postpartum period was associated with the duration of exclusive breastfeeding in Nepal.

## **Methods**

### **Study setting**

The study was conducted in the Rupandehi district located in the south-western plain (Terai) of Nepal. This district shares an open border with India. The human development index is 0.498, which is lower than the average 0.541 of the whole country (19). The majority of the population of Rupandehi district live in rural areas. In 2011, the total population was 880,196 (432,193 males, 448,003 females), with an annual population growth rate of 2.17% since 2001 (20; 21). Infant mortality rate was 38.06 per 1000 live births (21). The adult (>15 years) literacy rate was 53.1%, with female literacy (42.4%) being much lower than male (63.6%) (22).

### **Study design**

A community-based prospective cohort study was conducted between January 2014 and October 2014 in the Rupandehi district of Nepal. A total of fifteen village development committees and twelve wards of two municipalities (the lowest administrative units in Nepal) were randomly selected for the survey. The number of participants required from each location was decided by a proportionate sampling scheme based upon the population size of < one-year old infants. Mother-infant pairs were randomly selected from the compiled list of eligible participants. When an adequate sample was not met in a selected area, the recruitment process was extended to its adjacent areas. Trained female enumerators conducted face-to-face interviews using a structured questionnaire adapted from the Nepal Demographic and Health Survey(11) and a previous cohort study(12). A total of 735 mothers who were local residents, had living infants, and gave birth to a singleton child, were recruited within 30 days of postpartum; and followed up twice at 90 to 120 days (3 to 4 months), and 150 to 180 days (5 to 6 months) respectively. Figure 1 shows the flow chart of 649 participants included in the analysis.

Ethics approval was obtained from the Human Research Ethics Committee of Curtin University, Australia (HR 184/2013) and the Nepal Health Research Council, Nepal (773/2014). Informed consent was obtained from mothers for themselves and their infants. Personal identifiers were removed from the database before statistical analyses.

### **Variables**

The outcome variable was ‘exclusive breastfeeding’ which was defined as “no food items other than mother’s milk including expressed breastmilk, medicine, vitamin and mineral syrup, and oral rehydration salt”(23). The measurements were taken at three times: within 30 days, 90-120 days, and 150-180 days, using ‘recall since birth’ at the first interview, and ‘recall since last interview’ during the follow up interviews. To assist with dietary recall, common food items were also read out to check if mothers have provided them to their infants, even when they reported to give “only mother’s milk”.

The main factor of interest was ‘breastfeeding promotion’ provided by health workers after birth. We collected this information from 649 (88.3%) mothers whose

childbirth was assisted by skilled birth attendants (doctors, nurses, health assistants, auxiliary health workers, auxiliary midwives), irrespective of place of birth. We asked mothers to recall whether they received breastfeeding supports or advices immediately after childbirth, by reading out a list of such messages. The eight exposure variables that composed 'breastfeeding promotion' were receiving advice to 'initiate breastfeeding within one hour of childbirth', 'skills on breastfeeding', 'not to provide food other than breastmilk', 'to keep mother and baby together', 'breastfeeding on demand', 'not to provide pacifier or teats', 'where to get support on breastfeeding when needed', and 'exclusively breastfeed for six months'. These messages were part of the baby friendly hospital initiative's recommendation given together by health workers(24; 25).

We also included other plausible independent variables based on literature review (12; 16; 26). Briefly, maternal occupation was defined as either 'salaried job', 'daily wage or small business', and 'household or agricultural work' (27). Frequency of antenatal care was recoded into: no visit, 1-3 visits, and 4 or more visits. Ethnicity was categorised into three groups based on similarities between groups: 'advantaged' (Brahmin, Chhetri, Jogi, Thakuri, Newar, Magar, Gurung), 'disadvantaged' (Janjati, non-Janjati, Muslim), and 'dalit-highly disadvantaged' (Bishwakarma, Dhawal, Kami, Pariyar, Pasi, Sunar) (28). Wealth status referred to household assets possessed by the respondents (29; 30): 'poor' (lower 40%), 'average' (middle 40%), and 'rich' (upper 20%) (31). Birthweight was originally recorded in grams but then classified as: 'low birthweight' (< 2500 g) and 'average or more' ( $\geq$  2500 g). Place of residence was either 'rural' (village development committees) or 'urban' (municipalities and suburbs). Early initiation of breastfeeding was defined as initiation of first breastfeeding within one hour of birth (23).

### **Statistical analysis**

The median duration of exclusive breastfeeding was estimated using the Kaplan-Meier method. In addition to reporting the rate of exclusive breastfeeding at sixth month using the 'recall since birth' method, associations between exclusive breastfeeding and independent variables were initially assessed via univariate statistics, and then confirmed using a multivariable Cox regression model. The

backward stepwise method was adopted to account for potential collinearity between variables. All statistical analyses were performed using the Statistical Package for Social Science Version 20 (IBM Corp. Armonk, NY, USA).

## **Results**

### **Characteristics of participants**

Response rate at the baseline interview was 97.6%. At 6 months postpartum, 628 mothers responded with a loss of follow up rate of 3.2%. Table 1 presents the characteristics of participants. The median age of mothers was 24 (standard deviation (SD) 4.6) years. Fewer than one-third (23.6%) of mothers had no education, three-quarters (76.3%) were involved in household or agricultural work, and the majority of them (80.1%) reported having four or more antenatal care visits. Only 16% of mothers gave birth by caesarean section.

Of the 649 mothers, 35% received all eight breastfeeding promotion advices, and 60% received six or more such advices. Specifically, they were given: advice on initiation of breastfeeding within one hour (90.3%), exclusively breastfeed for six months (80.9%), not to provide other food or drinks (66.4%), breastfeeding on demand (79.5%), information on where to go for breastfeeding support when needed (62.7%), and not to give pacifier or teats (48.4%). The great majority of mothers were kept together with their newborn infants (84.1%), and 70.4% were taught on breastfeeding skills.

### **Breastfeeding promotion and duration of exclusive breastfeeding**

For the cohort, the median breastfeeding duration was 100 days (95% confidence interval (CI) 95.5 to 104.5 days). Exclusive breastfeeding rate was 66.9% at first month, but reduced to 39.2% at fourth month, and only 8.4% at sixth month. Tables 1 and 2 present the univariate associations between the cessation of exclusive breastfeeding and selected confounding factors and the eight breastfeeding promotion advices, respectively. Table 3 shows the results from multivariable Cox regression analysis. After accounting for other pertinent factors, breastfeeding promotion advices 'breastfeeding on demand' (hazard ratio (HR) 0.74; 95% CI 0.59

to 0.92) and ‘not to provide pacifier or teats’ (HR 0.82; 95% CI 0.68 to 0.97) were confirmed to be significantly associated with a lower risk of exclusive breastfeeding cessation. The dose-response relationship was also significant for the number of advices received (HR 0.94; 95% CI 0.90 to 0.97).

## **Discussion**

Exclusive breastfeeding rate among infants of the Western region of Nepal was low (8.4%) at sixth months, with the median duration of exclusivity being only slightly more than three months (100 days). The median duration of exclusive breastfeeding was lower in our study than that reported in the Nepal Demographic and Health Survey 2011 (126 days) (11). Our rate of exclusive breastfeeding was also lower than that reported for women in central Nepal (29.7%)(12). It should be noted that, due to methodological differences, our result is not directly comparable with previous studies. In Nepal, child survival programs, such as community-based newborn care program (18; 32) and integrated management of childhood illness, strongly encourage exclusive breastfeeding for six months(33). The National Nutrition Policy and Strategy (2004) also recommended exclusive breastfeeding for six months(34). As part of breastfeeding promotion, public hospitals are expected to promote exclusive breastfeeding. To highlight the importance of exclusive breastfeeding, the Ministry of Health and Population has decided to celebrate the first week of August as ‘breastfeeding week’. Despite these efforts, exclusive breastfeeding rate was still low in western Nepal.

A significant finding is that mothers tended to exclusively breastfeed longer if they received breastfeeding advices immediately after childbirth. Breastfeeding promotion in the form of advice and skill support was originally recommended by the baby friendly hospital initiative (35; 36). These messages and support included advice on early initiation; no other food items but breastmilk, keeping infant and mother together, breastfeeding on demand, no teats or pacifiers, where to go when problems occur, and skill on position, holding newborn and latching. A Brazilian study also observed a longer exclusive breastfeeding duration among mothers who received breastfeeding support in hospital (37). Despite the fact that Nepal implemented its baby friendly hospital initiative in 1991, no evaluation has been undertaken on its

effect. Our finding suggests a positive association between postpartum breastfeeding promotion and the duration of exclusive breastfeeding for the first time.

Infants born by caesarean section were at higher risk of early cessation of exclusive breastfeeding, consistent with previous studies (12; 37; 38). Observations from hospitals indicated that the nurses in Nepal typically ask mothers to breastfeed newborn infants immediately after birth and to continue exclusive breastfeeding thereafter. If the mother is still suffering from the effects of anaesthesia or pain due to surgical procedure and is not allowed to raise her head for at least 24-hours, breastfeeding becomes difficult and requires support. Under such circumstances, skilful one-to-one teaching and support provided by midwives or nurses are essential to establish early breastfeeding (7), so that mothers can be more confident to continue breastfeeding exclusively. In settings such as the Rupandehi district of Nepal where hospital and birthing centres are readily accessible, and where the majority of births occur in a health facility, breastfeeding promotion through health workers would be a feasible option.

Previous studies in developing countries have reported that mothers from high socioeconomic status were less likely to exclusively breastfeed (39). We also found that the risk of cessation of exclusive breastfeeding was higher among mothers from middle or rich families than those from poor families. These population sub-groups could be targeted for exclusive breastfeeding promotion in the future in Nepal.

The major strength of this study is its prospective cohort methodology used for the data collection. Repeated measurements provided more accurate information on infant feeding via 'recall since birth' using a list of food items that are common in Nepal. Although this study represents the first investigation on the relationship between postpartum breastfeeding education and skill support received by mothers and exclusive breastfeeding duration, there are several limitations to be considered when interpreting the findings. In particular, we did not record whether the breastfeeding advices received were translated into action or actual practice for each individual mother. Another limitation concerns the small proportion of infants still being exclusively breastfed at the time of final interview. Their duration of exclusive breastfeeding could not be determined due to time and resource constraints. In

addition, we did not collect information on whether mothers received other breastfeeding promotion materials or support from other sources such as peers or female community health volunteers in Nepal.

Breastfeeding support immediately after childbirth appears to exert a positive impact on the duration of breastfeeding, with a significant dose-response relationship observed for our cohort. Future infant nutrition and breastfeeding programs in Nepal should incorporate postpartum breastfeeding promotion in all birthing centres and health facilities which provide childbirth services. The interventions suggested as part of the baby friendly hospital initiative should be promoted and evaluated in a timely manner within the context of local cultures. Health workers should continue to provide counselling and skill support to mothers after delivery as a standard practice to promote exclusive breastfeeding (18). A practical approach would be training them with skills to teach mothers on successful latching and lactation positioning, followed by breastfeeding education and support sessions when mothers come for postnatal care and immunization services.

## **Conclusion**

This study found that postpartum breastfeeding promotion through health workers was related to an increased duration of exclusive breastfeeding in the western region of Nepal. However, only a small proportion of infants were breastfed exclusively at the sixth month. The results suggest adapting the recommendations of the baby friendly hospital initiative for breastfeeding promotion in all maternity hospitals and birthing centres of Nepal.

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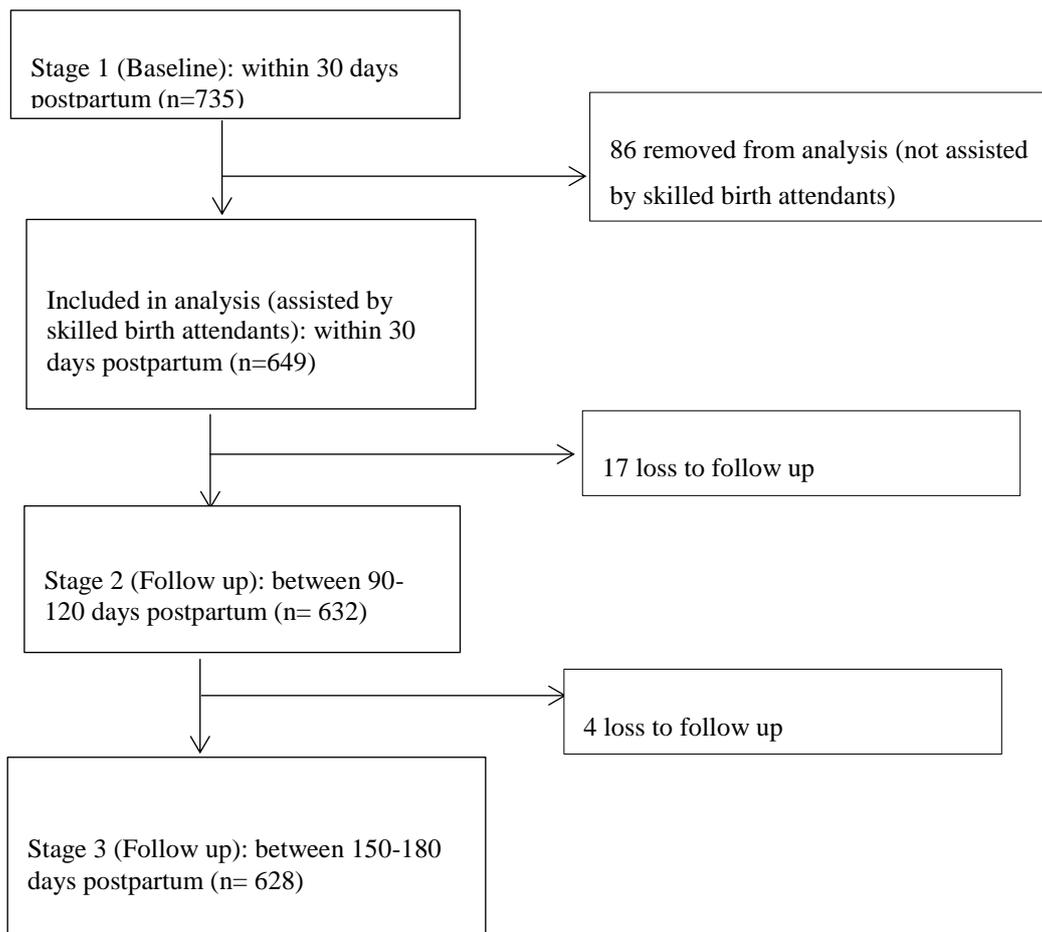
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**Figure 1. Flow chart of the prospective cohort study in Rupandehi district, Nepal, 2014**



**Table 1. Characteristics of participants in relation to the cessation of exclusive breastfeeding before six months, Rupandehi District, Nepal, 2014 (N=649)**

<b>Factor</b>	<b>Frequency n (%)</b>	<b>Cessation of exclusive breastfeeding n (%)*</b>	<b>P**</b>
<b>Mother's age<sup>#</sup> (years)</b>			0.032
15-19	59 (9.1)	53 (89.8)	
20-29	499 (77.0)	454 (91.0)	
30-45	90 (13.9)	89 (98.9)	
<b>Maternal education</b>			0.146
No education	153 (23.6)	146 (95.4)	
Primary to lower secondary	207 (31.9)	185 (89.4)	
Secondary	122 (18.8)	110 (90.2)	
Higher	167 (25.7)	156 (93.4)	
<b>Maternal occupation</b>			0.448
Salaried job	30 (4.6)	29 (96.7)	
Daily wage or small business	124 (19.1)	116 (93.5)	
Household or agricultural work	495 (76.3)	452 (91.3)	
<b>Antenatal care visit<sup>#</sup></b>			0.840
No visit	11 (1.7)	10 (90.9)	
1-3 visits	118 (18.2)	107 (90.7)	
4 or more visits	518 (80.1)	478 (92.3)	
<b>Mode of delivery</b>			0.036
Vaginal	545 (84.0)	496 (91.0)	
Caesarean	104 (16.0)	101 (97.1)	
<b>Ethnicity</b>			0.247

Advantaged	255 (39.3)	238 (93.3)	
Disadvantaged (Janjati, non Janjati, Muslim)	317 (48.8)	286 (90.2)	
Dalit-highly disadvantaged	77 (11.9)	73 (94.8)	
<b>Wealth status</b>			0.040
Poor	241 (37.1)	216 (89.6)	
Middle	270 (41.6)	257 (95.2)	
Rich	138 (21.3)	124 (89.9)	
<b>Place of residence</b>			0.343
Rural	321 (49.5)	292 (91.0)	
Urban	328 (50.5)	305 (93.0)	
<b>Sex of infant</b>			
Male	344 (53.0)	317 (92.2)	
Female	305 (47.0)	280 (91.8)	
<b>Birth order<sup>#</sup></b>			0.042
First	296 (45.7)	265 (89.5)	
Second or third	290 (44.8)	270 (93.1)	
Fourth or higher	62 (9.6)	61 (98.4)	
<b>Birth weight</b>			0.183
Low birth weight (<2500 g)	87 (13.8)	83 (95.4)	
Average or more (≥ 2500 g)	544 (86.2)	496 (91.2)	
Birth weight not reported	18		
<b>Early initiation of breastfeeding<sup>#</sup></b>			<0.001
No	357 (56.0)	341 (95.5)	
Yes	281 (44.0)	245 (87.2)	
<b>Grandmother's feeding preference<sup>#</sup></b>			0.111

Breastfeeding	567 (89.7)	517 (91.2)	
Others (bottle-feeding, mixed, animal milk)	65 (10.3)	63 (96.9)	
<b>Father's feeding preference<sup>#</sup></b>			<b>0.577</b>
Breastfeeding	583 (92.2)	534 (91.6)	
Others (bottle-feeding, mixed, animal)	49 (7.8)	46 (93.9)	

<sup>#</sup> Missing data present, \* row percentage, \*\* from Chi-square test

**Table 2. Association between breastfeeding promotion advices and the cessation of exclusive breastfeeding before six months, Rupandehi District, Nepal, 2014 (N=649)**

<b>Breastfeeding promotion during postpartum</b>	<b>Frequency n (%)</b>	<b>Crude hazard ratio (95% confidence interval)</b>	<b>P</b>
<b>Initiate breastfeeding within one hour of childbirth<sup>#</sup></b>			<b>0.305</b>
No	62 (10.0)	1	
Yes	557 (90.0)	0.87 (0.66, 1.14)	
<b>Skills on breastfeeding<sup>#</sup></b>			<b>0.635</b>
No	184 (29.7)	1	
Yes	435 (70.3)	0.96 (0.80, 1.14)	
<b>Not to provide food other than breastmilk<sup>#</sup></b>			<b>0.011</b>
No	210 (33.9)	1	
Yes	409 (66.1)	0.80 (0.68, 0.95)	
<b>Keep mother and baby together<sup>#</sup></b>			<b>0.940</b>
No	98 (15.8)	1	
Yes	521 (84.2)	1.01 (0.81, 1.25)	
<b>Breastfeeding on demand<sup>#</sup></b>			<b>0.028</b>

No	126 (20.4)	1	
Yes	493 (79.6)	0.80 (0.66, 0.98)	
<b>Not to provide pacifier or teats<sup>#</sup></b>			0.010
No	318 (51.4)	1	
Yes	301 (48.6)	0.81 (0.69, 0.95)	
<b>Where to get support on breastfeeding when needed<sup>#</sup></b>			0.090
No	228 (36.8)	1	
Yes	391 (63.2)	0.87 (0.73, 1.02)	
<b>Exclusively breastfeed for six months<sup>#</sup></b>			0.395
No	114 (18.4)	1	
Yes	505 (81.6)	0.91 (0.74, 1.12)	

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<sup>#</sup> *Missing data present*

**Table 3. Factors influencing the cessation of exclusive breastfeeding before six months, Rupandehi District, Nepal, 2014 (N=649)**

<b>Factor</b>	<b>Adjusted hazard ratio (95% confidence interval) *</b>	<b>P</b>
<b>Mode of delivery</b>		<0.001
Vaginal	1	
Caesarean	1.60 (1.27, 2.01)	
<b>Wealth status</b>		0.003
Poor	1	
Middle	1.39 (1.15, 1.69)	
Rich	1.17 (0.93, 1.47)	
<b>Breastfeeding promotion advice: breastfeeding on demand</b>		0.006
No	1	
Yes	0.74 (0.59, 0.92)	
<b>Breastfeeding promotion advice: not to provide pacifier or teats</b>		0.026
No	1	
Yes	0.82 (0.68, 0.97)	

*\* Variables excluded during backward stepwise regression were mother's age, maternal education, maternal occupation, antenatal care visit, ethnicity, place of residence, sex of infant, birth order, birth weight, early initiation of breastfeeding, grandmother's feeding preference, father's feeding preference, and six other breastfeeding promotion advices*

#### **4.6.4 Paper -4: Incidence of mastitis in the neonatal period in a traditional breastfeeding society: Results of a cohort study**

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**Short title:** Mastitis among breastfeeding women of Nepal

**Journal:** Breastfeeding Medicine

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## **Abstract**

**Background:** Mastitis is a painful problem experienced by breastfeeding women, especially in the first few weeks postpartum. There have been limited studies of the incidence of mastitis from traditionally breastfeeding societies in South Asia. This study investigated the incidence, determinants and management of mastitis in the first month postpartum, and its association with breastfeeding outcomes at four, and six months postpartum in western Nepal.

**Subjects and methods:** Subjects were a sub-sample of 338 mothers participating in a larger prospective cohort study conducted in 2014 in western Nepal. Mothers were interviewed during the first month postpartum, and again at four, and six months to obtain information on breastfeeding practices. The association of mastitis and determinant variables was investigated using multivariable logistic regression and the association with breastfeeding duration using Kaplan-Meier estimation.

**Results:** The incidence of mastitis was 8.0% (95% confidence interval: 5.1% to 10.8%) in the first month postpartum. Prelacteal feeding (adjusted odds ratio 2.76, 95% confidence interval 1.03, 7.40) and cesarean section (adjusted odds ratio 3.52, 95% confidence interval 1.09, 11.42) were associated with a higher likelihood of mastitis. Kaplan-Meier estimation showed no significant difference in the duration of exclusive breastfeeding among the mothers who experienced an episode of mastitis and those who did not.

**Conclusions:** Roughly one in ten (8.0%) women experienced mastitis in the first month postpartum and there appeared to be little effect of mastitis on breastfeeding outcomes. Traditional breastfeeding practices should be encouraged, and the management of mastitis should be included as a part of lactation promotion.

## Introduction

Maternal problems during breastfeeding commonly have been reported to be one of the reasons for early discontinuation of breastfeeding<sup>1,2</sup>. Studies from developed countries including Australia have reported sore nipples, breast pain, and mastitis as common problems during breastfeeding<sup>2,3</sup>. Mastitis is a major problem experienced by breastfeeding women, especially in the first few weeks postpartum and mastitis incidence rates of around 20% have been reported in developed countries<sup>4-6</sup>, but with wide variations among studies. For example, Vogel et al.<sup>4</sup> reported a 12 months incidence rate of 23.7% (N=350) amongst a cohort of women in New Zealand, whereas a much lower incidence rate of 9.5% (N=946) was reported for a cohort of women followed for three months in the USA<sup>7</sup>. The time of occurrence is an important consideration when measuring the incidence of mastitis and a number of studies have reported that incidence is highest in the first few weeks postpartum<sup>6,8</sup> and the rate declines thereafter. For instance, Scott et al.<sup>6</sup> reported a six month incidence of 18% amongst a Scottish cohort, of which 53% of the cases (30 of 57) occurred in the first four weeks postpartum. Similarly, Amir et al.<sup>8</sup> reported a 17.3% (N=1,193) cumulative incidence in the first six weeks postpartum, of which 53% of cases occurred in the first four weeks.

While many factors have been associated with lactation mastitis<sup>5,9</sup>, knowledge of the cause and disease process remains limited. The most convincing and acceptable disease process is insufficient removal of breastmilk leading to milk stasis<sup>10</sup>. Early diagnosis and treatment of mastitis is important; if inflammation persists, it can block the lactiferous tissues, and cause milk stasis leading to breast abscess and sepsis<sup>11</sup>. Mastitis should be managed with breastfeeding frequently or expressing milk from the affected breast in an effort to clear blocked ducts and reduce engorgement, complemented if necessary with the use of analgesics, hot compresses, and antibiotics<sup>10</sup>.

While there have been numerous observational studies of mastitis in developed countries, very little published data are available from developing countries. A prospective cohort study from China<sup>12</sup> reported a 6.3% (N=670) 6 months incidence of mastitis; of which half of the cases occurred in the first four weeks postpartum.

There have been no published cohort studies of the incidence of mastitis in South Asian countries.

While breastfeeding is universally practised in Nepal, continuation of exclusive breastfeeding up to six months remains low (29%)<sup>13</sup>. Support for postpartum breastfeeding problems from trained health personal is rarely available<sup>14</sup>. The existing maternal care programs in Nepal focus on safe childbirth, and the provision of skilled birth attendants<sup>15,16</sup>. The management of lactation problems is not a part of routine postpartum assessment and care<sup>15</sup>. Lactation problems experienced by Nepalese mothers have not been reported previously. The objective of this study; therefore, was to report the incidence, determinants and management of mastitis in the first month postpartum, and its association with breastfeeding outcomes at four and six months postpartum in western Nepal. Findings from this study will be useful to inform and justify future postpartum lactation support programs.

### **Materials and methods**

A prospective cohort study was conducted in the Rupandehi district of western Nepal during January-October, 2014<sup>17</sup>. The district benefits from a plain terrain with relatively good access to hospitals in urban areas, and rural health facilities (health posts and primary health care centers) in rural areas. Briefly, we recruited 735 mothers (rural 378, urban 357) from a total of 15 Village Development Committees in rural areas and 12 communities from urban areas which were randomly selected from a list of communities provided by the local public health office<sup>17</sup>. Lists of eligible mothers were prepared in the selected areas with the help of local female community volunteers, and health facilities. The required numbers of mothers were selected randomly from the lists. The number of mother-infant pairs recruited from each community was proportionate to population size based on the monthly target of expected numbers of infants aged <30 days.

Mothers who were local residents, had living infants, were within one month postpartum, and had a singleton child, were recruited into the study. Mothers were excluded if they were seriously ill, or if they were not a local resident of the selected communities. Participants were followed-up during the fourth (90-120 days) and sixth months (150-180 days) postpartum. Information on infant feeding practices was

collected at baseline and each follow-up visit. Trained female enumerators collected the data using structured questionnaires adapted from the Nepal Demographic and Health Survey <sup>18</sup> and a published study on mastitis <sup>6</sup>. The questionnaires were translated into the Nepali language and pre-tested before being used in the field. The baseline interviews were conducted in the first month (0-30 days) postpartum and information on socio-demographic characteristics and lactation problems was collected at this time.

## **Variables**

The response variable used in this study was the incidence of mastitis in the neonatal period, which was based on self-reported signs and symptoms. We defined mastitis as: at least two breast symptoms (pain, redness or lump) and at least one of the ‘flu-like symptoms’ (fever, shivering/chills, and headache) based on the definition used by Amir et al. <sup>8</sup>. The breastfeeding problems experienced during the neonatal period were recorded as ‘yes’ or ‘no’ responses to prompted questions. Information on mastitis used in this analysis was collected at the baseline interview. Mothers whose infants were in the age group 20-30 days were included for reporting the incidence of mastitis to ensure that most cases of mastitis in the neonatal period were included, and this provided us with a final sample size of 338 (*Figure 1*). We compared the mothers excluded with those included in the analysis and there were no differences in the major demographic characteristics between the two groups, including maternal age, education, type of delivery and parity. We also collected information on the management of mastitis, the sources of advice and advice received. Information on breastfeeding outcomes was collected from all mothers with and without mastitis during the fourth and sixth month postpartum interviews.

The World Health Organization (WHO) breastfeeding definitions were used in this study <sup>19</sup>. Exclusive breastfeeding was defined as ‘breast milk (including expressed milk or from a wet nurse), vitamin or mineral syrups, medicine and oral rehydration salt, and no other liquid or solid food items’. Predominant breastfeeding was defined as ‘breast milk (including milk expressed or from a wet nurse) as the predominant source of nourishment; including certain liquids (water and water-based drinks, fruit juice), ritual fluids and oral rehydration salt, drops or syrups (vitamins, minerals,

medicines) and does not allow anything else (in particular, non-human milk, food-based fluids)'. We used the 'recall-since-birth' method to report exclusive breastfeeding and predominant breastfeeding and not the current breastfeeding status<sup>20</sup>.

The selection of independent variables was based on a literature review of plausible factors associated with lactation mastitis<sup>6, 8, 9, 12</sup>. Independent variables included in the study were maternal age (years) [15-19, 20-29, and 30-45]; maternal education [no education, primary to lower secondary' (up to grade 8), 'secondary' (grade 9-10) and 'higher' (grade 11-12 and university degree)]; and place of delivery [health facility (public hospital, private hospital, clinic, health post, sub-health post, primary health care, birthing centres) and home (home or on the way to health facility)]. Other independent variables included were: prelacteal feeding (yes and no), time of initiation of breastfeeding (within one hour and after one hour), mode of delivery (vaginal and cesarean), and birthweight [low birth weight (<2500 grams) and average or greater ( $\geq 2500$  grams)].

### **Statistical analysis**

Factors associated with mastitis were screened using the chi-square test and those factors significantly associated with the incidence of mastitis were further investigated using multivariable logistic regression<sup>21</sup>, adjusting for the duration of exposure (days since childbirth) using the 'off-set' term in Stata 14. This was deemed necessary in order to adjust for the unequal duration of exposure since childbirth to recruitment among the participants. The stepwise backward elimination method was performed in the logistic regression.

The association between mastitis and exclusive and predominant breastfeeding at four and six month were determined using multivariable logistic regression adjusting for other independent variables (maternal education, maternal age, place of residence, mode of delivery, birth weight, time of initiation of breastfeeding, place of delivery) investigated in the study. We further examined the duration of exclusive breastfeeding using the Kaplan-Meier method. Statistical analyses were performed using the Stata 14 and Statistical Package for Social Sciences, Version 20 (IBM Corporation).

## Results

The mean age of infants at recruitment was 26 days. *Table 1* illustrates the characteristics of participants at baseline (N=338). About a quarter (26.9%) had no education, 47.0% were from poor families, 86.4% delivered in a health facility and 13.6% delivered by cesarean section. All of the mothers were breastfeeding at recruitment, and 31.7% reported providing prelacteal feeds to their newborn infants.

*Table 2* presents the description of breastfeeding problems reported by mothers. A total of 27 (8.0%; 95% confidence interval: 5.1% to 10.8%) mothers reported having at least one episode of mastitis within the neonatal period (*Table 2*). In addition, 9.8% reported cracked nipples and 8.9% reported breast abscess. Findings from logistic regression after accounting for duration of exposure showed that those women who provided prelacteal feeds to their newborn infants (Adjusted odds ratio: 2.76; 95% confidence interval: 1.03 to 7.40), and who had delivered by cesarean section (Adjusted odds ratio: 3.52; 95% confidence interval: 1.09 to 11.42) had higher likelihood of mastitis (*Table 3*).

Mothers were mainly advised to express and empty their breasts (29.6%), continue breastfeeding as usual (25.6%), and to breastfeed more frequently than before (18.5%) showing a strong support towards avoiding milk stasis (*Table 4*). Only one mother was advised to stop breastfeeding, while 3 (11.1%) reported stopping breastfeeding due to mastitis. *Table 4* also presents practices employed by mothers to manage mastitis (n=27), the most common being breastfeeding frequently from the affected breast (55.6%), followed by expressing breast milk (40.7%), and the use of pain killers (22.2%). Doctors and other health workers (35.7%), mothers/mothers-in-law (35.7%), other family members and relatives (35.7%) were the major sources of advice.

Of the 338 mothers, all were breastfeeding at baseline, 326 (99.4%; n=328) were still breastfeeding in the fourth month and 324 (99.0%, n=327) in the sixth month. While 220 (65.1%; N=338) of the mothers breastfed exclusively at baseline, this proportion was reduced to 124 (37.8 %; n= 328) in the fourth month and to 24 (7.3%; n=327) in the sixth month. Three-quarters (254; 75.1%) of the mothers were breastfeeding predominantly at baseline followed by 190 (57.9%) in the fourth month and 45

(13.8%) in the sixth month. The median duration of exclusive breastfeeding (N=338) was 102 days (95 % confidence interval: 95.12 to 108.84 days) with no significant difference (log-rank p-value: 0.358) between the mothers with and without mastitis. *Table 5* shows the breastfeeding outcomes of the groups of mothers with and without mastitis, and shows that the exclusive breastfeeding and predominant breastfeeding rates did not differ significantly among those with and without mastitis. Multivariable logistic regression also confirmed that there was no significant difference in breastfeeding rates at four months (see *table 5*).

## **Discussion**

We found that 8.0% of mothers reported having an episode of mastitis within the first 30 days postpartum in western Nepal. Published studies from Scotland (9.5%)<sup>6</sup> and Australia (9.1%)<sup>8</sup> reported comparable incidence of mastitis when the results from those studies are confined to the first 4 weeks of the postpartum period. Lactation mastitis is relatively common in the first few weeks when breastfeeding is being established and declines thereafter<sup>3</sup>. In our setting, despite a universal practice of breastfeeding, the current rate of lactation mastitis is comparable to developed countries with lower breastfeeding rates, and it justifies the need for lactation support during the postpartum period. However, two major points must be considered when interpreting the incidence of mastitis and comparing rates between studies. Firstly, the reporting periods may differ among the cohort studies which might explain some of the variations in the reported incidence<sup>22</sup>. For instance, Vogel et al.<sup>4</sup> followed a cohort of New Zealand for 12 months and reported that 15.7% of cases experienced their first instance of mastitis when their infant was older than six months. Secondly, we adapted the definition used by Amir et al.<sup>8</sup> of at least two breast symptoms (pain, redness or lump) and at least one of the ‘flu-like symptoms’ (fever, shivering/chills, and headache) whereas, studies in China<sup>12</sup> and Glasgow<sup>6</sup> have used a slightly different definition. While the majority of earlier studies used self-reported symptoms to define mastitis, Foxman et al.<sup>7</sup> reported the incidence of provider-diagnosed mastitis which might account for the relatively low incidence of mastitis 9.5% reported in their study. A study of Scottish women reported that roughly one third of women self-managed their mastitis and did not seek health professional care

for their condition and hence would not have been considered to be cases if a provider-diagnosed definition had been applied <sup>6</sup>.

While Fetherston <sup>2</sup> reported that 18% of the mothers cited mastitis as a reason for cessation of breastfeeding, Amir et al. <sup>8</sup> did not find any significant difference in the duration of breastfeeding, both of these studies were from Australia. In contrast, other groups have found <sup>4,6</sup> that mothers with mastitis tended to breastfeed longer than those who did not experience mastitis. In our study, there was no significant difference in the duration of exclusive breastfeeding between mothers who did and did not experience mastitis, which is an important finding. In Nepal breastfeeding is deemed the best practice <sup>23</sup> and universally practised. The traditional cultural practice of universal breastfeeding, and community and family encouragement and support to continue breastfeeding could have been major factors to continue breastfeeding among the mothers who had mastitis. Our finding demonstrates that the adverse effect of mastitis on breastfeeding practices can be minimized if mothers are encouraged and supported to continue breastfeeding.

This is the first study to report on the methods used by women in Nepal to manage mastitis and the types of professional and lay advice they receive. WHO recommends emptying breast by frequent breastfeeding or expressing <sup>10</sup> and our study found that most of the mothers had received advice to this effect which they were following. However, a small proportion of women had stopped breastfeeding as a result of their mastitis, or had been told to do so, and future lactation promotion programs in Nepal should discourage this practice.

It should be noted that when mothers had mastitis, female elders such as mothers-in-law were as an important a source of advice as health workers. In Nepal, female elders are key to decision-making related to reproductive health <sup>24</sup> and breastfeeding <sup>25</sup>; and this appears to remain the case when mothers have mastitis. Postpartum mothers in Nepal are kept in isolation and are not allowed to leave the home for the first few weeks of childbirth <sup>16</sup> which is when mastitis occurs the most <sup>12</sup>. During this period female elders are the most accessible source of advice and support; they should be a target group for lactation support programs.

We found that mothers who reported providing prelacteal feeds to their newborn infants and who had delivered by cesarean section were more at risk of having an episode of mastitis. These factors are linked to delayed initiation of breastfeeding and, therefore, increased the risk of milk stasis which is a major risk factor for mastitis<sup>10</sup>. Mothers who undergo cesarean section may still be under the effect of anesthesia for many hours after surgery, and are not able to move out of bed. In such circumstances, unless their infant is brought to their bedside, their breasts are not emptied regularly, thereby increasing the risk of milk stasis and breast engorgement<sup>10</sup>. Future lactation support programs should focus on these groups to prevent mastitis.

Our study is the first study reporting the incidence of mastitis from the traditional breastfeeding communities of South Asia. The methodology used in this study reduces the likelihood of recall bias as the information on mastitis was collected within 30 days postpartum. The major limitations of this study resulted from the pragmatic conduct of the study and it being a community-based study. As a result it was not possible to conduct the baseline and follow-up surveys at set-time points in days since childbirth and we had to use a time period to allow reasonable flexibility. Limiting the analysis population to those women with infants aged 20-30 days at baseline resulted in a relatively small sample. While the incidence of mastitis is based on self-reporting of symptoms, and as such might be considered a limitation, it can be argued that provider-diagnosis of mastitis under-estimates the true incidence of mastitis as a sizeable proportion of women self-manage their condition. Moreover, collecting data on mastitis within 30 days postpartum might not capture cases that would occur after that period, leading to under-reporting of the incidence. A small number of observations in certain sub-categories, such as in cesarean delivery, resulted in wide confidence intervals. Future studies with a larger sample of infants recruited within the first few days of birth and with information on mastitis routinely collected at set time points for at least the first six months of life would provide more rigorous information.

Nevertheless, despite these limitations our study has reported an incidence of mastitis in the first month postpartum which is remarkably consistent with the findings of studies in developed countries suggesting that this is a relatively common condition

even in societies which promote traditional breastfeeding practices. To our knowledge it is the first study to report the incidence of mastitis in South Asian countries and has identified vulnerable groups that need further support to prevent mastitis. Mothers with mastitis should receive supportive counseling on proper attachment positions, instructed how to effectively remove breastmilk via frequent breastfeeding and breastfeeding on demand, and if symptoms persist provided with antibiotic therapy<sup>10</sup>. The current postpartum care guidelines in Nepal should include the management of mastitis and lactation support.

## **Conclusion**

Our study reported that roughly one in ten mothers experienced mastitis in the first month postpartum. Mastitis did not have a significant adverse effect on the duration of exclusive breastfeeding and the rates of predominant and any breastfeeding rates at four and six months. Nevertheless, mastitis is a painful but preventable condition, and health workers should provide support to mothers to prevent and manage mastitis appropriately. The maternal health programs of Nepal should include screening for and management of lactation problems during the postpartum period as a routine maternal care practice.

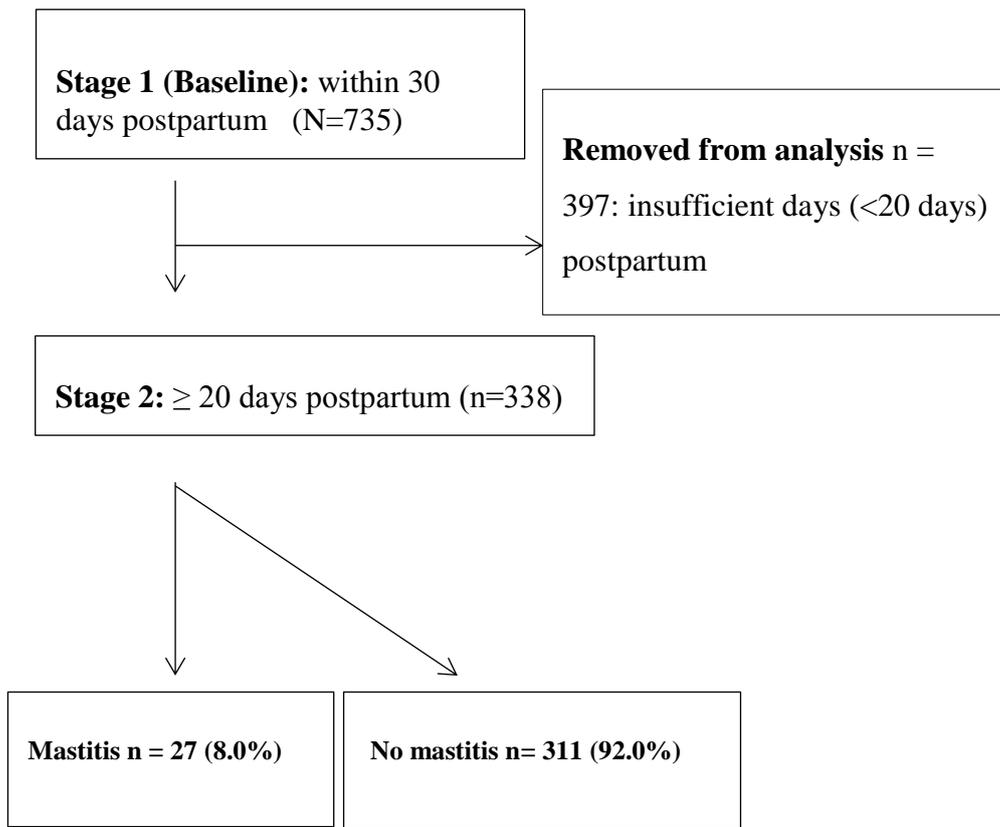
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**Figure1. Flow chart of cohort study**



## Tables

**Table 1. Incidence of mastitis by participant characteristics, Nepal, 2014 (N=338)**

<b>Characteristic</b>	<b>Frequency (%)</b> N=338	<b>Mastitis (%)</b> n=27	<b>P</b>
<b>Maternal age<sup>#</sup> (years)</b>			0.039
15-19	30 (8.8)	6 (20.0)	
20-29	252 (74.6)	17 (6.7)	
30-45	56 (16.6)	4 (7.1)	
<b>Maternal education</b>			0.006
No education	91 (26.9)	2 (2.2)	
Primary to lower secondary	122 (36.1)	8 (6.6)	
Secondary	55 (16.3)	5 (9.1)	
Higher	70 (20.7)	12 (17.1)	
<b>Place of residence</b>			0.344
Rural	192 (56.8)	13 (6.8)	
Urban	146 (43.2)	14 (9.6)	
<b>Place of delivery</b>			N/A
Home	46 (13.6)	2 (4.3)	
Health facility	292 (86.4)	25 (8.6)	
<b>Mode of delivery</b>			<0.001
Vaginal	292 (86.4)	17 (5.8)	
Cesarean	46 (13.6)	10 (21.7)	
<b>Time of initiation of firstbreastfeeding<sup>#</sup></b>			0.798
After one hour	198 (58.8)	17 (8.3)	
Within first one hour	133 (40.2)	10 (7.5)	
<b>Prelacteal feeding</b>			0.019
No	231 (68.3)	13 (5.6%)	

Yes	107 (31.7)	14 (13.1)	
<b>Birth weight<sup>#</sup></b>			N/A
Low birth weight (<2500 grams)	46 (14.8)	1 (2.2)	
Average or greater (≥2500 grams)	234 (85.2)	23 (8.7)	

*P: from Chi-square test of association with mastitis. <sup>#</sup> missing data present. N/A: not applicable due to small sample size.*

**Table 2. Lactation problems within the first month postpartum, Nepal, 2014 (N=338)**

<b>Problems</b>	<b>Frequency (%)</b>
Cracked or sore nipple	33 (9.8)
Breast abscess (wound )	30 (8.9)
Mastitis	27 (8.0)
Red*	29 (8.6)
Pain*	95 (28.1)
Lump*	18 (5.3)
Fever *	57 (16.9)
Shivering/chills*	47 (13.9)
Headache/body ache*	92 (27.2)

*\*Signs and symptoms of mastitis. Mastitis was defined as: at least two breast symptoms (pain, redness or lump) and at least one of the flu-like symptoms (fever, shivering/chills, headache)*

**Table 3. Factors associated with mastitis, Nepal, 2014**

<b>Factors</b>	<b>Crude odds ratio 95% confidence interval</b>	<b>Adjusted odds ratio 95% confidence interval</b>
Prelacteal feeding	P=0.02	P=0.05
No	1.00	1.00
Yes	2.08 (0.90, 4.78)	2.76 (1.03, 7.40)
Mode of delivery	P=0.003	P=0.04
Vaginal	1.00	1.00
Cesarean	4.01 (1.58, 10.18)	3.52 (1.09, 11.42)

*Variables excluded: maternal age, maternal education. Time of interview was used as the measure of exposure.*

**Table 4. Advice received and methods used by mothers to manage mastitis (n=27)**

<b>Response</b>	<b>Frequency (%)</b>
Advice received*	
Express breast milk and empty breasts	8 (29.6)
Continue breastfeeding as usual	7 (25.6)
Breastfeeding more frequently than before	5 (18.5)
Take medicine	3 (11.1)
Use home medicines	2 (7.4)
Stop breastfeeding	1 (3.7)
Methods *	
Breastfeeding frequently from affected breast	15 (55.6)
Expressing breast milk	11 (40.7)
Use of pain killers	6 (22.2)
Massaging affected breast before breastfeeding	6 (22.2)
Hot compress before and after breastfeeding	5 (18.5)
Stopped breastfeeding	3 (11.1)
Started weaning	3 (11.1)
Use of antibiotics <sup>#</sup>	1 (3.7)

*\*multiple responses allowed.<sup>#</sup> Patients can buy antibiotics without any prescription in Nepal.*

**Table 5. Association between mastitis and breastfeeding outcomes, Nepal, 2014**

Breastfeeding practices	Breastfeeding outcome		Adjusted odds ratio*#	P
	Yes (%)	No (%)		
<b>Exclusive breastfeeding in 4<sup>th</sup> month (n=328)</b>				
Mastitis (n=27)	6 (4.8)	21 (10.3)	0.47 (0.15, 1.50)	0.204
No mastitis (n=301)	118 (95.2)	183 (89.7)	1.00	
<b>Exclusive breastfeeding in 6<sup>th</sup> month (n=327)</b>				
Mastitis (n=27)	0 (0.0)	27 (8.9)	N/A	
No mastitis (n=300)	24 (100.0)	276 (91.1)		
<b>Predominant breastfeeding in 4<sup>th</sup> month (n=328)</b>				
Mastitis (n=27)	11 (5.8)	16 (11.6)	0.66 (0.25, 1.75)	0.399
No mastitis (n=301)	179 (94.2)	122 (88.4)	1.00	
<b>Predominant breastfeeding in 6<sup>th</sup> month (n=327)</b>				
Mastitis (n=27)	2 (4.4)	25 (8.9)	N/A	
No mastitis (n=300)	43 (95.6)	257 (91.1)		
<b>Any breastfeeding in 4<sup>th</sup> month (n=328)</b>				
Mastitis (n=27)	27 (8.3)	0 (0.0)	N/A	
No mastitis (n=301)	299 (91.7)	2 (100.0)		
<b>Any breastfeeding in 6<sup>th</sup> month (n=327)</b>				
Mastitis (n=27)	26 (8.0)	1 (33.3)	N/A	
No mastitis (n=300)	298 (92.0)	2 (66.7)		

*Note: each row presents the result from logistic regression. N/A: not applicable due to small numbers. \*Adjusted for: maternal education, maternal age, place of residence, mode of delivery, birth weight, time of initiation of breastfeeding, place of delivery. P: p-value*

## **CHAPTER 5 SUMMARY, LIMITATIONS AND RECOMMENDATIONS**

### **5.1 Summary of findings**

The most important findings of the study are summarised in this section:

#### **5.1.1 Early initiation of breastfeeding**

It was found that only four in every 10 (42.2%) mothers had initiated breastfeeding to their newborn infants within one hour of childbirth (objective 2). A number of factors were found to be associated with initiation of breastfeeding within hour after childbirth (objective 5). Having childbirth attended by traditional birth attendants, delivery by caesarean section and low birth weight of infants were associated with lower likelihood of early initiation. Mothers from the poorest families and “not introducing any prelacteal feeds” were associated with increased rates of early initiation (sub-sections 4.3 and 4.6.1)

#### **5.1.2 Prelacteal feeding**

About one-third (30.6%) of the mothers had introduced prelacteal feeds to their newborn infants (objective 3). Infant formula (41.7%) was the most common prelacteal feeds followed by animal milk (26.6%). Mothers who were in their higher parity, who had an infant with low birth weight, who had caesarean delivery and who were from wealthy families were more likely to provide prelacteal feeds to their newborn infants (objective 6; sub-section: 4.3 and 4.6.2).

#### **5.1.3 Any and exclusive breastfeeding rates**

Breastfeeding rates were almost universal during the first, fourth and sixth months (objective: 1). Rates of exclusive breastfeeding rapidly changed with increasing infant age. The rate of exclusive breastfeeding was 66.3% during the first month and decreased rapidly to 39.2% during the fourth month and to 8.9% during the sixth month (objective 1; sub-section: 4.4).

The median duration of exclusive breastfeeding among mothers who received ‘high intensity’ breastfeeding promotion message (median: 108.0, 95% CI: 100.8 to 115.2 days) was significantly higher (p-value= 0.017) than those receiving ‘low to medium intensity’ support (median: 94.0, 95% CI: 90.1 to 97.9 days) (objective: 4). The postpartum breastfeeding promotion was significantly associated with longer duration of exclusive breastfeeding (objective 7; sub-section:4.4 and 4.6.3). While, breastfeeding on demand and not to provide pacifier or teats were significant in the final model, there was also a dose-response relationship with increasing number of breastfeeding promotion messages given to mothers and duration of exclusive breastfeeding.

#### **5.1.4 Mastitis**

The incidence of lactation mastitis during the neonatal period was 8.0% (objective 8). Factors that were likely to contribute to milk stasis such prelacteal feeding and caesarean delivery were associated with higher likelihood of mastitis (objective 9).

Maternal pain or discomfort is a major concern of mastitis; as it may affect mothers’ capacity to sustain breastfeeding. In this study, we did not find any association between discontinuation of exclusive breastfeeding and mastitis during the neonatal period (objective 10; sub-section: 4.5 and 4.6.4).

#### **5.1.5 Limitations of current study**

There are some limitations that need to be considered when interpreting the results of this present study. The study included only one district of Nepal. The postpartum experience of mothers from this district might differ from other regions of the country and therefore, the breastfeeding rates might also vary. In relation to breastfeeding promotion education, the study did not record whether each mothers translated the breastfeeding advices into practice. The small sample of infants who were in the exclusive breastfeeding category might have reduced the power of the study in this outcome variable. In addition, this study did not collect information on whether mothers received other breastfeeding promotion materials or support from other sources such as peers or female community health volunteers.

Data collected during the first, fourth and sixth months. It was not possible to collect data more frequently due to resource and time constraints. Collecting data more frequently using telephone was not feasible as the telephone service is not available in most of the rural areas, and post-partum mothers do not use telephones consistently. In many instances, the telephones batteries would lose their charges due to lack of electricity cuts of about 12-hours-a-day. Follow-up after the sixth month was also not feasible due to time constraints.

A further limitation includes not having double entry of data. This might have led into the some degree of data entry error. However, meticulous monitoring of data sets by experienced supervisors have minimised the chances of error related to this problem.

There are also few limitations related to the reporting of mastitis. The incidence of mastitis was based on self-reports, and a diagnosis was made by the researcher using the criteria in chapter 1. Also, limiting the sub-sample to 21-29 days might have resulted in under-reporting of the incidence that occurred after that period. Data on mastitis was collected in the second interview, but could not be reported with confidence due to inconsistent reporting and was removed from the analysis. Due to the small number of observations in few variables and categories, the confidence intervals were large with less precision in the estimates.

## **5.2 Recommendations**

### **5.2.1 Implications for health promotion programmes**

Assistance of health workers during childbirth, and health promotion messages given to postpartum mothers after childbirth, were found to be significantly associated with higher likelihood of timely initiation and exclusive breastfeeding. Therefore, the capacity building of health workers to teach mothers with necessary lactation skills may be of higher impact in settings similar to Nepal where skilled birth attendance are increasing and health workers are getting more chances to educate the post-partum mothers with relevant messages. In the future, making such support and health advice a part of routine postpartum care in tertiary maternity hospitals, rural

birthing centres and home deliveries assisted by skilled birth attendants would be helpful in increasing breastfeeding initiation rates to a universal level.

Caesarean section has remained the most significant barrier to breastfeeding in this setting. Mothers should be provided with support on initiating, establishing and continuation of breastfeeding after caesarean section. In other countries, caesarean section is undertaken under regional anaesthesia, and as the mother remains conscious, it facilitates early initiation of breastfeeding. In Nepal, this would mean a change in obstetric practice and a change in cultural beliefs about the need for mothers to completely rest after operative delivery. In addition, development and distribution of a lactation support booklet to mothers who undergo caesarean sections may be useful to establish and sustain breastfeeding practices.

If mothers are not supported in establishing breastfeeding, formula milk is readily available and is as prelacteal feeds in this study setting. Although no study has documented nurses' skills to support mothers for breastfeeding after caesarean delivery in Nepal, anecdotal evidence supports the view that mothers are told to breastfeed but are rarely given the support they need. Therefore, support of these mothers should be the highest priority in hospitals with caesarean delivery facilities.

There is also a lack of education related to discouraging prelacteal feeding and their harmful effects (see the educational material in paper 2). Future breastfeeding promotion and support programmes should discourage prelacteal feeding and including information on harmful effects associated with it. Given that Nepal has a higher burden of infection-related neonatal mortality and diarrhoeal incidence, such findings will help design prevention strategies to improve newborn survival.

This study found that delivering messages that conformed to the BFHI, the “ten steps of successful breastfeeding”, were helpful in increasing the rates of exclusive breastfeeding. This finding has a major implication for breastfeeding promotion in Nepal. The government of Nepal has been putting resources into increasing skilled birth attendants and in the future, a majority of mothers are likely to be assisted by skilled birth attendants during childbirth. Scaling up of the “ten steps to successful breastfeeding” to community level health facilities such as birthing centres, is likely to have a positive impact on breastfeeding in Nepal.

There are a few more recommendations specific to infant feeding practices. The vulnerable groups identified for prelacteal feeds were low birthweight infants, high parity and wealthier families. Promotion programmes could be focussed on these groups. Breastfeeding promotion materials should highlight on the many short and long-term benefits of breastmilk.

Attendance of traditional birth attendants was found to be associated with delayed initiation of breastfeeding. On the other hand, education and support from skilled birth attendants that support BFHI components were associated with a longer duration of exclusive breastfeeding. Therefore, the existing focus on the assistance of skilled birth attendants needs to be continued and their skills upgraded. Given the presence of 24 hours a day birthing centres in Nepal that serve rural areas, skill building of the nurses in these facilities is likely to have a positive impact on breastfeeding outcomes. Existing networks of female community volunteers would be helpful in identifying and educating the traditional birth attendants in the communities and health workers can actively support such a process.

In Nepalese cultures, there is a practice of isolating the newborn baby and postpartum mothers for about two weeks in order to protect them from “evil eyes and witchcraft”. In this period, access to the mother-infant dyad is restricted to outsiders. During this period, mothers are not allowed to go outside and therefore, they have limited access to any skilled care that is needed. This study found that senior women and mothers-in-law were a major source of advice during mastitis. Therefore, breastfeeding promotion programmes should also educate and counsel the senior women who give advice about infant feeding practices and the management of breastfeeding problems. Promotion of appropriate practices would help in sustaining the cultural preference of breastfeeding in this setting, and also promote recommended feeding practices and give support to lactating mothers.

Furthermore, the current findings can also help revise existing guidelines in Nepal. A greater focus on counselling across all maternal and child health programmes must have breastfeeding support as an integral part. Lactation support training, as part of pre-service and on-the-job training for nurses to support mothers who have caesarean sections, is essential. Management skills to doctors, and nurses for lactation mastitis

which remains neglected in existing programs which must be included in revised guidelines.

### **5.2.3 Implications for future research**

A search of literature confirms this study is only the second to report breastfeeding rates for months in Nepal using a cohort study design. Further study should focus on other regions in the country to report the status from other parts of the country. In such studies, frequent data collection, and longer duration of follow-up may help develop a more rigorous understanding of the duration and influencing factors of exclusive breastfeeding.

It is of concern that the difference in the rates of exclusive breastfeeding found in the literature review may be due to different definitions used in the measurement of breastfeeding rates. Many studies have asked about infant feeding in the previous 24 hours and assumed that this was applicable since birth. When reporting breastfeeding rates for six months, future research should report life-long data ( the recall-since-birth method) to estimate the rate of exclusive breastfeeding for six months(Greiner, 2014). Well-designed cohort studies taking repeated measurements are needed for monitoring purposes. Although the use of 24-hour reporting using cross-sectional samples is the easiest method for studies, the measurement has to be interpreted as '24 hour prevalence' instead of breastfeeding rates for six months. While the recall-since-birth method is more resource intensive, some sentinel sites can be established to represent the country, and prospective data can be collected periodically from these chosen sites to measure the rates of exclusive breastfeeding in Nepal. While this study reported the incidence of mastitis for the first time in South-Asia, research with a larger sample population, including different geographical areas and longer duration of follow-up, might provide stronger evidence.

While a third of the infants were provided with prelacteal feeds and Nepal has a high neonatal and infant mortality, no study has investigated the impact of prelacteal feeds on neonatal diarrhoea, neonatal infections and necrotising enterocolitis. Future research is required to investigate this aspect and the findings will be helpful in improving newborn survival programmes.

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## **APPENDICES**

**Appendix 1:** STROBE Statement—checklist of items that should be included in reports of observational studies

**Appendix 2:** Summary of exclusive breastfeeding studies and reported statistics in four South Asian countries, 2000-2015

**Appendix 3:** Methodological differences in measuring rates of exclusive breastfeeding in Nepal (Manuscript under review)

**Appendix 4:** The supplemental use of infant formula in the context of universal breastfeeding practices in Western Nepal ( Published)

**Appendix 5:** Ethics approval: Curtin University

**Appendix 6:** Ethics approval: Nepal Health Research Council

**Appendix 7:** Consent form

**Appendix 8:** Questionnaires (English version)

**Appendix 9:** Author contribution form

**Appendix 10:** Oral and poster presentation from the PhD project

**Appendix 1: STROBE Statement—checklist of items that should be included in reports of observational studies**

	<b>Item No.</b>	<b>Recommendation</b>	<b>Page No.</b>	<b>Relevant text from thesis</b>
<b>Title and abstract</b>	1	(a) Indicate the study’s design with a commonly used term in the title or the abstract	Title page	
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	V	
<b>Introduction</b>				
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	10-11	
Objectives	3	State specific objectives, including any prespecified hypotheses	9-10	
<b>Methods</b>				
Study design	4	Present key elements of study design early in the paper	69-73	
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment,	65-72	

		exposure, follow-up, and data collection		
Participants	6	<p>(a) <i>Cohort study</i>—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up</p> <p><i>Case-control study</i>—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls</p> <p><i>Cross-sectional study</i>—Give the eligibility criteria, and the sources and methods of selection of participants</p>	69-72	
		<p>(b) <i>Cohort study</i>—For matched studies, give matching criteria and number of exposed and unexposed</p> <p><i>Case-control study</i>—For matched studies, give matching criteria and the number of controls per case</p>	N/A	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	13-14	
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one	13-16	

		group		
Bias	9	Describe any efforts to address potential sources of bias	177-178	
Study size	10	Explain how the study size was arrived at	69	

Continued on next page

Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	74-76	
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	74-76	
		(b) Describe any methods used to examine subgroups and interactions	136-137, 158-159	
		(c) Explain how missing data were addressed	74-76	
		(d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed	74-76	

		<p><i>Case-control study</i>—If applicable, explain how matching of cases and controls was addressed</p> <p><i>Cross-sectional study</i>—If applicable, describe analytical methods taking account of sampling strategy</p>		
		(e) Describe any sensitivity analyses	N/A	
<b>Results</b>				
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	77	
		(b) Give reasons for non-participation at each stage	77	
		(c) Consider use of a flow diagram		
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	78	

		(b) Indicate number of participants with missing data for each variable of interest	77, 79	
		(c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	77	
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time	78-81	
		<i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure	N/A	
		<i>Cross-sectional study</i> —Report numbers of outcome events or summary measures	N/A	
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	91, 96-98, 130, 151- 153, 172, 174-175	
		(b) Report category boundaries when continuous variables were categorized	14-15	
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a	N/A	

		meaningful time period		
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	136-138, 157-160	
<b>Discussion</b>				
Key results	18	Summarise key results with reference to study objectives	176-177	
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	177-178	
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	176-178,	
Generalisability	21	Discuss the generalisability (external validity) of the study results	177-178	
<b>Other information</b>				
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	N/A	

\*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at [www.strobe-statement.org](http://www.strobe-statement.org).

**Appendix 2: Summary of exclusive breastfeeding (EBF) study and reported statistics in four South Asian countries, 2000-2015**

<b>Country</b>	<b>Author, Date</b>	<b>Study design</b>	<b>Definition of EBF used</b>	<b>Rate</b>	<b>Age of infant</b>	<b>Indicator measure</b>
<b>Nepal</b>						
	Chandrashekhar et al. (2007)	Cross-sectional (n=385)	The mother reporting that nothing else (except medicine) but breast milk was being given from birth till the time of the interview	82.3%	<2 months	From birth till the time of the interview
	Subba et al. (2007)	Cross-sectional (n=168)	Not reported	60.5%	Exclusive breastfeeding at 5 months	Not clear from methods. Reported as EBF at 5 months
	Pandey et al.	Cross-sectional	WHO definition	53.1%	0-5 month	24-recall

(2010)	(n=478)				
	NDHS 2006				
Subedi et al. (2012)	Cross-sectional (n=261)	WHO definition	81.6%	6-23 months	Recall at 6-23 month
Ulak et al.(2012)	Cross-sectional(n=325)	Only breast milk from his/hermother or a wet nurse, or expressed breast milk and noother liquids or solids with the exception of drops of syrup consisting of vitamins, mineral supplements or medicines	At one month: 74% At three month: 78% At six month: 9%	Recall at 9 months	Retrospective recall
Khanal et al.	Cross-sectional	WHO definition	53.2% in 2006,	0-5 months	24hour recall

(2013)	NDHS (2006 and 2011: n=482 & n=227)		66.3% in 2011		
Locks et al. (2013)	cross-sectional (subset of randomised control trial) (n=750)	Not reported	65%	0-5 months	24 hour recall
Karkee et al. (2014a)	Cohort (n=639)	The infant being given breastmilk only without any other feeds (aside room medications) since birth	At 4 weeks: 84.4% At 12 weeks: 67.2% At 22 weeks: 29.7%	Birth through six month	Recall since birth

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**Banglade**

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Haider et al. (2000)	Randomised controlled trail (n=312)	Only breastmilk (including medicines, vitamins, and oral rehydration solution)	70% among intervention group; 6% control group in 5 <sup>th</sup> month	Within 72hr of birth followed up through 5 <sup>th</sup> month	Recall since birth, ‘Mother was then asked if she had fed her baby anything other than breastmilk’.
Roy et al. (2002)	Cross-sectional (n=326)	If given only breastmilk (no other liquid or solid up to six months of age)	12.3% middle SES group	6-12 months infant	Information on infant- carefully taken at the beginning of interview, then at sixth month mothers recall
Mihrshahi et al. (2007)	Cross-sectional (n=1633)	WHO definition	Only 34.5% were being exclusively breastfed (prelacteal feeding included)  If the WHO definition of exclusive	0-3 months	Not allowing for prelacteal feeding, the ‘true’ rate of exclusive breastfeeding.

breastfeeding is used,  
 only 192 (11.7%)  
 children were  
 exclusively breastfed  
 at the time of  
 interview

Eneroth et al. (2009)	Prospective data from a clinical trial	WHO definition	7.0% for 180-days	Birth to six months	Data collected every 15-d: recall since birth.
Zongrone et al. (2012)	Cross-sectional  Bangladesh Demographic and Health Survey 2007(n= 2,096)	WHO definition	36.05%	0-5 months	24 hour recall

Islam et al. (2013)	Cross-sectional study (n=510)	Not reported	45%	0-24 months	Not reported
Muhammad (2013)	Cross-sectional Bangladesh Demographic and Health Survey	WHO definition	36.1%: 2004; 64.1%: 2011;	0-5 months	24 hour recall
Joshi et al. (2014)	Cross-sectional study (n=121)	WHO definition	36%	0-5 months	24 hour recall
Akhtaruzzaman et al. (2015)	Cross-sectional (n=128)	Not reported	31%	For six months	Not reported
Yu et al. (2015)	Prospective cohort study	WHO definition	45.2%	At 3 months	24 hour recall

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(n=2,178)

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**India**

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Chudasama et al. (2009)	Cross-sectional (n=498)	Proposed by WHO [12]: exclusive breastfeeding as when child is fed exclusively on human milk; predominant breastfeeding when child is fed on human milk and other liquids like water, tea, juices; general breastfeeding when all kind of milk, liquid and semisolid diet is given	37% at 6 months	0-11 month	Not reported.
Bagul & Supare	Cross-sectional	Not reported	36.84% for six months	Children below 1 year	Not reported

(2012)	(n=384)			of age	
Karande & Perkar (2012)	Cross-sectional (n= 238)	Not reported	34.9% for 4-6 months	6-12 months	Retrospective recall
Mahmood et al. (2012)	Cross-sectional study (n=123)	WHO definition	77.2%	0-11 month	Not reported
Meshram et al. (2012)	Cross-sectional (n=805)	Infants who had not taken anything including water except breast milk, syrup and vitamin solutions	46% at 5 months age	<3 year children	Not reported
Khan et al. (2012)	Cross - sectional (n=1 56)	WHO definition	57.0% among < 6 months	<6 months	24 hour recall
Suresh et al.	Cohort study	Not reported	69.5%	At 6 months	Not reported

(2014)	(n=400)					
Menon et al. (2015)	Cross-sectional (DHS 2005- 06)	WHO definition	42%		0-5 months	24 hour recall

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**Pakistan**

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Ali (2011)	Cross-sectional (n=200)	No drinking water or herbal water or any other fluids/feeds having been given to the infant within the first 6 months since birth or the time limit noted	54%		0-6 months	Not reported.
Hanif (2011)	Cross-sectional  (DHS surveys:	WHO definition	37.1%	(2006-2007)	0-5 months	24 hour recall

DHS 2001-  
2002; 2005-  
2006; )

Hazir et al. (2013)	Cross-sectional	WHO definition	37.1%	0-5 months	24- h recall
	(DHS 2006- 2007) (n=955)				

**Appendix 3: Methodological differences in measuring rates of exclusive breastfeeding in Nepal (Manuscript under review)**

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## **ABSTRACT**

**Background:** Regular support, correct measurement and continuous monitoring of exclusive breastfeeding are essential to promote exclusive breastfeeding. Measuring exclusive breastfeeding is a complex issue as rates can vary according to the definition, measurement period, questions asked, and infant's age. This article reviewed the methodology of reporting exclusive breastfeeding in Nepal, and compared exclusive breastfeeding rates using data from a cohort study undertaken in western Nepal.

**Methods:** A literature review was first conducted on studies published during 2000-2014. In our cohort study, 735 mother-infant pairs were recruited within the first month postpartum and followed up during the fourth and sixth months.

**Results:** The majority of studies in Nepal, including national surveys, used the World Health Organization (WHO) recommended definition (only breastmilk with the exception of medicine and vitamin syrup), and the most common measurement period was a 24-h recall. Our data demonstrated that the exclusive breastfeeding rate during the sixth month was 8.9% using the recall-since-birth method but was 18.7% using the 24-h recall method. Substantial differences in rates were also found during the first (66.3% vs 83.9%) and fourth months (39.2% vs 61.1%).

**Conclusion:** We found that the recent studies reporting exclusive breastfeeding in Nepal varied considerably in methodology. The most commonly used measurement, the 24-h recall, leads to over-estimation of the prevalence of exclusive breastfeeding when compared to the recall-since-birth method. A common standard of reporting exclusive breastfeeding is clearly needed for evidence-based decision making.

**Keywords:** Cohort studies, Exclusive breastfeeding rate, Infant feeding, Nepal, Review

## INTRODUCTION

Exclusive breastfeeding offers many short and long-term health and nutrition benefits. In the short term, it is the best source of nutrition, and supports optimum growth and development of the infant [1]. In the long term, exclusive breastfeeding is likely to protect from obesity, type-2 diabetes, and is associated with increased intelligence quotient scores [2]. Introduction of complementary foods before six months has also been found to be associated with increased risk of allergy [3]. Exclusive breastfeeding impacts on the infant gut microbiome which in turn may contribute to the programming of infant metabolism and immune function [4]. In low and middle income countries where supply of clean water is limited and hygiene of the mother and child is poor, substituting breastmilk with other fluids or food is likely to introduce pathogens resulting in infection- related infant mortality and morbidity [5]. Furthermore, the introduction of other fluids and foods reduces the frequency of breastfeeding and contributes to reduced milk production, ultimately affecting milk supply (Kent, 2007). It was estimated in 2008 that sub-optimal breastfeeding was responsible for a total of 11.6% child deaths in the low and middle income countries [6].

The World Health Organization (WHO) *Comprehensive implementation plan on maternal, infant and young child nutrition* was endorsed by the Sixty-fifth World Health Assembly in 2012[7]. This plan identified six global targets related to nutrition conditions that are responsible for a large burden of nutrition-related morbidity and mortality from conception through the first two years of life. Global target 5 was by 2025, to increase the rate of exclusive breastfeeding in the first six months up to at least 50% from the estimated 37% for the period 2006-2010. ‘This would involve a 2.3% relative increase per year and would lead to approximately 10 million more children being exclusively breastfed until six months of age’ [7, p. 9]. To measure the progress of member states in achieving this target it is essential to monitor the practice of exclusive breastfeeding regularly and consistently.

Measuring exclusive breastfeeding however, is a complex issue because the rate can vary with respect to the recall duration, questions asked, age of infant and definition adopted [8-10]. WHO originally defined exclusive breastfeeding as ‘infant has

received only breastmilk from his/her mother or wet nurse, or expressed breastmilk, and no other liquids or solids with the exception of drops or syrups consisting of vitamins, mineral supplements or medicine' [11]. In 2007, this definition was modified to allow a child to receive oral rehydration salts [12]. However, this strict definition of exclusive breastfeeding often is not applied in studies which purport to report levels of exclusive breastfeeding [8, 10, 13], making it difficult to compare the findings of studies both within and between countries.

One of the major issues with measuring exclusive breastfeeding is accounting for prelacteal feeding, which is common practice in countries in South Asia, [14, 15] where babies may receive prelacteal feeds for the first few days of life but after which mothers typically revert to exclusive breastfeeding for several months at least. However, accounting for prelacteal feeding is essential for some purposes due to possible infections in early infancy and the loss of the gut priming effect of colostrum as the first feed [4]. Nevertheless, including prelacteal feeding would dramatically reduce the exclusive breastfeeding rate since birth and suggest that a large proportion of infants had never been exclusively breastfed. [10].

The prevalence of exclusive breastfeeding also can vary widely depending on the indicator measure used. The indicator favoured by the WHO employs the 24-h recall methodology to determine the proportion of infants 0-5 months of age who received only breastmilk during the previous day [12]. This method has been adopted in countries where capacity and resources are limited and used in household surveys such as the Demographic and Health Surveys [16]. The 24-h recall method can lead to over-estimation due to its inability to capture prelacteal feeding and intermittent use of complementary feeds. That is, infants who only received breastmilk the previous day may have received other foods before that time [17]. On the other hand, measurements based on recall-since-birth can be affected by recall error. For instance, while maternal recall of initiation and duration of breastfeeding is generally valid and reliable over a short period ( $\leq 3$  yrs), recall of the age of introduction of other foods and fluids is less reliable [18]. Therefore, duration of exclusive breastfeeding is best measured prospectively using cohort methodology with short recall intervals [19, 20]. Binns et al. [20] reported wide discrepancies in the rates of exclusive breastfeeding in China and Japan when the results of national and regional

cross-sectional surveys which predominantly used the 24-h recall method were compared with data prospectively collected in separate studies using the recall-since-birth method. However, comparison of exclusive breastfeeding rates between the two methods using the same data source is rarely made. Significant differences between the two methods of more than 40 percentage points at two and four months of age were first observed in a study conducted in Sweden [17]. To our knowledge however, there has only been one report of a comparison study from a South Asian country reported in 2009 [21].

One of the strategies to reduce under nutrition in Nepal is promotion of exclusive breastfeeding for the first 6 months [22]. Monitoring of the success of this strategy requires surveillance data on exclusive breastfeeding ‘for six months’. However, the current knowledge of exclusive breastfeeding in Nepal is based almost entirely on cross-sectional studies [23-25] which likely overestimate the true rate of exclusive breastfeeding. The only study that has reported exclusive breastfeeding using prospectively collected data was from the Kaski district of Nepal [26]. To date, there has been no study that specifically addressed issues such as definition of exclusivity, duration of measurement, and age composition of infants, all of which can contribute to the reported rate variations in Nepal and the South Asian region. Further research to critically analyse the existing breastfeeding studies is deemed necessary for accurate monitoring and appropriate reporting of such data in the future. Such critical appraisal would also inform future breastfeeding research in Nepal and other countries in South Asia. The objectives of this study are: (1) to review the definitions and methods of reporting exclusive breastfeeding in Nepal used during the period 2000-2014; and (2) assess the magnitude of differences in exclusive breastfeeding rates between the 24-h recall and recall-since-birth methods using a single data set from a prospective cohort study undertaken recently in western Nepal.

## METHODS

Our paper presents findings from two different methods; a literature review and a large community-based prospective cohort study. Firstly, we conducted a literature review using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Guidelines [27]. A comprehensive literature search was conducted in PubMed, the Cumulative Index to Nursing and Allied Health Literature, and Web of Science databases, with key words ‘breastfeeding’, ‘breast-feeding’ or ‘breast feeding’ or ‘infant feeding’, and ‘Nepal’. Inclusion criteria were: (1) articles published during 2000-2014; (2) reporting exclusive breastfeeding; (3) study conducted in Nepal; and (4) published in the English language. We excluded those articles reporting qualitative findings, but included data sources which are the major policy informing tools in Nepal, namely: (1) Nepal Demographic and Health Surveys (NDHS 2001, 2002, and 2011); and (2) Multiple Indicator Cluster Survey (MICS) [28]. In addition, we performed a manual reference search of identified articles. *Figure 1* describes the process of selecting the articles for the review.

Secondly, we used data from a prospective cohort study of infant feeding practices conducted during January-October 2014 in the Rupandehi district of western Nepal. This district is located in the south-western plain areas (Terai) of Nepal bordering India in the south. The methodology of this study has been described previously [29, 30] but briefly 735 mother-infant pairs (rural 378, urban 357) were randomly recruited from 15 rural and 12 urban locations. Mothers were recruited from their communities within 30 days of giving birth and followed up during the fourth (90-120 days) and sixth months (150-180 days). The main outcome, exclusive breastfeeding, allowed breastmilk, vitamin or mineral syrups, medicine and oral rehydration salt, but no other liquid or solid/semi-solid food, in accordance with the current WHO definition [12]. We used two methods (24-h recall and recall-since-birth) to estimate the rate of exclusive breastfeeding during the first, fourth, and six months after delivery. For the recall-since-birth method, information was obtained based on recall-since-birth at the first interview, and recall-since-the last interview during the fourth month and sixth month interviews. Information was collected through a questionnaire adapted from the NDHS [23] and a former cohort study [26] which were in accordance with the WHO’s *Indicators for assessing infant and young*

*child feeding practices part 2: measurement* [31]. Pre-testing was done and only a few minor changes were needed to make our questionnaire understandable in our study setting. Mothers were prompted with a list of food items. Ethics approval was obtained from the Human Research Ethics Committee of Curtin University (HR 184/2013) and the Nepal Health Research Council. Mothers provided consent for themselves and their infants, and personal identifiers were removed before analysis.

## **RESULTS**

### **Selection of studies in the review**

Our literature review found only 9 articles which reported exclusive breastfeeding in Nepal. In addition, three NDHS, and one MICS were subsequently included. On reviewing the articles in full, it was found that two studies [32, 33] had analysed the same dataset and used the same methods (e.g. indicator measure and definitions) as in the NDHS 2006 [25] therefore, these papers were removed from the review leaving 11 studies (*Figure 1*). Of these 11 studies, 10 used unique datasets and one used the NDHS 2006 and 2011 but analysed the data differently from the original NDHS 2006 report using the WHO 2007 definition of exclusive breastfeeding. Only one of them was a cohort study [26] and the rest were cross-sectional studies.

### **Definitions used in measuring exclusive breastfeeding**

Four national surveys (NDHS and MICS) [23-25, 28], one secondary analysis of NDHS 2006 and 2011 [34], and two other studies [35, 36] followed the WHO definition of exclusive breastfeeding of the time. It should be noted that the 2001 and 2011 NDHS defined exclusivity as “only breastmilk”. The 2006 NDHS did not provide the actual definition in the report, but advice from researchers involved confirmed that they followed the WHO 1991 definition [11] (personal communication, Mr. Sujan Karki, March, 2015 ). Two studies [26, 37] used a slight variant of the WHO definition and described exclusive breastfeeding as ‘nothing else (except medicines) but breast milk’ and ‘given breastmilk only without any other feeds (aside from medications) since birth’, respectively. Two cross-sectional studies [38, 39] did not give any definition.

### **Indicator measure**

There were variations in the indicator measure used to estimate prevalence of exclusive breastfeeding. Six studies used the 24-h recall measure [23-25, 28, 34, 39]. One study used recall-since-birth using repeated measures in a prospective cohort study up to 6 months [26], and one used recall-since-birth at two months [37]. Two studies used retrospective recall of mothers of infants aged 6 to 23 months [35] and 9 months postpartum [36], and asked mothers how long they had breastfed exclusively.

### **Age of infant**

Age of infant is another important aspect as younger infants are more likely to be breastfed exclusively than their older counterparts. Whilst most studies reported on infants aged 0-5 months [23-25, 28, 34, 39], one study [38] estimated exclusive breastfeeding rate at the 5<sup>th</sup> month. On the other hand, the study conducted by Subedi et al. [35] reported on the prevalence of breastfeeding up to six months among infants aged 6 to 23 month, while Chandrashekar et al. [37] considered young infants less than 2 months, and Karkee et al. [26] reported exclusive breastfeeding rates at 1, 4, and 6 months.

### **Reported exclusive breastfeeding rates in Nepal**

In view of the above methodological discrepancies, it is not surprising to find large variations in the rates of exclusive breastfeeding between studies. With the exception of one prospective cohort study which observed a low rate (29.7%) of exclusive breastfeeding at sixth months (22 weeks) using recall-since-birth [26], other studies reported a higher prevalence of greater than 50% amongst infants less than 6 months [35, 37, 38]. Ullak et al. [36] reported 9% exclusive breastfeeding prevalence at 6<sup>th</sup> month.

### **Comparison of breastfeeding rates in a cohort study**

We used data from our cohort study to compare exclusive breastfeeding rates during the first, fourth, and sixth months (*Figure 2*); results are presented in Table 2. All

infants were breastfed at the time of recruitment. Almost one-third of infants were provided with prelacteal feeds, leaving only 69.4% of them being exclusively breastfed at their first feed. The rates of exclusive breastfeeding are substantially different between the 24-h recall and the recall-since-birth methods at all three time points. During the first month, the prevalence of exclusive breastfeeding based on the 24-h recall method was 83.9% but was 66.3% using recall-since-birth, which accounted for prelacteal feeds. Similarly, the exclusive breastfeeding rate during the sixth month was 18.7% from the 24-h recall method and was half of that (8.9%) using recall-since-birth.

## **DISCUSSION**

This study reviewed and compared the definition and methods of reporting exclusive breastfeeding in Nepal. We found three main issues related to the measurements and reporting of exclusive breastfeeding namely, inconsistent definition of exclusive breastfeeding, indicator measurement and interpretation of the WHO indicator based on 24-h recall.

Data collected from the same participants in our cohort study were used to demonstrate the differences in exclusive breastfeeding rates between methods. Our findings suggest that the extensive use of NDHS data based on 24-h recall would inevitably over-estimate the prevalence of lifelong exclusive breastfeeding. In other words, estimates of exclusive breastfeeding rates in Nepal are probably much lower than those previously reported. Such differences in rates between recall-since-birth and 24-h recall have also been demonstrated by others [17, 20, 21]. It should be noted, however, that precise estimation of exclusive breastfeeding duration might be difficult due to incorrect recall by the mothers in our cohort study. However, our data was collected prospectively with relative short recall intervals, thereby reducing the likelihood for recall bias.

In surveys such as NDHS and MICS, age group of infants is another concern when 0-5 month old infants are aggregated to be the denominator for the 24-h recall prevalence. In our cohort study, exclusive breastfeeding during the sixth month was

18.7% by 24-h recall. For illustration purposes, let us regard the study as a cross-sectional survey that had similar number of infants in each age group (1<sup>st</sup>, 4<sup>th</sup>, and 6<sup>th</sup> months), i.e. 2161 infants in total available for interview from Table 2. The number of infants being exclusively breastfed based on 24-h recall would be  $617+437+133=1187$ , giving a prevalence of 54.9% which is comparable to those of previous studies in Table 1. This is not however the proportion of infants exclusively breastfed for the entire six month period, which is how cross-sectional data derived by this method often are misinterpreted [9, 10, 21] . This difference has been demonstrated also in two other cross-sectional studies conducted in Nepal and East-Timor [34, 40] where the actual 24-h prevalences of exclusive breastfeeding at the sixth month (33.1 % and 24.9%, respectively) was lower than the commonly reported 0-5 month exclusive breastfeeding prevalence of 66.3 % and 49 %, respectively. If infants should be breastfed for six months according to the WHO recommendation, then the indicator must reflect ‘exclusive breastfeeding for six months’.

Traditionally the use of prelacteal feeds have been a common practice in Nepal, and more recently the use of formula feeding is becoming increasingly prevalent [41]. Previous studies have reported that that introduction of prelacteal feedings or early supplementation of food or fluid is likely to interfere with normal gut microbiome [4], introduce infections [42] and interfere with the duration of breastfeeding. While, it is sometimes claimed that accounting for prelacteal and a few intermittent feeds can greatly under-estimate the rate of exclusive breastfeeding [10], ignoring prelacteal feeding would lead to losing focus on the harmful effects of prelacteal feeds as well as the early supplementation of infant formula. For instance, in our study, if prelacteal feeds were ignored, the rate of exclusive breastfeeding at first feed would be 100% as there was universal breastfeeding initiation [29]. Such interpretation of breastfeeding is also likely to mislead breastfeeding promotion programs providing a false sense of security.

Furthermore, although most studies in the past claimed to adhere to the WHO definition of exclusive breastfeeding [11, 12], we found they did not follow the definition exactly, and particularly with respect to measurement using the 24-h recall and recall-since-birth methods. Consequently, it is difficult to compare rates across

studies. Similar comparability problems were also noted in Japan [43] and Australia [13] .

For health policy advocacy and planning, consistency in definition of exclusive breastfeeding and the measurement indicator is necessary in order to monitor and compare the changes in exclusive breastfeeding rate over time, across regions and between population subgroups. In addition, future research in breastfeeding needs to provide the evidence that aligns with the target of the Ministry of Health Nepal [22] and the 2025 Global targets [7]. As a priority, future research should report both the point-in-time (24-h recall method) and life-long data (recall-since-birth method) [10] to estimate the 24-h prevalence and rate of exclusive breastfeeding for 6 months, respectively and should be used in conjunction with a well-designed cohort study taking repeated measurements. While this method is known to be more resource intensive, some sentinel sites can be established to represent the country, and prospective data can be collected periodically from these chosen sites to measure the rates of exclusive breastfeeding in Nepal [20].

The 24-h recall method is commonly adopted because of its feasibility in large nationally representative studies for evidence-based decision making in developing countries including Nepal [16, 23, 44] and is likely to continue in nationwide Demographic and Health Surveys. However, it should be noted that the statistics generated from these studies do not provide reliable data for monitoring exclusive breastfeeding rates for six months. Therefore, the resulting estimate should be reported as the ‘24-h prevalence of exclusive breastfeeding’ to avoid misinterpretation. It is recommended to increase the sample size in each infant age group from newborn up to six months. This will enable accurate reporting of the 24-h prevalence as well as the proportion of infants being exclusively breastfed according to infant age with a high power to detect any apparent changes and patterns.

## **CONCLUSION**

This study found that the use of the 24-hour-recall measurement indicator significantly over-estimates the life-long exclusive breastfeeding rates. To facilitate

uniform and accurate reporting of exclusive breastfeeding rates and monitor national targets for breastfeeding, future efforts should be on reporting exclusive breastfeeding based on the recall-since-birth method, using a cohort study design and repeated measurement to collect infant feeding information.

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## **CONFLICT OF INTEREST**

No conflict of interest.

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## **AUTHORS CONTRIBUTION**

VK contributed to study design, literature review, data collection, data analysis and interpretation, and writing the first draft. CB, JS and AL supervised the project, contributed to study design, data interpretation and revised the manuscript. AL and RK contributed in data analysis and interpretation of findings. All authors revised and agreed on the views expressed in the manuscript.

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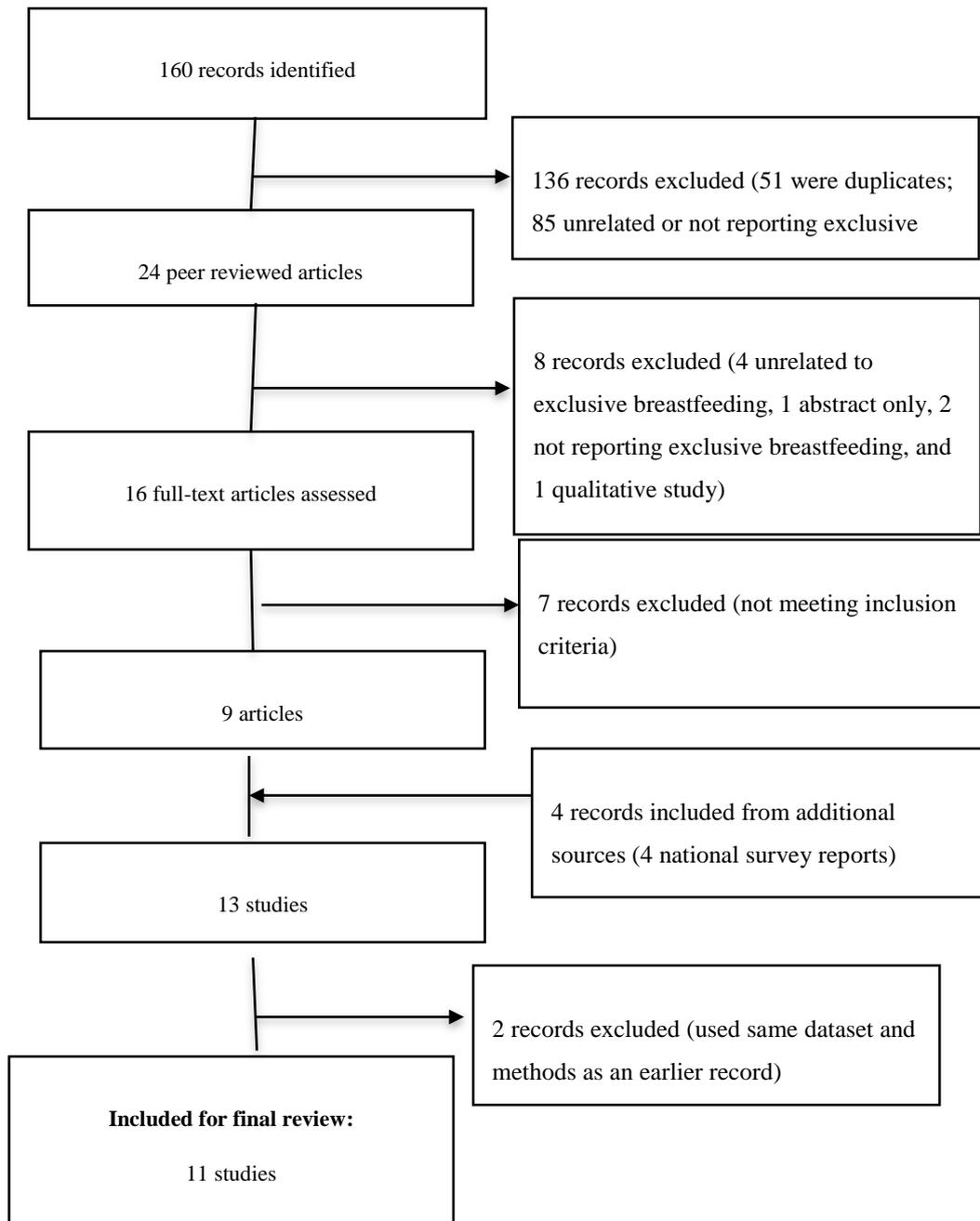
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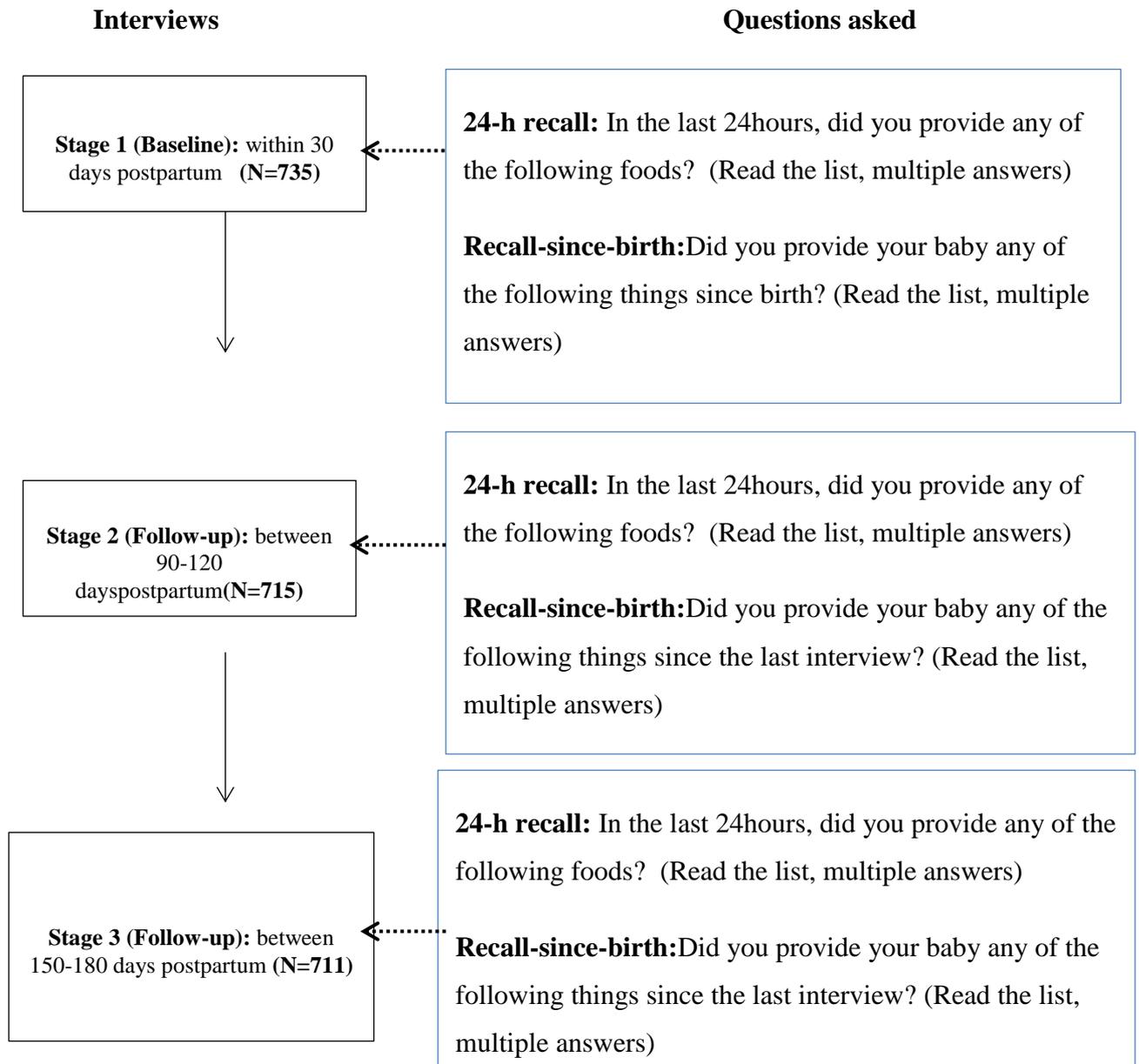
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**Figure 1. PRISMA flow chart for review of exclusive breastfeeding studies in Nepal, 2000-2014**



**Figure 2. Study interview flow chart and questions asked to measure breastfeeding rates**



**Table 1. Studies reporting exclusive breastfeeding in Nepal, 2000-2014**

Reference	Study design	Source of data and sample size	Definition of exclusive breastfeeding	Measurement indicator	Reported EBF rate
Peer reviewed publications					
Chandrashekhar et al. (2007)	cross-sectional	primary data (n= 385)	nothing else (except medicines) but breast milk	recall-since-birth	82.3% among <2 months infants
Subba et al. (2007)	cross-sectional	primary data (n=168)	not detailed	not reported	60.5% at 5 <sup>th</sup> month
Subedi et al. (2012)	cross-sectional	primary data (n= 261)	WHO, 2007 definition	recall at 6-23 month	81.6% upto 6 months
Ulak et al. (2012)	cross-sectional	primary data (n= 325 )	WHO, 2007 definition	recall-at-9 <sup>th</sup> month	at 1 <sup>st</sup> , 3 <sup>rd</sup> and 6 <sup>th</sup> months were 74%, 24% and 9%
Khanal et al. (2013)	cross-sectional	NDHS 2006 (n= 482 ) and NDHS 2011(n=227 )	WHO, 2007 definition	24-h recall	53.2% in 2006 and 66.3% in 2011 among 0-5 month infants

Locks et al. (2013)	cross-sectional (subset of randomized control trial)	primary data (n=750 )	not reported	24-h recall	65% among 0-5 month infants
Karkee et al. (2014)	cohort	primary data (n= 639 )	given breastmilk only without any other feeds (aside from medications) since birth	recall-since-birth	84.4% during first month, 67.2% during 3 months, and 29.7% EBF at 6 <sup>th</sup> month
National surveys					
Ministry of Health and Population et al. (2001) (NDHS 2001)	cross-sectional	primary data (n= 648)	WHO, 1991 definition	24-h recall	68.3% among 0-5 month infants
Ministry of Health and Population et al. (2007)	cross-sectional	primary data (n= 477)	WHO,1991 *	24-h recall	53.0% among 0-5 month infants

(NDHS 2006)

Ministry of Health and Population et al.	cross-sectional	primary data (n= 537)	WHO, 1991	24-h recall	69.6% among 0-5 month infants
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(2012)

(NDHS 2011)

Central Bureau of Statistics et al. (2010)	cross-sectional	primary data (n= 452 )	WHO, 2007 definition*	24-h recall	63.9% among 0-5 month infants
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(MICS)

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\*from personal communication with researcher involved in NDHS and MICS 4. EBF: exclusive breastfeeding. NDHS: Nepal Demographic and Health Survey. MICS: Multiple Indicator Cluster Survey

**Table 2. Prevalence of exclusive breastfeeding from a cohort study using two measurement indicators, Nepal, 2014**

<b>Exclusive breastfeeding</b>	<b>1<sup>st</sup> month</b>		<b>4<sup>th</sup> month</b>		<b>6<sup>th</sup> Month</b>	
	<b>Method</b>					
	24-h recall (N=735)	recall-since- birth (N=735)	24-h recall (N=715)	recall-since- birth (N=715)	24-h recall (N=711)	recall-since- birth (N=711)
Rate (%)	617 (83.9%)	487 (66.3%)	437 (61.1%)	280 (39.2%)	133 (18.7%)	63 (8.9%)
95% confidence interval	81.3%, 86.6%	62.8%, 69.7%	57.5%, 64.7%	35.6%, 42.7%	15.8% , 21.6%	6.8% , 11.1%



#### **Appendix 4: The supplemental use of infant formula in the context of universal breastfeeding practices in Western Nepal**

Link to full text: <http://bmcpediatr.biomedcentral.com/articles/10.1186/s12887-016-0602-1> ( Open access)

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## **Abstract**

### **Background**

While the initiation of breastfeeding is universal in Nepal, little has been reported on formula feeding practices. This study aimed to report the prevalence of, and factors associated with, the use of infant formula as supplementary feeds in the Western region of Nepal.

### **Methods**

A community-based cohort study was conducted to collect infant feeding information among 735 postpartum mothers using structured questionnaires. Complete formula feeding data were collected from 711 women in the first, fourth and sixth month postpartum. Factors independently associated with formula feeding were investigated using multiple logistic regression.

### **Results**

All mothers were breastfeeding their infants at the time of recruitment. The prevalence of formula feeding was 7.5% in the first month and 17% in the sixth month. About a quarter of mothers (23.8%) reported providing infant formula at least once during the first six months of life. Infant formula was used commonly as top-up food. Stepwise logistic regression showed that infants born to families residing in urban areas (adjusted odds ratio (aOR): 2.14; 95% confidence interval (CI): 1.37 to 3.33), mothers with higher education (aOR: 2.08; 95% CI: 1.14 to 3.80), and infants born by caesarean section (aOR: 1.96; 95% CI: 1.21 to 3.18) were at greater risk of formula feeding.

### **Conclusion**

The current findings indicate that health workers should support mothers to initiate and continue exclusive breastfeeding particularly after caesarean deliveries. Furthermore, urban health programs in Nepal should incorporate breastfeeding programs which discourage the unnecessary use of formula feeding. The marketing of formula milk should be monitored more vigilantly especially in the aftermath of the April 2015 earthquakes or other natural disasters.

Keywords: Breastfeeding, Baby formula, Cohort studies, Infant food, Infant Formula, Nepal, Urban Health

## **Background**

Worldwide sub-optimal breastfeeding is contributing solely to about 13% of child mortality and 10% of childhood diseases [1-3] and about 50 per cent of diarrheal episodes could be avoided with optimal breastfeeding practices [4]. The early introduction of supplemental infant formula increases the risk of childhood diarrhoea [3, 5] as formula does not contain the bioactive and immune protective properties of breastmilk [6, 7]. Furthermore, providing infants with infant formula requires powdered formula to be mixed with boiled water under hygienic conditions. Therefore, if formula powder is reconstituted with unsafe water or prepared and fed under unhygienic conditions the risk of infants suffering diarrhoea is increased [3]. In addition, the risk of disease and deaths as a result of infant formula use are higher in developing countries due to low literacy levels and inadequate skills of carers required to prepare infant formula safely [3, 8].

The initiation of breastfeeding is universal in Nepal; however, the use of animal milk and other fluids as supplementary feeds is relatively common [9]. While the Nepal Demographic and Health Survey 2011 reported that only 0.8% of infants aged <1 month, and 2.6% aged 6-8 months were provided infant formula [10], a more recent longitudinal study from central Nepal found a much higher prevalence of usage of 1.7 % among infants aged less than 1 month and 13.7% among infants in their sixth month [9]. Diarrhoea is one of the most frequent illnesses among Nepalese children and infants [11] and the use of infant formula is a likely contributor to the high incidence of diarrhoea which in the years 2010/2011, 2011/2012 and 2012/2013 was 500, 528 and 578 per 1000 under five-year children, respectively [10].

Infant formula has been marketed aggressively in developing countries where government capacity to monitor and regulate their marketing is limited [3]. Nepal has adopted the 1981 '*International Code of Marketing Breastmilk Substitutes*' of the

World Health Organization (WHO), and in 1992 passed the '*Mother's Milk Substitutes (Control of Sale and Distribution) Act, 2049 (1992)*'. According to this Act, the marketing, advertisement, and the promotion of infant formula is prohibited in Nepal [12]. Within a few years of endorsement of the Act however, the country underwent severe political unrest for more than a decade [13] which may have affected the implementation of the Act. While none of the public hospitals allow the advertising of infant formula on their premises, distribution through pharmacies, grocery shops, and departmental stores is unrestricted. These selling outlets are rapidly proliferating in the urban areas of Nepal.

Infant formula is frequently donated by multinational companies and distributed by humanitarian agencies following natural disasters in developing countries [8]. These donations are often unsolicited and their distribution uncontrolled and widespread [5, 14]. Not only does the uncontrolled distribution of donated infant formula pose a health risk in the immediate aftermath of a natural disaster [5], there is some suggestion that the continued availability of donated formula following the emergency period may undermine traditional breastfeeding practices and contribute to increased rates of prelacteal feeding [8].

To date, few studies have reported on complementary feeding practices in Nepal [15, 16] and none have investigated the factors associated with formula feeding. This study aimed to investigate the prevalence of supplementing breastmilk with infant formula and factors associated with this practice in Western Nepal where the practice of breastfeeding is universal.

## **Methods**

### **Study setting**

The study was conducted in the Rupandehi district that is located in the South-western plain area (Terai) of Nepal bordering India. The district has 69 village development committees in rural areas and two municipalities in urban areas which are the lowest administrative units in Nepal. The district has two medical colleges, one zonal hospital (referral hospital), one district hospital, five primary health care centres, six health posts, and 58 sub-health posts [17]. The estimated number of

infants in this district for fiscal year 2013/204 was 20,061 (each month: 1672) [Source: District Public Health Office, Rupandehi, Annual Target 2013/2014].

### **Study design and sample**

A community-based cohort study was conducted between January and October, 2014. A total of 735 (rural 378, urban 357) postpartum mothers who were local residents, had living infants, were within one month postpartum, and had a singleton child, were recruited in the study. The process of participant selection is published in detail elsewhere [18] but briefly participants were recruited from 12 randomly selected communities of urban areas, and 15 village development committees of rural areas. List of eligible participants were prepared with the help of local female community volunteers, and health facilities. The required number of participants was then selected from the list using random sampling. The numbers of mother-infant participants was proportionate to population size based on monthly target of expected number of infants aged <30 days. Participants were recruited from adjacent communities when enough participants could not be recruited from the selected community.

### **Instrument and data collection**

Face-to-face interviews were conducted by trained female enumerators using structured questionnaires, which were adapted from the Nepal Demographic and Health Survey 2011 [10] and a previous cohort study conducted in central Nepal [19]. The Nepali version of questionnaires was pre-tested among 30 eligible participants to ensure cultural appropriateness before use in this study. Some words were replaced with equivalent local terms however, no significant changes to individual questions were necessary. A 24-hour-recall method was used to collect information on infant feeding practices including formula feeding, during the first (within 30 days), fourth (90-120 days), and sixth month (150-180 days). Prompted responses were collected by reading a list of common food items provided to infants to ensure better recall by mothers.

### **Variables**

The binary outcome variable of this study was ‘formula feeding’ coded as 1 (provided infant formula) and 0 (not provided infant formula). An infant was considered ‘formula fed’ if their mother reported providing her infant with formula at any one of the three interviews. A number of independent variables identified in the literature as being associated with the introduction of formula were investigated (*Table 1*). Briefly, ‘maternal occupation’ was categorised as ‘employed’ (salaried job), ‘semi-employed’ (daily wage, small business), and ‘household or agricultural work’ [20]. Ethnicity was categorised based on caste group similarities into ‘advantaged caste groups’ (Brahmin, Chhetri, Newar, Gurung, Jogi, Thakuri), ‘middle caste groups’ (Janjati, non-Janjati and Muslim), and ‘Dalit caste’ (Bishwakarma, Dhawal, Kami, Pariyar, Pasi, Sunar) [21]. ‘Birthweight’ was recorded as a continuous variable and then categorised into ‘low’ (< 2500 grams) and ‘average or greater’ ( $\geq$  2500 grams).

### **Statistical analysis**

Types of complementary food including infant formula were descriptively reported as frequency and percentage of infants in the first, fourth and sixth months. Factors associated with formula feeding were investigated using chi-square test followed by logistic regression analyses. The backward stepwise process was used in a multiple logistic regression. Analyses were conducted using the Statistical Package for Social Sciences (SPSS, IBM Statistics, Version. 20).

### **Ethics**

Ethics approval was obtained from the Nepal Health Research Council (773/2014), and the Human Research Ethics Committee (HR 184/2013) at Curtin University, Australia. Mothers provided consent for themselves and their infants. The participants were also advised that they had the right to refuse to participate or to withdraw from the study at any time without prejudice.

## **Results**

### **Characteristics of participants**

*Figure 1* illustrates the interview flow chart of the cohort study that included 735 participants enrolled in the first interview; of which 715 (97.3%) and 711 (96.7%) responded to the second and third interviews, respectively. About one in five (22.9%) of recruited mothers had higher education while only a small proportion (4.1%) was employed in a salaried job. The majority (76.2%) of mothers attended four or more antenatal care visits, delivered in health facilities (88.2%) and 14.1 % delivered via caesarean section. About half (51.4%) of the participants were from rural areas.

### **The use of formula feeding as supplementary feeding**

All mothers were breastfeeding at the time of recruitment. *Table 2* presents the types of complementary foods that were provided to infants in the first, fourth and sixth months. In the first month, infant formula was the most common (7.5%) food given to infants and was used to supplement breast milk. The proportion of infants receiving infant formula increased to 17.0 % in the sixth month (*Figure 2*). A total of 169 (23.8%) of the 711 mothers who completed the third interview reported ‘ever feeding’ infant formula at some time in the first six months. *Figure 3* shows the proportion of infants receiving animal milk which was 4.6% in the first month with a sharp rise in the fourth (16.1%) and sixth (60.8%) months.

A total of 55 mothers who were formula feeding their babies at the time of the first interview were asked what brand they were using. Lactogen<sup>®</sup> (n=16, 29.1%) and Nestogen<sup>®</sup> (n=2, 3.6%) were the two brands most commonly used; the rest of the mothers could not recall the brand name. The brand of formula chosen was based on: hospital advice (n=24, 43.6%), other people’s advice (n=4, 7.3%), brand loyalty(n=1, 1.8%), and advertisement (n=1, 1.8%). It appeared that formula was mostly provided as top-up food to infants as the methods of formula feeding were reported as: mother’s milk topped-up with formula: (n=29, 52.7%), half breastmilk and half formula (n=15, 27.3%) only formula milk (n=3, 5.4%) and usually formula feeding topped-up with other foods (n=2, 3.6 %).

### **Factors associated with formula feeding**

Factors associated with formula feeding are presented in *Table 3*. The results of the stepwise multiple logistic regression indicates that infants who were born to mothers

with higher education (adjusted odds ratio (aOR): 2.08; 95% confidence interval (CI): 1.14 to 3.80), born by caesarean section (aOR: 1.96; 95% CI: 1.21 to 3.18), and born to families residing in urban areas (aOR: 2.14; 95% CI: 1.37 to 3.33) were more likely to be formula fed. *Figure 2* illustrates that formula feeding prevalence in the first, fourth and sixth months was higher in the urban areas than the rural areas.

## **Discussion**

About one in every four infants was provided infant formula within the first six months of life. An earlier cohort study [9] from Central Nepal reported lower prevalence of formula feeding of 1.7%, 6.3% and 13.4% at 4, 12, and 22 weeks, respectively compared to our findings 7.5%, 6.8%, and 17.0%. Another study from the Bhaktapur districts, near the capital city of Nepal reported that 31% of infants aged nine months were provided powdered milk or infant formula [22]. The Government of Nepal has banned the advertising of infant formula in health facilities, and enforced the '*Mother's Milk Substitutes (Control of Sale and Distribution) Act, 2049 (1992)*' [12]. As a result, the provision of infant formula as gifts or free samples is non-existent in public hospitals in Nepal. Similarly, childhood illness management protocols for health workers discourage formula feeding [23]. Despite these efforts, the use of infant formula in Nepal appears to be on the rise; therefore, there is further need to curtail such practice.

In this study, urban mothers were twice as likely as rural mothers to provide formula to their babies. Urban areas have a number of characteristics which make infants particularly vulnerable to formula feeding. The majority of departmental stores and retail pharmacies are located in the urban areas of Nepal, and they sell infant formula without any restriction. Mothers who experience some difficulties in breastfeeding can easily find infant formula in urban areas, and use as an alternative to breastfeeding [24, 25]. Sethi & Mishra [24] reported that the demonstrating of bottles and nipples in pharmacies and grocery stores was used as a form of advertising to promote formula and bottle feeding in India. They argued that the effects of such demonstrations were similar to that of direct television and radio advertising of infant formula. Infant formula displays are commonly found in pharmacy and grocery shops in urban areas of Nepal. We observed the infant formulas displayed in a

pharmacy located in front of the entrance of an urban tertiary hospital which is BFHI (baby friendly hospital initiative) accredited, and found that the message on the harmful effect of the use of unboiled water during preparation of infant formula was in English language only and this carries no value in Nepal as the majority of the population cannot understand it due to the language barrier (*Photo not shown due to copyright issue associated with brand name of infant formula*). Nepal's public health system is designed with special focus on the rural areas [26]. There are usually inadequate public health networks and health promotion programs in the urban areas. Therefore, urban health programs of Nepal should incorporate breastfeeding programs to help discourage the use of infant formula and counteract the widespread marketing of infant formula in urban areas.

The household financial impact of formula feeding has not been studied before in Nepal. At the time of the study we observed that the price of infant formula ranged 460-480 Nepali Rupees (which was equivalent to 3-4 USD at the time). Given that a quarter of the Nepali population lives on an income of less than 1.25 USD per day [27], the expense of 3-4 USD for each formula packet is very costly for the majority of the local population. There is lack of study on the economic impact of formula feeding and further research is needed to provide more information.

Nepal follows the WHO guideline in infant feeding and encourages and promotes exclusive breastfeeding in the first six months of life. When mother's milk is no longer sufficient due to maternal illness and death, the child health guidelines of the Ministry of Health recommends clean and boiled cow's milk to avoid contamination and also protect from under nutrition in early infancy [28]. The same recommendation is not given for infant formula for several reasons: (1) likelihood of contamination during preparation, (2) lower literacy rates of mothers and the senior women that is likely to impact their capacity to safely prepare and handle formula milk and (3) poor sanitation status, mainly in rural parts of the country [27]. These factors would lead to an increased rate of childhood diarrhoea which is already one of the leading causes of morbidity and mortality among infants and children of Nepal.

Caesarean delivery was a risk factor for infant formula feeding. A mother who has undergone a caesarean section is often exhausted, usually confined to bed, under the effect of anaesthesia or analgesia, and may suffer anxiety and stress [29]. As a consequence such women are often separated from their newborn or unable to hold and breastfeed their newborn infants, and mothers and families may find it easier to introduce infant formula in such circumstances[30]. Once a newborn is accustomed to infant formula; it is hard to re-establish breastfeeding unless mothers are encouraged and provided support [31]. In addition, the suckling ability of infants delivered by caesarean section tends to be less than their exclusively breastfed counterparts [32]. Mothers, who have undergone caesarean section, are in need of support in the early postnatal period to establish and continue exclusive breastfeeding. When infant formula is the only viable option, for example when the mother is seriously ill or cannot breastfeed, a safe way of preparation should be well communicated, and the harms that can be caused by inappropriately prepared formula feeding must be advised [8]. For example, a guide to the safe use of bottle feeding has been published by the WHO [33] and could be adapted in the Nepalese context.

Higher education of mothers was independently associated with increased likelihood of formula feeding. Highly educated women are also likely to work. While there is a two-month paid maternity leave in the public sector, there is no provision of such leave in the private sector. Thus, these mothers might face difficulties in breastfeeding because of full-time work leaving them with the options to introduce animal milk or infant formula [34, 35].

Within the six months of our data collection, Nepal on 25 April 2015 experienced a devastating earthquake measuring 7.9 on the Richter scale that led to the damage of 750,000 houses, over 8,600 deaths and 17,000 injuries [36]. Hipgrave et al. [5] reported that 80% of households with children received donated infant formula after a similarly devastating earthquake in Yogyakarta and Central Java, Indonesia in 2006. Follow-up of these children showed that 25.4% of infants who received donated milk experienced diarrhoea compared with 11.5% of those infants who did not. Allegedly infant formula donated after the 2015 Nepal earthquake and distributed in Laprak, Gorkha district was date-expired [14] and as such posed a

potential health risk. Following natural disasters water supplies are typically contaminated and there is no heat to boil the water and containers [37]. In Nepal, unless strict measures are taken by the Government, the unrestricted sale and distribution of infant formula could result into an increased risk of contamination and childhood diarrhoea and deaths in the post-earthquake period [8, 37].

This study is one of the few longitudinal studies to investigate formula feeding practices in Nepal. An important limitation of this study is that feeding practices were self-reported and may be subject to recall and social desirability bias. However, such self-reported prevalence of infant feeding has been widely used in a number of studies [38-40]. While the short recall time of 24-hour used in cross-sectional studies such as the Demographic and Health Survey is likely to reduce recall bias, there is the possibility of missing the short-term, intermittent use of infant formula resulting in the likelihood of under reporting of prevalence. For instance, the 24 hour recall method, or current status method, has been shown to overestimate the prevalence of exclusive breastfeeding and underestimate the prevalence of partial breastfeeding, when compared to the “since birth” recall method [41]. No attempt was made to collect data on infant illnesses and future studies should focus on reporting additional risk of childhood diarrhoea due to formula feeding.

## **Conclusion**

This study found that one in every four infant was provided infant formula at some time in their first six months. Infants born to educated mothers, born by caesarean section and born to a family residing in urban areas were more at risk of formula feeding. The ‘*Mother's Milk Substitutes (Control of Sale and Distribution) Act, 2049 (1992)*’ should be strongly enforced, and breastfeeding promotion programs should focus on the mothers with higher education, living in urban areas, and women delivering by caesarean method should be targeted for extra support in the early postnatal period. It should be noted that health promotion programs in the urban areas of Nepal are very limited; therefore, breastfeeding promotion programs should focus on urban areas. Nepal is a country often affected by natural disasters such as landslides and earthquakes; the government should be firm on its position to support

breastfeeding and discourage the unrestricted distribution and use of infant formula unless medically indicated.

### **Consent for publication**

Not applicable

### **Availability of data and materials**

The datasets supporting the conclusions of this article are available at the institutional repository of Curtin University (<http://www.curtin.edu.au>). According to the data protection regulation of Curtin University, authors are not permitted to deposit the data elsewhere.

### **Competing interest**

The authors declare that there is no conflict of interest.

### **Funding**

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### **Author's contribution**

VK contributed to study design, literature review, data collection, data analysis and interpretation, and writing the first draft. CB, JS and AL supervised the project, contributed to study design, data interpretation and revised the manuscript. AL and RK contributed in data analysis and interpretation of findings. All authors revised and agreed on the views expressed in the manuscript.

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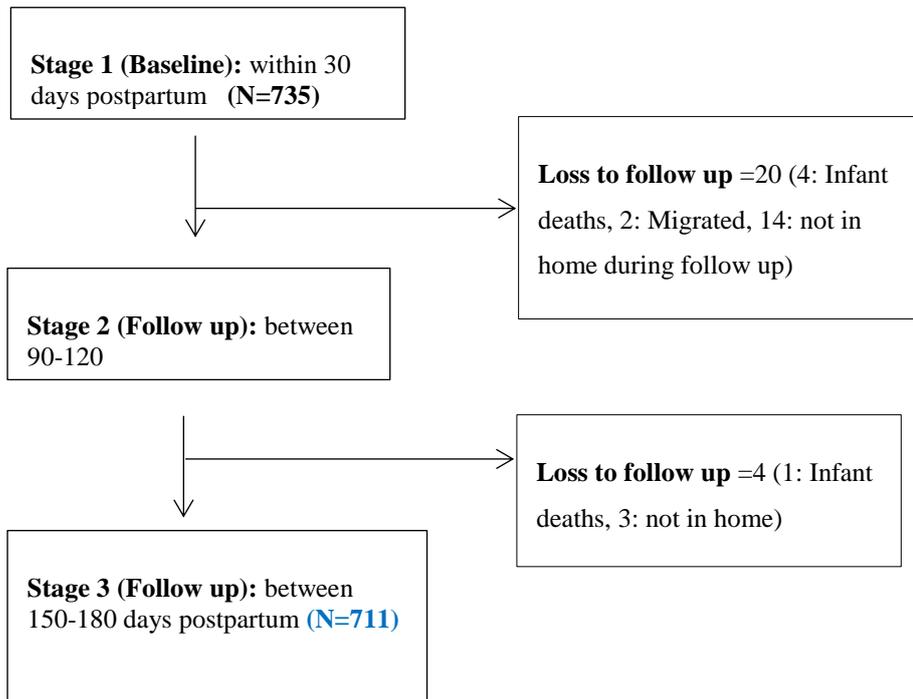
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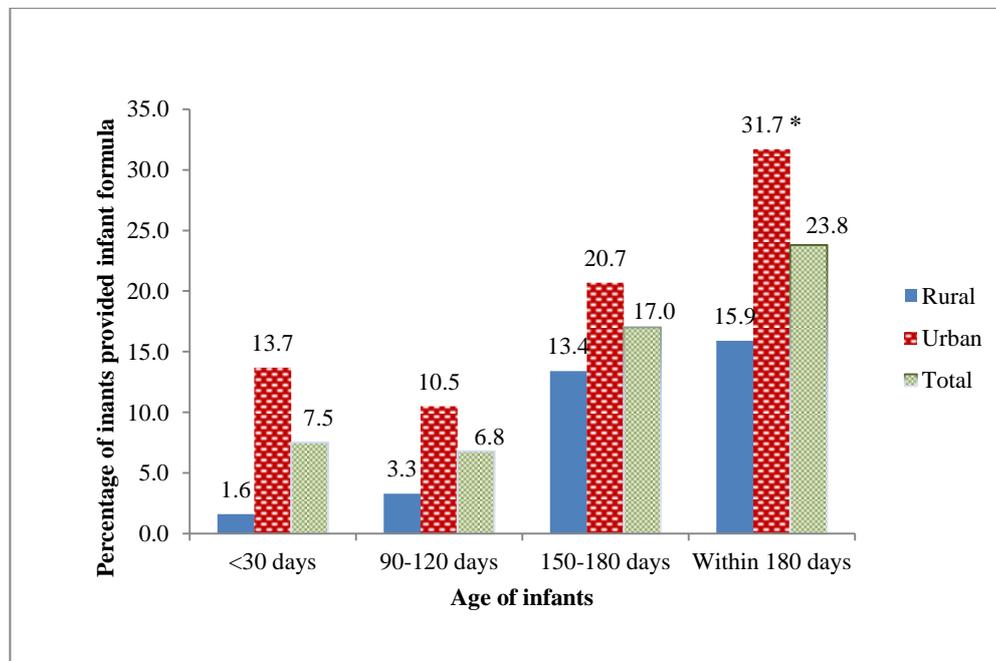
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**Figure 1. Study interview flow chart**

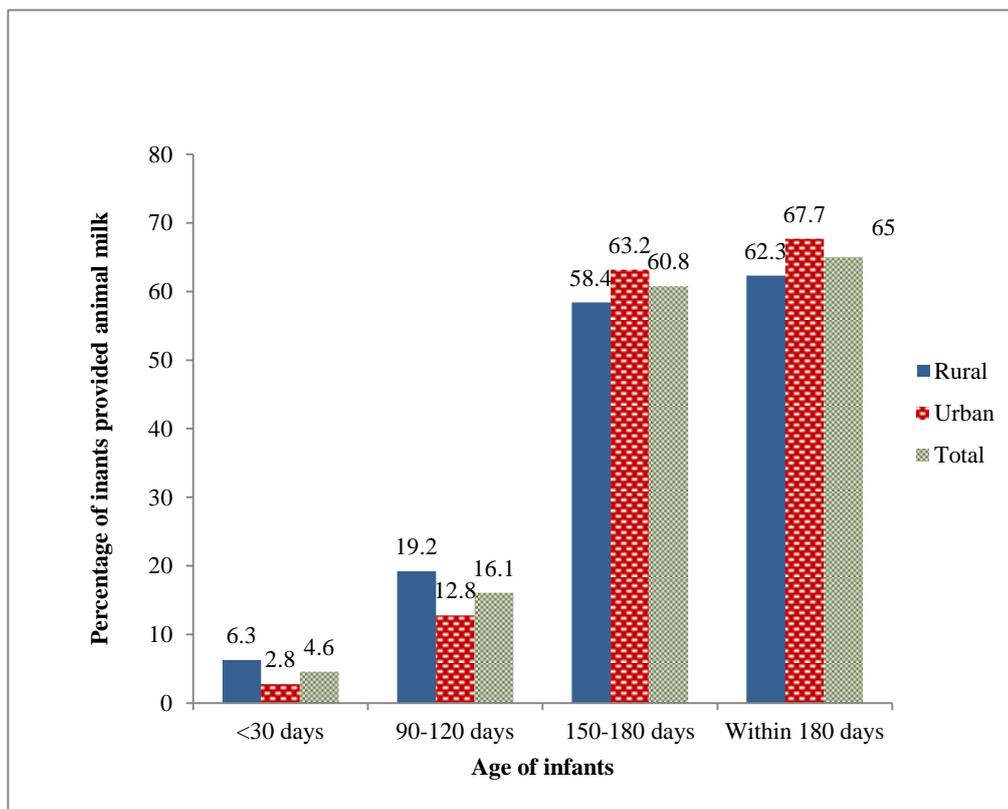


**Figure 2. Prevalence of formula feeding among infants upto six months in Western Nepal**



\*statistically significant

**Figure 3. Prevalence of animal milk feeding among infants upto six months in Western Nepal**



**Table 1. Characteristics of participants and the practice of formula feeding in Western Nepal, 2014**

Factor	Infant ever fed infant formula (n= 711)		p-value*
	No n (%)	Yes n (%)	
<b>Maternal age</b> (years)#			0.425
15-19	51 (9.4)	14 (8.3)	
20-29	396 (73.2)	132 (78.1)	
30-45	94 (17.4)	23 (13.6)	
<b>Maternal education</b>			<0.001
No education	152 (28.0)	33 (19.5)	
Primary to lower secondary	201 (37.1)	37 (21.9)	
Secondary	94 (17.5)	30 (17.8)	
Higher	95 (17.5)	69 (40.8)	
<b>Maternal occupation</b>			<0.001
Employed–salaried job	15 (2.8)	15 (8.9)	
Semi-employed	118 (21.8)	19 (11.2)	
Household or agricultural work	409 (75.5)	135 (79.9)	
<b>Antenatal care</b> (Frequency)#			0.250
No visit	14 (2.6)	2 (1.2)	
1-3 visits	123 (22.8)	31 (18.5)	
4 or more visits	403 (74.6)	135 (80.4)	
<b>Place of delivery</b>			0.103
Home	70 (12.9)	14 (8.3)	
Health facility	472 (87.1)	155 (91.7)	
<b>Mode of delivery</b>			<0.001
Vaginal	484 (89.3)	124 (73.4)	
Caesarean	58 (10.7)	45 (26.6)	
<b>Ethnicity</b>			<0.001
Advantaged caste groups	169 (31.2)	96 (56.8)	
Middle caste groups	300 (55.4)	59 (34.9)	
Dalit caste	73 (13.4)	14 (8.3)	
<b>Sex of child</b>			
Male	277 (51.1)	92 (54.4)	

Female	265 (48.9)	77 (45.6)	
<b>Birth order#</b>			0.358
First	227 (42.0)	80 (47.3)	
Second or third	246 (45.4)	73 (43.2)	
Fourth or more	68 (12.6)	16 (9.5)	
<b>Birth weight #</b>			0.254
Low (<2500g)	72 (14.3)	16 (10.7)	
Average or more (≥2500g)	432 (85.7)	134 (89.3)	
<b>Place of residence</b>			<0.001
Rural	301 (55.5)	57 (33.7)	
Urban	241 (44.5)	112 (66.3)	

# missing data present. \*chi-square p-value

**Table 2 Complementary foods introduced during the first six months in Western Nepal, 2014**

<b>Complementary foods#</b>	<b>First month (N=735)</b>	<b>Fourth month (n=715)</b>	<b>Sixth month (n=711)</b>
Infant formula	55 (7.5%)	49 (6.8%)	121(17.0%)
Plain water	24 (3.3%)	203 (28.4%)	485 (68.2%)
Animal milk	34 (4.6%)	115 (16.1%)	432 (60.8%)
Sugar water	0	4 (0.6%)	26 (3.7%)
Sugar salt water	4 (0.5%)	12 (1.7%)	19 (2.7%)
Ghee	12 (1.6%)	26 (3.6%)	26 (3.7%)
Honey	8 (1.1%)	33 (4.6%)	27 (3.8%)
Honey and ghee mixed	2 (0.3%)	16 (2.2%)	20 (2.8%)
Tea	1 (0.1%)	1 (0.1%)	0
Porridge	0	11 (1.5%)	206 (29.0%)
Jaulo Khichadi*	0	10 (1.4%)	131(18.4%)
Adult food	0	2 (0.3%)	27(3.8%)
Others food items deemed healthy by parents	0	1 (0.1%)	27 (3.8%)
<b>Any complementary feeding</b>	<b>118 (16.1%)</b>	<b>278 (38.9%)</b>	<b>578 (81.3%)</b>

*Note: dietary recall is based on 24-hour recall method. # multiple response. \* local food that is a mixture of rice, pulses and cereals. It is well cooked to make soft and salt and turmeric are sometime added to improve taste.*

**Table 3. Factors associated with formula feeding in Western Nepal, 2014**

<b>Factors</b>	<b>Adjusted odds ratio* (95% CI)</b>	<b>p-value<sup>#</sup></b>
<b>Maternal education</b>		0.007
No education	1.00	
Primary to lower secondary	1.77 (0.79, 3.98)	
Secondary	1.23 (0.65, 2.33)	
Higher	2.08 (1.14, 3.80)	
<b>Mode of delivery</b>		0.006
Vaginal	1.00	
Caesarean	1.96 (1.21, 3.18)	
<b>Place of residence</b>		0.001
Rural	1.00	
Urban	2.14 (1.37, 3.33)	

\* From stepwise logistic regression model: all variable in Table 1 were included in initial model. <sup>#</sup> from multiple logistic regression

## Appendix 5: Ethics approval: Curtin University



### Memorandum

<b>To</b>	Professor Colin Binns, Public Health
<b>From</b>	Professor Stephan Millett, Chair, Human Research Ethics Committee
<b>Subject</b>	Protocol Approval <b>HR 184/2013</b>
<b>Date</b>	21 November 2013
<b>Copy</b>	Vishnu Khanal Public Health Professor Andy Lee Public Health

Office of Research and Development  
Human Research Ethics Committee

TELEPHONE 9266 2784

FACSIMILE 9266 3793

EMAIL [hrec@curtin.edu.au](mailto:hrec@curtin.edu.au)

Thank you for providing the additional information for the project titled "A Cohort Study of Exclusive Breastfeeding Rates and Infant Feeding Practices by Mothers Using Traditional Birth Attendants and Health Workers in Western Nepal". The information you have provided has satisfactorily addressed the queries raised by the Committee. Your application is now **approved**.

- You have ethics clearance to undertake the research as stated in your proposal.
- The approval number for your project is **HR 184/2013**. Please quote this number in any future correspondence.
- Approval of this project is for a period of four years **21-11-2013 to 21-11-2017**.
- Your approval has the following conditions:
  - i) Annual progress reports on the project must be submitted to the Ethics Office.
- **It is your responsibility, as the researcher, to meet the conditions outlined above and to retain the necessary records demonstrating that these have been completed.**

#### Applicants should note the following:

It is the policy of the HREC to conduct random audits on a percentage of approved projects. These audits may be conducted at any time after the project starts. In cases where the HREC considers that there may be a risk of adverse events, or where participants may be especially vulnerable, the HREC may request the chief investigator to provide an outcomes report, including information on follow-up of participants.

The attached **Progress Report** should be completed and returned to the Secretary, HREC, C/- Office of Research & Development annually.

Our website [https://research.curtin.edu.au/guides/ethics/non\\_low\\_risk\\_hrec\\_forms.cfm](https://research.curtin.edu.au/guides/ethics/non_low_risk_hrec_forms.cfm) contains all other relevant forms including:

- Completion Report (to be completed when a project has ceased)
- Amendment Request (to be completed at any time changes/amendments occur)
- Adverse Event Notification Form (If a serious or unexpected adverse event occurs)

Yours sincerely

Professor Stephan Millett  
Chair Human Research Ethics Committee

## Appendix 6: Ethics approval: Nepal Health Research Council



# Nepal Health Research Council

Estd. 1991

Ref. No.: 802

17 January 2014

**Mr. Vishnu Khanal**  
Principal Investigator  
Curtin University, Australia

Ref: **Approval of Research Proposal** entitled **A cohort study of exclusive breastfeeding rates and infant feeding practices by mothers using Skilled birth attendants and health workers in western Nepal**

Dear Mr. Khanal,

It is my pleasure to inform you that the above-mentioned proposal submitted on 24 November 2013 (**Reg. no. 180/2013** please use this Reg. No. during further correspondence) has been approved by NHRC Ethical Review Board on 30 December 2013 (2070-09-15).

As per NHRC rules and regulations, the investigator has to strictly follow the protocol stipulated in the proposal. Any change in objective(s), problem statement, research question or hypothesis, methodology, implementation procedure, data management and budget that may be necessary in course of the implementation of the research proposal can only be made so and implemented after prior approval from this council. Thus, it is compulsory to submit the detail of such changes intended or desired with justification prior to actual change in the protocol.

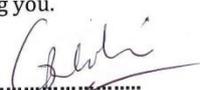
If the researcher requires transfer of the bio samples to other countries, the investigator should apply to the NHRC for the permission.

Further, the researchers are directed to strictly abide by the National Ethical Guidelines published by NHRC during the implementation of their research proposal and submit progress report and full or summary report upon completion.

As per your research proposal, the total research amount is US\$. 4,399.00 and accordingly the processing fee amounts to NRs. 10,090.00. It is acknowledged that the above-mentioned processing fee has been received at NHRC.

If you have any questions, please contact the research section of NHRC.

Thanking you.

  
.....  
**Dr. Guna Raj Lohani**  
Executive Chief

## **Appendix 7: Consent form**

CURTIN UNIVERSITY, PERTH, AUSTRALIA

A Cohort Study of Exclusive Breastfeeding Rates and Infant Feeding Practices by Mothers Using Traditional Birth Attendants and Health Workers in Western Nepal – Information sheet

The School of Public Health at Curtin University is studying how babies are breastfed and what problems the mothers experience during breastfeeding. As part of this project, mothers of newborns in Rupandehi district, Nepal are being asked about their experiences and opinions. Initially as a mother you will be asked to provide us with the information about breastfeeding, health service use and the food items you provided to your infant. We will ask you to help us with further interviews at 4<sup>th</sup> and 6<sup>th</sup> months for follow up. During follow up, you will be given similar questionnaire but of shorter duration than of the first interview. You have right to participate or not to participate, and withdraw from this study even after your interview, or not to respond any question if you do not like to. There will be no favour or discrimination for or against you, your infant and the family due to participation status. Your name, family's name, or the village/municipality name will be not be used in my report for confidentiality. If you have any question, research the person interviewing you, the researcher or the supervisor will be able provide you with more information. If you are able to help us with our research, please sign the consent form below and provide us with your name, address and telephone number.

Thank you in anticipation of your assistance.

Yours sincerely

Vishnu Khanal

PhD Candidate  
Public Health

School of Public Health

Curtin University

Colin Binns

Professor of

Curtin University

GPO Box U1987

GPO Box U1987

Perth WA 6102

Perth WA 6102  
0401 103 639

Tel: 9266-4341 or

Tel: 9266-4341

Fax: 9266-2958;

September, 2013

September, 2013 \_

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Curtin University, A Cohort Study of Exclusive Breastfeeding Rates and Infant Feeding Practices by Mothers Using Traditional Birth Attendants and Health Workers in Western Nepal- Consent Form

I agree to participate in the study of A Cohort Study of Exclusive Breastfeeding Rates and Infant Feeding Practices by Mothers Using Traditional Birth Attendants and Health Workers in Western Nepal. I understand that my participation is completely voluntary and I may withdraw from the study at any time. I understand that my participation will be limited to completing a few questionnaires during my baby's first year of life. I understand that all interviewers working on the study are qualified health professionals and that all individual data will be kept strictly confidential.

\_\_\_\_\_  
\_\_\_\_\_

Signature

Date

\_\_\_\_\_  
\_\_\_\_\_

Name (please print)  
number

Telephone

\_\_\_\_\_Address

## Appendix 8: Questionnaires (English version)

### Baseline Questionnaire

#### Participant's identification and basic information

Respondent ID /_____/_____/_____/	Name of the mother .....
Village/Ward ID /_____/_____/	Sex of child:
Interviewer ID /_____/_____/	Name of child:
Date of interview Month.....Day.....	Age of the infant .....days
Contact phone: .....	Height of the mother (in Centimetres).....
Next to kin: .....	Mode of delivery: Vaginal / Instrumental/ Caesarean
Are of residence: (i) Rural (ii) Urban	

*If the age of the infant is more than 30 days, stop this interview.*

#### Socio-economic and demographic information

			Skip Pattern
100	What is your age (years)?	..... Years	
101	Marita status?	Married/ de-facto Separated/divorced Single	
102	At what age did you get married?	..... Years	
103	What is your ethnicity/caste?	.....(write based on the response)  Please select one of the following category for the ethnicity of the respondent: 1. Dalit 2. Disadvantaged janajati 3. Disadvantaged non-dalit terai people 4. Religious minorities (Muslim)	

		5. Advantaged janajatis (Gurung/Newar) 6. Upper caste (Brahmin/Chhetri) 7. Others (specify)	
104	What is your religion?	1. Hindu 2. Buddhist 3. Muslim 4. Christian 4. Other (Specify).....	
106	What is the highest level of education you attended?	1. No schooling 2. Primary (grade 1-5) 3. Lower secondary (grade 6-8) 4. Secondary (grade 9 & 10) 5. Higher secondary (grade 11 and 12) 6. Some university degree ( Bachelor and above)	
107	What is the highest level of education your husband attended?	1. No schooling 2. Primary (grade 1-5) 3. Lower secondary (grade 6-8) 4. Secondary (grade 9 & 10) 5. Higher secondary (grade 11 and 12) 6. Some university degree ( Bachelor and above)	
108	How many members are there in your house?  Decide whether this family is <u>joint or nuclear</u> .	.....  1. Joint and extended 2. Nuclear	
109	What is your main occupation? <i>(Tick only one; Don't read the list)</i>	1. Employed/ salaried job (name.....) .....) 2. Semi-employed a. wage based labour b. small business c. employed aboard 3. Agriculture 4. Unemployed (housewife)	
110	What is your husband's main occupation? <i>(Tick only one; Don't read the list)</i>	1. Employed/ salaried job (name.....) .....) 2. Semi-employed a. wage based labour b. small business c. employed aboard 3. Agriculture	

		4. Unemployed	
111	What is your family income per month?	NPR..... .....	
112	How many children have you given birth, including stillbirths?	1. Male 2. Female 3. Still born	
113	If this was second or more childbirth, how long did you space (birth interval)?	.....months	
114	Do you smoke cigarette/hokka- piped smoke/bidi/any tobacco product?	1. Daily user 2. Occasional user 3. Non user, never smoked 4. Non user, former smoker	
115	Does your partner (father) smoke cigarette/hokka- piped smoke/bidi/any tobacco product?	1. Daily user 2. Occasional user 3. Non user, never smoked 4. No user, former smoker	

### Breastfeeding

116	Have you ever breastfed NAME (child)?	O: No 1: Yes	
117	Are you currently breastfeeding?	O: No 1: Yes	
A	If Yes, how long are you intending to breastfeed?	.....months..... year/s	
B	If No, how long did you breastfeed?	.....days	
118	How long after birth did you first breastfeed NAME (the child)?	1. Less than or within 1 hour 2. After 1 hr till 6 hours 3. 7-24 hours 4. 1-3 days. 5. 3 days or more 6. Not yet 7. Do not know	
119	Before you initiated to breastfeed, did you provide	1. Only mother's milk is provided	

	<p>NAME (child) anything aside from breast milk?</p> <p><i>( Please read the list to help mother to recall)</i></p> <p><b>Decide if mother provided prelacteal feeds</b></p>	<ol style="list-style-type: none"> <li>2. Plain water</li> <li>3. Cows' or buffalos' milk</li> <li>4. Sugar/glucose water</li> <li>5. Sugar/salt water</li> <li>6. Ghee</li> <li>7. Honey</li> <li>8. Ghee and honey</li> <li>9. Fruit juice</li> <li>10. Infant Formula</li> <li>11. Breast milk from other mothers</li> <li>12. Other (specify).....</li> </ol> <ol style="list-style-type: none"> <li>1. Not provided</li> <li>2. Provided</li> </ol>	
<p>120</p> <p>A</p> <p>B</p>	<p>If you have given any food to NAME (of baby) other than breast milk for the first time, why did you do so?</p> <p>What do you think is the benefit of providing the foods other than breast milk (. ....<b>pick the name from list of Q 119</b>) as the baby's first food?</p> <p>In your opinion, is there any harm in providing such foods (<b>..... pick up the name Q119</b>) from the list above?  <i>( more than one answer possible)</i>  <i>(Do not read the options )</i></p>	<ol style="list-style-type: none"> <li>1. Was not able to breastfeed after childbirth due to exhaustion</li> <li>2. Was not able to breastfeed as I has caesarean delivery</li> <li>3. This is our culture that we first provide other foods to our babies</li> <li>4. Other reason.....</li> </ol> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <ol style="list-style-type: none"> <li>1. I do not think there any harm</li> <li>2. Increased chances of infection</li> <li>3. Increased diarrhoea</li> </ol>	

C	<p>Who advised you to provide such foods (<b>.....pick the name of food from above list Q119</b>) to your baby?  <i>( more than one answer possible )</i>  <i>(Do not read the options )</i></p>	<p>4. Difficult to establish breastfeeding after providing other foods  5. Others  .....  .....</p> <p>1. My mother/Mother-in-law  2. Nurse/ ANM  3. Female Community Health Volunteers  4. Traditional attendant  5. Senior women  6. Doctor/Health Assistant/CMA  7. Others .....  8. No one</p>	
121	<p>Did you provide the yellowish first breastmilk (<i>Nepali Term: Bigauti dudh</i>) to NAME (your baby)?</p> <p><b><i>If No: ask the following questions</i></b></p> <p>What was the reason for not giving colostrum for the child?</p> <p>A</p> <p>B</p> <p>Who told you to not to provide colostrum NAME?</p>	<p>1. Yes  0: No</p> <p>1. Colostrum is not digestible for the infant  2. Colostrum is harmful for the infant  3. Colostrum is not clean enough to provide the infant  4. Colostrum does not look nice (Pus like appearance)  5. Others.....  .....</p> <p>1. My mother/mother-in-law  2. Nurse/midwife/MCHW  3. FCHV  4. Traditional attendant/Dai  5. Senior women  6. Doctor/ HA/CMA</p>	

		7. Others..... 8. No one	
122	Did you provide your baby any of the following food or drink since birth?  <i>(Read the list , multiple answers)</i>	1. Nothing other than mother's breastmilk 2. Infant formula (Cerelac/Nestle) 3. Plain water 4. Cow or buffalo's milk 5. Breast milk from another woman 6. Sugar water 7. Sugar salt water 8. Ghee 9. Honey 10. Tea 11. Adult foods 12. Other food perceived good for child (write the name if any) .....	
123	In last 24hours, did you provide any of the following foods?  <i>(Read the list, multiple answers)</i>	1. Nothing other than mother's breastmilk 2. Infant formula (Cerelac/Nestle) 3. Plain water 4. Cow or buffalo's milk 5. Breast milk from another woman 6. Sugar water 7. Sugar salt water 8. Ghee 9. Honey 10. Tea 11. Adult foods 12. Other food perceived good for child (write the name if any) ..... .....	If option 1 and/or 5 (Only)- go to Q 130 .....
124	How old was NAME (child) when you introduced the food (other than breast milk)?	.....weeks	
For mothers who are feeding their infant only formula/cow/buffalo milk i.e not able to breastfeed (If you tick option 2 in question ... ; otherwise go to Next section			
125	Did you try to breastfeed your	1. Yes	

	baby?	0. No	
126	Which formula are you using (if bought from market)? (Please, try to see and write the name)	..... ...	
A.	What factors are most important for you to choose the infant formula?	<ol style="list-style-type: none"> <li>1. Price</li> <li>2. Place of origin</li> <li>3. Brand</li> <li>4. Advertising</li> <li>5. Word of mouth</li> <li>6. Ingredient of formula</li> <li>7. Recommended by hospital</li> <li>8. Others _____</li> </ol>	
127	What is your pattern of infant feeding? ( <b>Do not read the answers</b> )	<ol style="list-style-type: none"> <li>1. Infant formula exclusively</li> <li>2. Half breastfed, half infant formula</li> <li>3. Mostly breastfed, sometimes infant formula feeding</li> <li>4. Mainly infant formula, but mixed with other foods</li> </ol>	
128	What is your pattern of cow/buffalo milk feeding? ( <b>Do not read the answers</b> )	<ol style="list-style-type: none"> <li>1. Cow/buffalo milk exclusively</li> <li>2. Half breastfed, half Cow/buffalo milk</li> <li>3. Mostly breastfed, sometimes Cow/buffalo milk</li> <li>4. Mainly Cow/buffalo milk, but mixed with other foods</li> </ol>	
129	What were the reasons that you chose of bottle-feeding or cow/buffalo milk feeding?  (You may tick more than one option. <b>Do not read the option.</b> )	<ol style="list-style-type: none"> <li>1. Bottle-feeding/Cow, buffalo is as good as breastfeeding</li> <li>2. Bottle-fed is easier</li> <li>3. I have to go to work</li> <li>4. Breastfeeding will make my breast sag</li> <li>5. the baby's father prefers bottle-feeding</li> <li>6. I have problem on breastfeeding</li> <li>7. Other (specify).....</li> </ol>	

130	When you were pregnant, how long did you plan to breastfeed exclusively? <i>(Explain: providing breastmilk and nothing else is called exclusive breastfeeding.)</i>	.....months.	
131	<i>Do not ask this question if already introduced any food item.</i> How long are you intending to breastfeed exclusively?	.....months.	

### Problems during breastfeeding

132	Did/do you have any problems during breastfeeding your child	1. Yes	0. No	
133	Have you experienced any of the following since you started breastfeeding?			
A	A painful swelling part of breast	1. Yes	0. No	
B	Cracked or sore nipple	1. Yes	0. No	
C	Inverted nipples	1. Yes	0. No	
D	Did you generally feel more stressed than normal as a result of breastfeeding?	1. Yes	0. No	
E	Did you generally feel more tired or run down, than normal?	1. Yes	0. No	
F	Baby has problems in sucking milk	1. Yes	0. No	
G	Baby does not wake up for feeding	1. Yes	0. No	
H	My breast milk is not enough	1. Yes	0. No	
I	Breast abscess (wound )	1. Yes	0. No	
J	Illness of the infant	1. Yes	0. No	
K	Illness of the mother	1. Yes	0. No	
L	Return to work			
134	<b>Now I want you to recall about the breast pain.</b>  Did you have any of the following in your breast?	1. Yes	0. No	

A	Red,	1. Yes	0. No	
B	Pain,	1. Yes	0. No	
C	Lump			
<b>D</b>	<b>Along with these signs/symptoms, did you have any of following?</b>			
DA	Fever .....(temperature/ felt by mother)	1. Yes	0. No	
DB	Shivering/chills	1. Yes	0. No	
DC	Hot sweats	1. Yes	0. No	
DD	Headache/body ache	1. Yes	0. No	
<b>135</b>	<b>If there was pain/redness/lump in breast,</b>			
A	Could you please tell me when you noticed first?	.....	week	
B	How many times did you get such symptoms?	.....	times	
C	If you got for more than one times, please tell me when you got again? (weeks refers to week of childbirth)	Second time in .....weeks. Third time in .....weeks Fourth time .....weeks .		
136	Did you ask for advice or help from anyone when suffering this problem (Mastitis)?	1. No 2. Yes		<b>1.No :GO to Q137</b>
A	If Yes, who did you ask for? <i>(You can tick more than one answer)</i>	1. Doctor 2. Other health professional e.g. nurse, midwife 3. My mother or mother-in-law 4. Other family members or relatives		

B	<p>If Yes, what were the suggestions the suggestions provided by them? <i>(More than one answers possible).</i></p>	<p>5. Other (please specify) _____</p> <ol style="list-style-type: none"> <li>1. Continuing breastfeeding as previous</li> <li>2. Continuing breastfeeding more frequently</li> <li>3. Discontinue breastfeeding</li> <li>4. Express breast milk</li> <li>5. Medicines</li> <li>6. Homemade medicines</li> <li>7. Dietary restrictions..... .....(specify)</li> <li>8. Any other advices (Please..... .....)</li> </ol>	
137	<p>How did you manage when you were having such painful swollen breast ( mastitis) [Do not read the list]</p>		
A	Stop feeding form the affected breast	1. Yes      0. No	
B	Wean your baby	1. Yes      0. No	
C	Feed frequent from the affected breast	1. Yes      0. No	
D	Express breastmilk	1. Yes      0. No	
E	Massage the affected breast prior to and after the feed	1. Yes      0. No	
F	Apply heat on the affected breast prior to and after the feed	1. Yes      0. No	
G	Apply cold packs after feeding	1. Yes      0. No	
H	Use of medicine ( pain killer)	1. Yes      0. No	
I	Use of Medicine (antibiotics)	1. Yes      0. No	
J			

K	Avoid eating some of the foods  If avoided some food, write the names .....  Others.....	(..... Specify)	
138	Were you diagnosed with mastitis from a doctor before this delivery?	1. Yes 0. No	
139	Did you experience these symptoms (breast pain, elevated temperature, or diagnosed mastitis by health workers) in your previous childbirth?	1. First time mothers (not applicable) 2. Yes  If yes..... times.	

### Tea consumption

140	Did you drink tea before your current pregnancy?	0: No :Go toQ..146  1: Yes	
141	Which kind of tea did you drink?	1. Green tea 2. Black tea 3. Oolong tea 4. Black tea with milk	
142	When you drank tea..... (green or black), how did you drink?	1. Only tea (with/without sugar) 2. Mix with milk and boil 3. First prepare tea and add milk on it	
143	How many times did you drink tea?	.....cups ( size 150 ml/200 ml)	
144	How many years had you been drinking tea?	.....years	

145	<p>Since NAME (of child) was born, have you changed your tea drinking habit?</p> <p>If changed the habit, please tell me what did you change?</p>	<p>1. No 2. Yes</p> <p>.....</p>	
-----	---	--------------------------------------	--

**Section 2. Pregnancy and childbirth**

Now I would like to ask you about the services that you used during your pregnancy and delivery.

<b>Now please try to recall <u>all of your</u> past pregnancies and deliveries:</b>		
146	<p>What is the weight of NAME (the child) when he/she was born?</p> <p>(see the child card/birth certificate from health facility if available)</p>	<p>1.....grams: 2. Do not know</p> <p>Weight of the child 1. Told by mother 2. From card</p>
147	<p>When (NAME) was born, was he/she very large, larger than average, average, smaller than average, or very small?</p>	<p>1. Very large 2. Larger than average 3. Average 4. Smaller than average 5. Very small</p>
148	<p>In how many weeks the baby was born? (See the antenatal care card if available or record based on mother's recall).</p>	<p>.....weeks.....mont hs.</p> <p><b>Source:</b> 1. Based on the antenatal/maternity card 2. Told by mother</p>
<b>Antenatal care</b>		

14 9	How many antenatal care visits did you make in this recent pregnancy?	.....Times ( If No=0)	<b>If No: go to Q153</b>
15 0	At which months of pregnancy did you visit for antenatal check-up for the first time?	.....week.....months	
15 1	Where did you receive antenatal care for this pregnancy?  <i>(also write down the name of the health care facility, if more than one, tick all applicable)</i>	<b>Home</b> 1. Respondent's home via VHW/FCHV 2. Health personal's home  <b>Public Facility</b> 3. Hospital 4. PHCC ( <i>Gaun ghar Clinic</i> ) 5. HP  <b>Private</b> 6. Nursing Home 7. Pharmacy 8. Other (specify)..... .....	
15 2	During your antenatal visits, did you		
A	receive information on breastfeeding such as time to start breastfeeding, importance of breastfeeding.	1. Yes 2. No 3. DK	
B	Blood pressure taken	1. Yes 2. No 3. DK	
C	Weighed	1. Yes 2. No 3. DK	
D	Received iron tablets	1. Yes 2. No 3. DK	
E	De-worming tablets	1. Yes 2. No 3. DK	
F	TT injections	1. Yes 2. No 3. DK	
G	Education on nutrition, hygiene	1. Yes 2. No 3. DK	
H	Education on danger signs during pregnancy	1. Yes 2. No 3. DK	
I	Education on natal care	1. Yes 2. No 3. DK	
J	Education on the need of skilled birth attendants	1. Yes 2. No 3. DK	
15 3	Why did not you visit for antenatal care?	1. Did not see need 2. Family didn't see need or allow 3. Facility too far	

	<i>(You may tick more than one option. Do not read the options.)</i>	4. Too expensive 5. Services are poor 6. No time to go 7. Nobody to accompany 8. Did not know where to go 9. Other (specify)..... ...	
15 4	Did you take iron supplementations during your pregnancy	0: No 1: Yes.	
A	If you have taken iron supplements during your pregnancy, how many months did you continue?  <i>(Full duration: Start at fourth month of pregnancy continue through child birth)</i>	1. Full duration.....months .....weeks  2. Not full duration .....months.....weeks	
15 5	Did you take any vitamin syrup/tablets during your pregnancy	0: No 1: Yes 2: Do not know	
15 6	Did you smoke (Cigarette/Bidi/Hukka) during pregnancy?	0: No 1: Yes.	
15 7	Did any person in your home smoke during pregnancy?	0: No 1: Yes.	
<b>Prenatal Illness</b>			
15 8	During this pregnancy, did you experience any health problems related to the pregnancy <u>before you deliver your baby?</u>	1. Yes 0. No →	<b>If No: go to ...Q 160</b>
15 9	<u>If yes, what sort of problems did you have during your pregnancy before you deliver your baby??</u>  <i>You may tick more than one option. Do not read the options. Tick options depending on what respondent says.) Probe: Any others?</i>	1. Vaginal Bleeding a. any bleeding b. soaked clothes, bed or floor 2. High Fever 3. Foul smelling vaginal discharge 4. Swollen hands and body 5. Loss of consciousness and convulsions 6. Something coming out from vagina 7. Others (specify)	

		.....	
--	--	-------	--

### Childbirth

160	Where did you deliver your baby?	<ol style="list-style-type: none"> <li>1. Public Hospital</li> <li>2. Private Hospital</li> <li>3. Private clinics/pharmacy</li> <li>4. PHCC/HP</li> <li>5. Birthing centre</li> <li>6. Home</li> <li>7. Others....</li> </ol>	
161	Who attended the delivery and helped during the childbirth?  <i>(Tick only one option)</i>	<ol style="list-style-type: none"> <li>1. Doctor/HA/Nurse/ANM/MCHW</li> <li>2. VHW/FCHV/TBA</li> <li>3. Traditional birth attendant</li> <li>4. Mother-in-law/Other family member</li> <li>5. Relative/Friend/neighbour</li> <li>6. No one</li> <li>7. Other (Specify).....</li> </ol>	
162	During labour and birth, did you experience any health problems related to birth?	<ol style="list-style-type: none"> <li>1. Yes</li> <li>0. No →→Go to Q. 165</li> </ol>	
163	What problems did you experience?  <i>(You may tick more than one option. Do not read the options)</i>	<ol style="list-style-type: none"> <li>1. Severe vaginal bleeding</li> <li>2. Prolonged labour for more than <ol style="list-style-type: none"> <li>i) 12hrs ii) 24 hrs iii) 48 hrs</li> </ol> </li> <li>3. Placenta not delivered within <ol style="list-style-type: none"> <li>i) half an hour ii) 1 hour iii) 2 hours</li> </ol> </li> <li>4. Swollen hands and body</li> <li>5. Loss of consciousness and convulsions</li> <li>6. Others (Specify).....</li> </ol>	
164	Did you have any of the problems since the NAME was born?	<ol style="list-style-type: none"> <li>1. Vaginal bleeding <ol style="list-style-type: none"> <li>i. any vaginal bleeding</li> <li>ii. bleeding which soaked clothes, bed or floor</li> </ol> </li> <li>2. High fever</li> </ol>	

	<i>(You may tick more than one option. Do not read the options. Tick options depending on what respondent says.)</i>	3. Smelly water discharge from vagina 4. Swollen hands and body 5. Loss of consciousness and convulsions 6. Prolapsed uterus (Feeling something coming out of vagina) 6. Other (specify).....	
165	A Have you had any check up by health workers after the childbirth?  B If yes, how many times since NAME was born?  C When did you go for/receive such check-up/postnatal care?  D Where did you go for postnatal care?	1. Yes 0. No----- <b>Goto Q 166</b>  .....times  .....days .....week  <b>Government:</b> 1. Hospital 2. PHCC 3. HP <b>Private:</b> 4. Nursing Home 5. Pharmacy 6. Other (Specify).....	

### Economic Information

166	Major source of drinking water	1. Tap water in own home 2. Tap water in public place 3. Swallow water (river, well and lake)	
167	Toilet facilities in home	1. Flush toilet 2. Ventilated improved pit latrine 3. Dig well latrine 4. No toilet	
168	Do you share a toilet with other houses	1. Yes 2. No	
169	Major source of cooking fuel	1. Electricity/LPG 2. Biogas	

		3. Kerosene 4. Wood	
170	Do you have separate kitchen for cooking?	1. Yes 2. No	
171	Floor materials of house	1. Natural (mud) 2. Semi-cemented 3. Cemented (Cement/Marble/Carpet)	
172	Do you have these things in your house:		
A	Electricity	1 Yes      2 No	
B	Radio	1 Yes      2 No	
C	Television	1 Yes      2 No	
D	Mobile phone	1 Yes      2 No	
E	Sofa	1 Yes      2 No	
F	Cupboard	1 Yes    2 No	

THANK YOU VERY MUCH FOR YOUR PARTICIPATION!

Your next follow up interview, which will be shorter than this, will be \_\_\_/\_\_\_/\_\_\_ (DD /MM/ YYYY)

The possible place for next interview will be \_\_\_\_\_

The possible telephone number for next contact is \_\_\_\_\_ or \_\_\_\_\_ or \_\_\_\_\_

The best time for next interview Daytime: \_\_\_\_\_ Evening: \_\_\_\_\_ Weekend: \_\_\_\_\_

Interviewer sign: \_\_\_\_\_

**Follow up questionnaire: during 3-4 months**

**Participant's identification and basic information**

Interviewers ID /_____/_____/_____/	Name of the mother .....
Village/Ward ID /_____/_____/	Age of the child .....Months
Date of Interview: .....	Sex of child:.....
Place of residence: 1 Rural 2 Urban	Name of child:.....
	Date of birth of child: .....

**Breastfeeding information**

201	Are you currently breastfeeding?	No Yes- ..... <b>Go to Q 204</b>	
202	If No, how long did you breastfeed?	.....weeks .....months.	
203	If discontinued breastfeeding:  Why did you discontinue breastfeeding?  <i>(More than one answer possible)</i>	1. Baby was crying 2. Baby did not gain weight 3. My breastmilk was insufficient 4. I had to go to work 5. I was tired and fatigued 6. I did feel well (illness) 7. My family members advised me to do so 8. Other reasons .....	<b>Go to Q 208</b>
204	Did you provide your baby any of the following things since the last interview? (read the list)	1. Nothing provided except my (or someone else's) breastmilk 2. Vitamin syrup/ ORS (Jeevanjal)/Medicine (for illnesses)  3. Plain water 4. Cows' or buffalos' milk 5. Porridge 6. Superflour porridge or mixture of cereal and rice. 7. Sugar water 8. Sugar salt water 9. Ghee 10. Honey 11. Ghee and honey 12. Tea	If 1 and or 2..... <b>Go to Q207</b>

		13. Adult foods 14. Infant formula such as cerelac 15. Other food perceived good for child (write the name if any) .....	
205	IF you have provided any thing other than breastmilk and medicine, when did you start to do so	Infant's age:.....weeks ..... months	
206	If you provided other foods other than breastfeeding:  Why did you introduce other foods?  <i>(More than one answer possible)</i>	1. Baby was crying 2. Baby did not gain weight 3. My breast milk was insufficient 4. I had to go to work 5. I was tired and fatigued 6. I didnt feel well (illness) 7. My family members advised me to do so 8. Other reasons .....	
207	In the last 24 hours, did you give any of following food to your baby (NAME)	1. Nothing provided except my (or someone else's) breastmilk 2. Vitamin syrup/ ORS (Jeevanjal)/Medicine (for illnesses)  3. Plain water 4. Cows' or buffalos' milk 5. Porridge 6. Superflour porridge or mixture of cereal and rice. 7. Sugar water 8. Sugar salt water 9. Ghee 10. Honey 11. Ghee and honey 12. Tea 13. Adult foods 14. Infant formula such as cerelac 15. Other food perceived good for child (write the name if any)	<b>If other than 1 or 2: please go back to Q205 and 206</b>
208	Where did you have your childbirth?	1. Government hospital 2. Private hospital 3. Private clinics 4. PHC/HP/SHP 5. Birthing Centre_____	<b>Go to Q 210</b>

		6. Home  7. Others ..	
209	Who assisted your during your childbirth?	1. Doctor/HA/Nurse/ANM/AH W/MCHE 2. VHW/FCHV/TBA  3. Mother-in-law/other family member 4. Relatives/friends/neighbours 5. No one	<b>If 3,4&amp;5 : go to Q 211</b>
210	<b>Breast feeding promotion:</b>	<b>Baby friendly hospital initiatives recommendations for community level</b>	
A	Did your health worker advise you of the followings:  Breastfeeding initiation within one hour?	0: No      1: Yes	
B	No food or drinks to be provided other than breast milk?	0: No      1: Yes	
C	Rooming in i.e. Mother and baby kept together all time?	0: No      1: Yes	
D	Breastfeed the baby when the baby demands/cries?	0: No      1: Yes	
E	Give no pacifiers or teats	0: No      1: Yes	
F	Information on breastfeeding support: where can you seek help if you have any problem regarding breastfeeding?		
211	Does your mother/mother-in law have any preferences for how you feed your baby?	1. Infant formula 2. Breastmilk 3. Animal milk (cow and buffalo) 4. Does not mind how I feed	

		<ul style="list-style-type: none"> <li>5. Breastmilk and animal milk mixed</li> <li>6. Breastmilk and infant formula mixed</li> <li>7. Others.....</li> </ul>	
212	Did your mother/ mother in law encourage you to breastfeed?	<ul style="list-style-type: none"> <li>1. Yes</li> <li>2. No</li> </ul>	
213	Does the baby's father have any preferences for how you feed your baby?	<ul style="list-style-type: none"> <li>1. Infant formula</li> <li>2. Breastmilk</li> <li>3. Animal milk (cow and buffalo)</li> <li>4. Does not mind how I feed</li> <li>5. Breastmilk and animal milk mixed</li> <li>6. Breastmilk and infant formula mixed</li> <li>Others.....</li> </ul>	
214	Did the baby's father encourage you to breastfeed?	<ul style="list-style-type: none"> <li>1. Yes</li> <li>2. No</li> </ul>	
215	Have you received any breastfeeding education and information from anywhere on how to feed your baby?	<ul style="list-style-type: none"> <li>1. Yes, for this pregnancy</li> <li>2. Yes, for a previous pregnancy</li> <li>3. No → .....<b>Go to Q218</b></li> </ul>	
216	Where did you receive the breastfeeding information?	<ul style="list-style-type: none"> <li>1. Antenatal Clinic</li> <li>2. During hospital stay during childbirth</li> <li>3. Other (specify).....</li> </ul>	
217	Which is the main source of breastfeeding information for you?	<ul style="list-style-type: none"> <li>1. Booklets</li> <li>2. TV</li> <li>3. Lectures</li> <li>4. Individual consultation (doctor, nurse, community health worker)</li> <li>5. Others specify).....</li> <li>..</li> </ul>	
218	<p>Why did you decide to breast-feed?</p> <p><i>(You may tick more than one option. Do not read the options. )</i></p>	<ul style="list-style-type: none"> <li>1. Breastfed babies are healthier</li> <li>2. Breastfeeding is the best for baby</li> <li>3. Mother and baby become closer</li> <li>4. Emptying breast is good for mother</li> <li>5. Breast-fed babies are more intelligent</li> </ul>	

		6. Breastfeeding is right of baby 7. The baby's father wanted me to breast-feed 8. Breastfeeding is cheaper 9. ....advised me to breastfeed 10. Others.....	
--	--	---	--

**Problems during breastfeeding**

219	Did/do you have any problems during breastfeeding your child since the last interview?	1. Yes    0. No	
220	Remember your breastfeeding breastfeeding (only used by researcher)	Mastitis    No Mastitis	
221	Now I want you to recall about the breast pain since the last interview? Did you have any of the following in your breast?		
A	Red,	1. Yes    0. No	
B	Pain,	1. Yes    0. No	
C	Lump	1. Yes    0. No	
<b>D</b>	<b>Along with these signs/symptoms, did you have any of following? (Read the list)</b>		
DA	Fever .....	1. Yes    0. No	
DB	.....(temperature/ felt by mother)	1. Yes    0. No	

DC	Shivering/chills	1. Yes    0. No	
DD	Hot sweats	1. Yes    0. No	
	Headache/body ache	<b>If there was none....Go to Q 223</b>	
A	If there was pain/redness/lump in breast since the last interview,  When did you noticed first?	.....week	
B	How many times did you get such symptoms?	.....times	
C	If you got for more than one times since the last interview, please tell me when you got again? (weeks refers to week of childbirth)	.....weeks. .....weeks .....weeks.	
222	How did you manage when you were having such painful swollen breast ( mastitis)		
A	Stop feeding form the affected area	1. Yes    0. No	
B	Weaning	1. Yes    0. No	
C	Feed frequent from the affected breast	1. Yes    0. No	
D	Express breastmilk	1. Yes    0. No	
E	Massage the affected breast prior to and after the feed	1. Yes    0. No	
F	Apply heat on the affected breast prior to and after the feed	1. Yes    0. No	
G	Apply cold packs after feeding	1. Yes    0. No	
H	Use of medicine ( pain killer)	1. Yes    0. No	

I	Use of Medicine (antibiotics)	1. Yes      0. No	
J	Avoid eating some of the foods write the names .....	1. Yes      0. No  (.....S pecify)	
K	Others.....	..... ..... .....(Specify)	
223	Were you diagnosed with mastitis from a doctor before this delivery?	No-----0 Yes-----1	
224	In previous childbirth, did you experience painful breast, fever and inflammation?	1. This is my first child  2. Yes .....times	

THANK YOU VERY MUCH FOR YOUR PARTICIPATION!

Your next interview will be shorter than today's interview.

Your next follow up interview will be \_\_\_/\_\_\_/\_\_\_ (DD /MM/ YYYY)

The possible place for next interview will be \_\_\_\_\_

The possible telephone number for next contact is \_\_\_\_\_or  
\_\_\_\_\_or \_\_\_\_\_

The best time for next interview: Daytime: \_\_\_\_\_ Evening:  
\_\_\_\_\_ Weekend: \_\_\_\_\_ ..... Interviewer sign:  
\_\_\_\_\_

## Follow-up during sixth month

### Participant's basic information

Respondent ID /_____/_____/_____/	Name of the mother ..... ....
Village/Ward ID /_____/_____/	Sex of child:
Date of Interview Month.....Day..... ...	Age of the child .....months
Phone number of respondent: .....	Name of child: ..... Date of birth of child: .....

### Exclusive breastfeeding and complementary food

301	Are you currently breastfeeding?	1. No 2. Yes- ..... <b>Go to                  .....Q304</b>	
302	If no, how long did you breastfeeding?	.....weeks.....month s	
303	If discontinued breastfeeding:  Why did you discontinue breastfeeding?  <b>(More than one answer possible)</b>	1. Baby was crying 2. Baby did not gain weight 3. My breast milk was insufficient 4. I had to go to work 5. I was tired and fatigued 6. I didnot feel well (illness) 7. My family members advised me to do so 8. Other reasons..... ..... <b>Go to Q 308</b>	

304	<p>If you are currently breastfeeding,</p> <p>Did you provide your baby with any of the following things since the last interview?</p>	<ol style="list-style-type: none"> <li>1. Nothing provided except my (or someone else's) breastmilk</li> <li>2. Vitamin syrup/ ORS (Jeevanjal)/Medicine (for illnesses)</li> <li>3. Plain water</li> <li>4. Cows' or buffalos' milk</li> <li>5. Porridge</li> <li>6. Super flour porridge or mixture of cereal and rice.</li> <li>7. Sugar water</li> <li>8. Sugar salt water</li> <li>9. Ghee</li> <li>10. Honey</li> <li>11. Ghee and honey</li> <li>12. Tea</li> <li>13. Adult foods</li> <li>14. Infant formula such as cerelac</li> <li>15. Other food perceived good for .....</li> </ol>	<p><b>If response 1 and 2: Go to Q 307</b></p>
305	<p><i>If provided food other than mother's milk,</i></p> <p>When did you introduce?</p>	<p>Child's age...weeks.....months</p>	
306	<p>Why did you introduce food other than breastmilk?</p>	<ol style="list-style-type: none"> <li>1. Baby was crying</li> <li>2. Baby did not gain weight</li> <li>3. My breast milk was insufficient</li> <li>4. I had to go to work</li> <li>5. I was tired and fatigued</li> <li>6. I didnot feel well (illness)</li> <li>7. My family members advised me to do so</li> <li>8. Other reasons....</li> </ol>	
305	<p>In last 24hours, did you provide any foods beside breast milk?</p>	<ol style="list-style-type: none"> <li>1. Nothing provided except my (or someone else's)</li> </ol>	

	<i>Interviewer: read the list above and confirm none of the food listed above were given by probing.</i>	breastmilk 2. Vitamin syrup/ ORS (Jeevanjal)/Medicine (for illnesses)  3. Plain water 4. Cows' or buffalos' milk 5. Porridge 6. Super flour porridge or mixture of cereal and rice. 7. Sugar water 8. Sugar salt water 9. Ghee 10. Honey 11. Ghee and honey 12. Tea 13. Adult foods 14. Infant formula such as cerelac 15. Other food perceived good for .....  If provided other than no.1 and 2..... <b>Go to back and complete Q 305 and 306</b>	
308	Who decided to introduce complementary food?	1. Myself (mother) 2. Child's father 3. Mother-in-law 4. Father-in-law 5. Priests/Pundits	
309	Since the last interview, did you receive any information on recommended time of exclusive breastfeeding?	1. Yes 2. No	
	<b>Infant's Illness</b>		
310	Since the last interview, has NAME (infant) suffered any illness?	1. No ..... <b>Go to Q311</b> 2. Yes	
A	<b>Ask what illness?</b>	1) Respiratory illness	

		(Pneumonia, cough, shortness of breathing, & running nose).....(times of illness) 2) Diarrhoea ( Loose stool for three times or more in a day, blood in stool) .....(times of illness) 3) Others (specify).....	
	Details of infant feeding in last 24-hrs.		
311	In the last 24 hours, did you provide any of the following foods to the baby: [ <i>Read the list</i> ]		
A	Plain water	1. Yes 0. No	
B	Juice or juice drinks	1. Yes 0. No	
C	Soup	1. Yes 0. No	
D	Animal milk	1. Yes 0. No	
	<b><i>If</i></b>		
E	<b><i>yes.....times</i></b> Infant formula like lactogen, cerelac <b><i>If yes.....times</i></b>	1. Yes 0. No	
F		1. Yes 0. No	
G	Any other liquids Yogurt <b><i>If yes.....times</i></b>	1. Yes 0. No	
H	Any fortified baby food like:	1. Yes 0. No	

I	Cerelac, Nestum, Champion, Roti, rice, maize, millet, noodles, porridge, or other foods made from grains?	1. Yes 0. No	
J	Pumpkin, carrots, squash or sweet potatoes that are yellow or orange inside?	1. Yes 0. No	
K	White potatoes, white yams, colocasia, or any other foods made from roots?	1. Yes 0. No	
L	Any dark green, leafy vegetables like spinach, amaranth leaves, mustard leaves?	1. Yes 0. No	.....(Times )
M	Ripe mangoes, papayas or apricot	1. Yes 0. No	
N	Any other fruits or vegetables	1. Yes 0. No	
O	Liver, kidney, heart or other organ meats	1. Yes 0. No	
P	Any meat, such as pork, buff, lamb, goat, chicken, or duck	1. Yes 0. No	
Q	Eggs	1. Yes 0. No	
R	Fresh or dried fish or shellfish	1. Yes 0. No	
S	Any foods made from beans, peas, lentils, or nuts	1. Yes 0. No	
T	Cheese or other food made from milk	1. Yes 0. No	
U	Any other solid, semi-solid,		

	or soft food (Jaulo, lito, sarbottam pitho etc.)		
312	<p>How many times did (NAME) eat solid, semisolid, or soft foods yesterday during the day or at night?</p> <p>IF 7 OR MORE TIMES, RECORD '7'.</p>	<p>.....times</p> <p><b>Not applicable</b> – if provided breastmilk only.</p>	

## Appendix 9: Author contribution form

### To whom may it concern

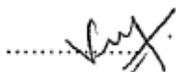
I, Professor Andy H. Lee, contributed as a co-supervisor of the **PhD Project of Vishnu Khanal**. I had an ongoing involvement with the research during project design, instrument design, field work, data analysis, interpretation of results and manuscript writing and revision for the following papers. Vishnu Khanal, the candidate, was responsible for all decisions related to design and implementation of research, data analysis, drafting of manuscript and interpretation of findings.

1. Vishnu Khanal, Jane A. Scott, Andy H. Lee, and Colin W. Binns. *Incidence of Mastitis in the Neonatal Period in a Traditional Breastfeeding Society: Results of a Cohort Study*. *Breastfeeding Medicine* (2015).
2. Vishnu Khanal, Andy H. Lee, Rajendra Karkee, & Colin W. Binns. *Postpartum Breastfeeding Promotion and Duration of Exclusive Breastfeeding in Western Nepal*. *Birth* (2015).
3. Vishnu Khanal, Andy H. Lee, Rajendra Karkee, & Colin W. Binns. *Prevalence and factors associated with prelacteal feeding in Western Nepal*. *Women and Birth* (2015).
4. Vishnu Khanal, Jane Scott, Andy Lee, Rajendra Karkee, & Colin Binns. *Factors associated with early initiation of breastfeeding in Western Nepal*. *International Journal of Environmental Research and Public Health* (2015).



Andy H. Lee (Co-author)

Professor

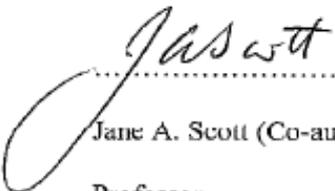


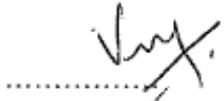
Vishnu Khanal (PhD Candidate)

**To whom may it concern**

I, Professor Jane A. Scott, contributed as a co-supervisor of the **PhD Project of Vishnu Khanal**. I had an ongoing involvement with the research during project design, instrument design, field work, data analysis, interpretation of results and manuscript writing and revision for the following papers. The candidate was responsible for all decisions related to design and implementation of research, data analysis, drafting of manuscript and interpretation of findings.

1. Vishnu Khanal, Jane A. Scott, Andy H. Lee, and Colin W. Binns. *Incidence of Mastitis in the Neonatal Period in a Traditional Breastfeeding Society: Results of a Cohort Study*. Breastfeeding Medicine (2015).
2. Vishnu Khanal, Jane Scott , Andy Lee, Rajendra Karkee, & Colin Binns. *Factors associated with early initiation of breastfeeding in Western Nepal*. International Journal of Environmental Research and Public Health (2015).

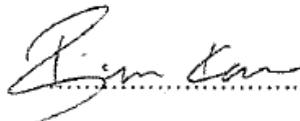
  
.....  
Jane A. Scott (Co-author)  
Professor

  
.....  
Vishnu Khanal (PhD Candidate)

## To whom may it concern

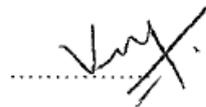
I, Dr. Rajendra Karkee, provided advice on the measurement instruments, manuscript conceptualisation, reviewed drafts and suggestions the revision of the following papers. Vishnu Khanal, the candidate, was responsible for all decisions related to design and implementation of research, data analysis, drafting of manuscript and interpretation of findings.

1. **Vishnu Khanal**, Andy H. Lee, Rajendra Karkee, & Colin W. Binns. *Postpartum Breastfeeding Promotion and Duration of Exclusive Breastfeeding in Western Nepal*. Birth (2015).
2. **Vishnu Khanal**, Andy H. Lee, Rajendra Karkee, & Colin W. Binns. *Prevalence and factors associated with prelacteal feeding in Western Nepal*. Women and Birth (2015).
3. **Vishnu Khanal**, Jane Scott, Andy Lee, Rajendra Karkee, & Colin Binns. *Factors associated with early initiation of breastfeeding in Western Nepal*. International Journal of Environmental Research and Public Health (2015).



Dr. Rajendra Karkee, (Co-author)

Associate Professor



Vishnu Khanal (Candidate)

### To whom may it concern

I, Professor Colin W. Binns, contributed as the main supervisor of the **PhD Project of Vishnu Khanal**. I had an ongoing involvement with the research during project design, instrument design, field work, data analysis, interpretation of results and manuscript writing and revision for the following papers. Vishnu was responsible for all decisions related to design and implementation of research, data analysis, drafting of manuscript and interpretation of findings.

1. Vishnu Khanal, Jane A. Scott, Andy H. Lee, and Colin W. Binns. *Incidence of Mastitis in the Neonatal Period in a Traditional Breastfeeding Society: Results of a Cohort Study*. Breastfeeding Medicine (2015).
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9/5/2016

Colin W. Binns, (Co-author)

John Curtin Distinguished Professor



Vishnu Khanal (PhD Candidate)

**Appendix 10: Oral and poster presentation from the PhD Project**

**Oral presentation certificate: Mark Liveris Seminar, Faculty of Health Sciences, Curtin University, November, 2015**



Faculty of Health Sciences

**CERTIFICATE OF PARTICIPATION**

This is to certify that

Vishnu Khanal

Represented the School of Public Health at

**THE MARK LIVERIS HEALTH SCIENCES RESEARCH STUDENT SEMINAR**

Thursday, 3 September, 2015

Presenting a paper entitled:

*Methodological differences in measuring the rates of exclusive breastfeeding in Nepal*

A handwritten signature in blue ink that reads "M. Berndt".

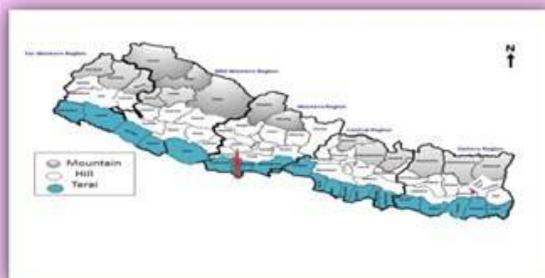
Professor Michael Berndt  
Pro Vice-Chancellor  
Faculty of Health Sciences

Thursday 3 September, 2015

## Methodological differences in measuring rates of exclusive breastfeeding in Nepal

Vishnu Khanal \*<sup>1</sup>, Andy H. Lee<sup>1</sup>, Jane A. Scott<sup>1</sup>, Rajendra Karkee<sup>1</sup>, Colin W. Binns<sup>1</sup>

\*Correspondence: [khanal.vishnu@gmail.com](mailto:khanal.vishnu@gmail.com); <sup>1</sup> School of Public Health, Curtin University, Perth, Australia.



### Methods..

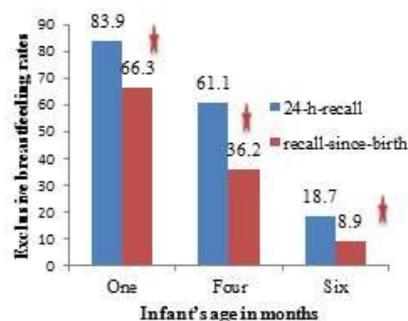
A prospective cohort study was conducted during January-October 2014 in the Rupandehi district of western Nepal among 735 randomly recruited mother-infant pairs within the first month postpartum and followed up during the fourth and sixth months.

### Introduction

Measuring exclusive breastfeeding is a complex issue as rates can vary according to the definition, measurement period, questions asked, and infant's age<sup>1,2</sup>. This study compared exclusive breastfeeding rates using two methods of measurement i.e. '24-h-recall' and 'recall-since-birth' in a cohort study undertaken in western Nepal.

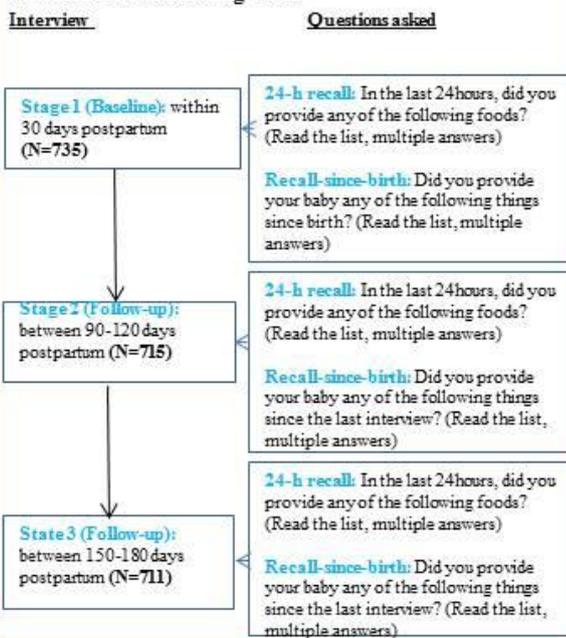
### Results

Figure 2: Exclusive breastfeeding rates by infant age and methods of reporting



### Methods

Figure 1. Study interview flow chart and questions asked to measure breastfeeding rates



### Conclusion and recommendations

The 24-h-recall method leads to over-estimation of the prevalence of exclusive breastfeeding when compared to the recall-since-birth method.

While recall since birth with repeated measure is costly and time consuming, some sentinel sites can be established to represent the country, and prospective data can be collected periodically from the chosen sites to measure the rates of exclusive breastfeeding for six months in Nepal.

### References:

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