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Nastassia L. Donoho Date

Determinants of Early Exclusive Breastfeeding among Ethiopian Infants: Cross-sectional Analysis from the Performance Monitoring for Action Data 2016

By

Nastassia L. Donoho
Master of Public Health
Hubert Department of Global Health
Rollins School of Public Health
Emory University

Dr. Melissa Fox Young
Committee Chair
Hubert Department of Global Health
Rollins School of Public Health
Emory University

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By
Nastassia Donoho
Master of Public Health
Hubert Department of Global Health
Rollins School of Public Health
Emory University

Bachelor of Science
Public Health: Health Promotion Health Behavior
Oregon State University
2014

Thesis Committee
Dr. Melissa Fox Young, PhD

A thesis submitted to the Faculty of the
Hubert Department of Global Health
Rollins School of Public Health
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Abstract

Introduction: Breastfeeding is a cost-effective child survival intervention that provides optimal nutrition for child health and development. Identifying the factors associated with EBF during the first six weeks of a child's life is vital to increasing overall exclusive breastfeeding rates. Additionally, understanding the association between infant illness and early exclusive breastfeeding practices provides insight into how to address barriers to early exclusive breastfeeding to improve infant survival.

Methodology: There were 333 mother-infant pairs identified as part of the Maternal and Newborn Health Survey from the Performance and Monitoring for Action project in Ethiopia. The objective of this study is to understand the determinants of exclusive breastfeeding in Ethiopia among infants at six weeks. Univariate and bivariate descriptive analysis was done in R to develop a multivariate logistic regression model on the mother's age, education status, wealth index, religion, antenatal care provider, and infant's health status.

Results: Exclusive breastfeeding was its highest at the seven-day time point at 88%, then dipped to 71% at six weeks, and finally dropped down to 16% at six months. At seven days to six weeks post-deliver (AOR=0.43, 95%CI=0.22-0.80), infant illness was associated with a 57% decrease in exclusive breastfeeding at six weeks. On the other hand, Muslim women (AOR=4.09, 95% CI=1.49013.39) or who saw a skilled antenatal care provider (AOR=3.61, 95%CI=1.63-8.16) during pregnancy were significantly more likely to exclusive breastfeed their infant at six weeks. At all three time points, if the infant is sick, the odds of being EBF are significantly decreased: at seven days (OR=0.32, 95% CI=0.14-0.65), at six weeks (OR=0.29, 95% CI=0.17-0.49), and six months (OR=0.41, 95% CI= 0.20-0.72).

Discussion: Early exclusive breastfeeding practices remain suboptimal in Ethiopia. Expanding access to skilled antenatal care (ANC) providers may help improve EBF in this context. Further work on targeting EBF support and counseling for feeding during illness may be merited. Our findings may help inform other programs and policies to support breastfeeding in Ethiopia.

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Chapter 1: Introduction

Neonatal mortality is responsible for 38% of all under-five childhood[2] deaths, which is the most vulnerable time for children with the highest risk of death[2]. In Ethiopia, the neonatal mortality rate is 30 deaths per 1,000 births[2], which in 2017 was approximately 95,000 deaths[3]. Eighty percent of neonatal deaths can be prevented with easy and affordable acts such as skin-to-skin contact, early initiation of exclusive breastfeeding, kangaroo mother care (KMC), and clean, safe facilities[3].

Significant progress has been made in reducing neonatal and infant mortality in Ethiopia over the past few decades. Neonatal mortality decreased from 166 to 67 deaths per 1,000 live births between 2000-2016[3]. This is enormous progress made; however, it still falls short of the desired markers. Early initiation of breastfeeding (EIBF) has been proven to be a determinant in reducing neonatal mortality[3-5]. Continuation of exclusive breastfeeding is also just as crucial for reducing neonatal mortality and morbidity[2,5-10].

Exclusive breastfeeding is one of the most cost-effective ways to ensure children are set up to thrive and survive past their fifth birthday. Recent studies show that exclusive breastfeeding in infants ranges between 29.3% and 81.1% depending on the region of Ethiopia[4,11-16]. Specifically looking at Southern Nations, Nationalities, and Peoples (SNNP), 63.8% of infants are exclusively breastfed[17]. However, except for the one study showing an 81.1% exclusive breastfeeding rate in the Afar region, most of Ethiopia is below the 50% exclusive breastfeeding rate the WHO has set for 2025 and far from the 2030 goal of 70%[18,19].

To increase the rates of exclusive neonatal breastfeeding—thus reducing neonatal, infant, and under-five mortality—there needs to be an understanding of what reasons determine whether women exclusively breastfeed their neonate, including when there might be a medical issue

during delivery or a few weeks after. Breastfeeding has been shown to help mothers prevent port-partum hemorrhages, reduces the risk of breast and ovarian cancer, and helps women space their pregnancies[1,20-22]. For children born prematurely or with low birth weight, exclusive breastfeeding provides healing properties through breast milk and skin-to-skin contact[10,23,24]. Early initiation of breastfeeding has been shown to help the women start healing from delivery quickly[1,25,26]. Additionally, exclusive breastfeeding helps the premature infant grow, increases weight for the low-birth-weight infant, and provides essential nutrients even if it is sick[6,25,27]. Understanding these determinants allows program and policy implementation to increase the prevalence of exclusive breastfeeding while also reducing neonatal mortality.

The objectives of this thesis are to:

1. Examine what factors are associated with exclusive breastfeeding at six weeks.
2. Examine the association between infant illness and early breastfeeding practices.

Terms & Definitions

Term	Definition
Exclusive breastfeeding	Feeding the newborn and infant child only breastmilk (no other food, liquid, or water), with the small exception of medication, minerals, and vitamins deemed necessary by medical professionals, for the first six months after birth[5].
Kangaroo mother care	Skin-to-skin contact between a mother and newborn with frequent, or exclusive, breastfeeding[27].

Low- and middle-income Countries	A country with a Gross National Income per capita between $1,026-$3,996 or less.
Morbidity	Disease or illness that is chronic, including those because of a previous treatment.
Mortality	Death
Neonate	An infant who is 0-28 days old.
Prelacteal feed	Any substance provided to an infant before breastmilk.
Prematurity, preterm	Babies who are born alive before 37 weeks. There are a few sub-categories of preterm birth based on at what week gestation the infant was born[28]. **Extremely preterm-** less than 28 weeks gestation[28] **Very preterm**- 28-32 weeks gestation[28] **Moderate to late preterm**- 32-37 weeks gestation[28]
Skin-to-skin contact	A clean and dry baby wrapped around the mother's bare chest[29].
Term infant	An infant who is born after 37 weeks gestation[28].

Acronyms

Acronym	Definition
ANC	Antenatal Care
BFHI	Baby-Friendly Hospital Initiative
DHS	Demographic Health Survey
EBF	Exclusive breastfeeding
EIBF	Early initiation of breastfeeding
ELBW	Extreme low birth weight
KMC	Kangaroo mother care
LBW	Low birth weight
LMIC	Low- and middle-income countries
PMA	Performance Monitoring for Action
UNICEF	The United Nations Children's Fund
VLBW	Very low birth weight
WHO	World Health Organization

Chapter 2: Literature Review

Overview

Globally each year, 2.6 million children die within their first month of life[30]. Neonatal mortality is responsible for 38% of all under-five childhood deaths[31]. A recent study has found that partial to no breastfeeding has been associated with a 2.23-fold higher risk of infant death for all infant death causes[6,24,32]. There is a 2.40-fold higher risk of deaths attributed to pneumonia and a 3.94-fold higher risk of death due to diarrhea for infants who breastfeed partially or not at all than those who exclusively breastfed[6]. Additionally, research findings have shown a 13% reduction in infant mortality through exclusive breastfeeding practices[8].

Focus on exclusive breastfeeding has grown as the continued effort to reduce neonatal and infant mortality rates, especially in low- and middle-income countries (LMIC). Neonatal mortality can be reduced in the first week of life globally by 22% just by initiating immediate breastfeeding after birth[26]. According to a Lancet article, suboptimal breastfeeding is linked to 1.4 million child deaths and 77% of child deaths from non-exclusive breastfeeding during the first six months after birth[33].

Neonatal Mortality

Neonatal mortality, also known as an infant's death during the neonatal period (the first 28 days of life), accounts for approximately 38% of all deaths in children under five years old[31,34]. In the 2019 Ethiopian Mini Demographic and Health Survey, the neonatal mortality rate was 30 deaths per 1,000 live births for the entire country[35]. The leading causes of neonatal mortality are sepsis, prematurity, low birth weight, and hypothermia[30,36-46]. In 2017, approximately 95,000 neonates died in Ethiopia[7]. There have been multiple studies, in Ethiopia and elsewhere, showing how vital breast milk is in reducing neonatal mortality.[5,30,47,48]

Sepsis

Neonatal sepsis, a systemic infection that plagues the body and ranges in severity, is highly fatal when left untreated (or treated improperly)[49]. For low- and middle-income countries, it accounts for approximately 25% of neonatal deaths[49]. Neonatal sepsis can be treated with low-cost and practical measures usually lacking in many health facilities in Ethiopia[38].

Prematurity

Prematurity is an infant who has been born before 37 weeks gestation and is responsible for approximately 37% of neonatal mortality[38]. The premature neonate is at higher risk for sepsis and infection, leading to an increased risk of neonatal mortality[38].

Low Birth Weight

There are three classifications of low-birth-weight infants: Low Birth Weight (LBW), who are born weighing less than 2500 grams, Very Low Birth Weight (VLBW) who are born weighing less than 1500 grams, and Extremely Low Birth Weight (ELBW) who are born weighing less 1000 grams[50]. LBW infants are also at an increase for sepsis, birth asphyxia, and hypothermia, increasing their risk of neonatal mortality[38].

Hypothermia

Neonatal hypothermia is defined as an abnormal thermal state in which the newborn has a lower body temperature than 36.5 degrees Celsius[51]. There are three categories of hypothermia: mild hypothermia 36.0-36.4 degrees Celsius, moderate hypothermia 32.0-35.9 degrees Celsius, and severe hypothermia, which is lower than 32 degrees Celsius[51]. Neonatal hypothermia can increase by 80% for every one-degree decrease in the core body temperature of the neonate[51].

Breastfeeding

Human breast milk is considered the gold standard for infant feeding guidelines[18]. Multiple childhood health advocacy groups, including the WHO and the Academy of Breastfeeding Medicine[52], express the importance of providing human breast milk to infants exclusively for six months and then supplementary until they are at least two years of age. Infants who receive human breast milk feedings have lower death rates and disease with long-lasting health benefits into adulthood[53]. Breastfeeding provides infants with protection against gastrointestinal disease, necrotizing enterocolitis, and respiratory tract infections while also decreasing incidents of sudden infant death syndrome (SIDS)[18,53].

Human breast milk is composed of nutrients and bioactive compounds that are essential for the newborn infant[53]. The first type of human breast milk released after delivery, called colostrum, is produced four days postpartum. Colostrum is extremely rich in whey proteins and minerals with lower lactose levels, fats, and minerals than mature milk[54]. It takes two weeks postpartum to have human breast milk transition from colostrum to fully mature breast milk[53]. Once breast milk has become fully mature, the composition is approximately 3-5% fat, 6.8-7.2% carbohydrate in lactose, 0.8-0.9% protein, and 0.2% mineral constituents[53]. The most abundant proteins found in human breast milk are casein, lactoferrin, lactalbumin, lysozyme, secretory immunoglobulin IgA, and serum albumin[53,54].

In addition to the macronutrients, there are vast amounts of bioactive compounds in human breast milk. One of these critical bioactive compounds is human milk oligosaccharides (HMOs). HMOs are complex glycans and prebiotic agents vital for gastrointestinal and brain development, found in higher levels in colostrum (20-25 ng/L) and decreasing in mature milk (5-15 ng/L)[53]. Other bioactive agents in human breast milk are antibodies, immunoglobulins,

lactoferrin, lysozyme, antimicrobial peptides, growth factors, white blood cells, and microRNAs[53].

Both the nutrients and the bioactive agents in breastmilk are vital to t an infant during its neonatal period (0-28 days of life) and set them up for success as they age[55]. Figure 1 depicts the different breastmilk components and how it benefits the infant as it ages.

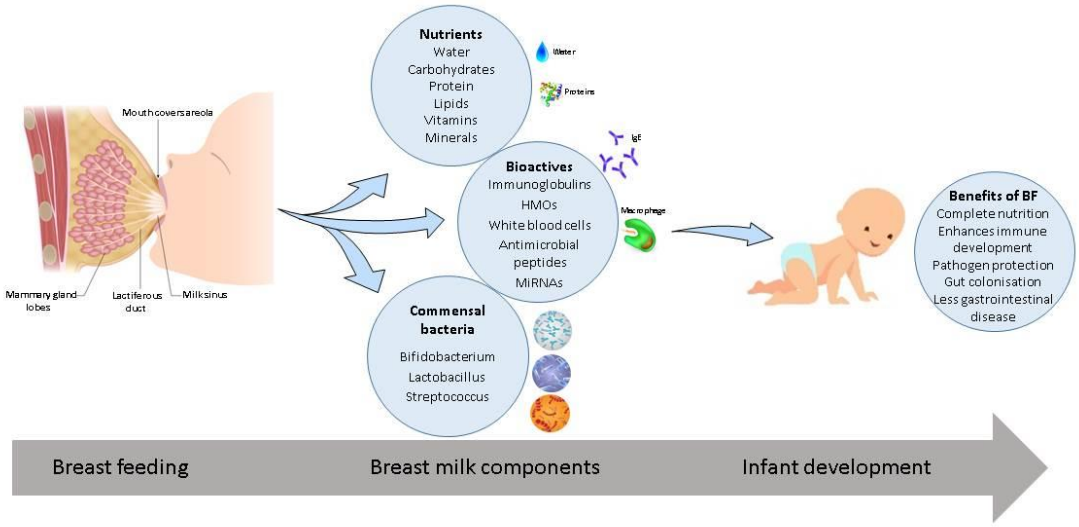

Figure 1: [47] Breastmilk Components

Exclusive Breastfeeding

Exclusive breastfeeding (EBF) is defined as giving breast milk to the infant without any additional water, food, or drink within the first six months except for medicine, vitamins, and mineral supplements that have been determined medically necessary to the infant's health by a doctor [56]. EBF is linked to multiple health benefits for the child, including protection against gastrointestinal infections and prevention of other respiratory deaths (including pneumonia) and

other infections the infant is vulnerable to[6]. Additionally, EBF has long-term benefits to reduce the risk of developing chronic health conditions and disease, such as diabetes mellitus type 2 and obesity[29]. Research has shown that exclusive breastfeeding can reduce infant mortality by approximately 13% in low- and middle-income countries (LMIC).

Despite the benefits from EBF, approximately 36% of infants are exclusively breastfed in LMIC, with 31% in Sub-Saharan Africa[29]. In Ethiopia, suboptimal breastfeeding contributes to approximately 70,000 infant deaths, accounting for 24% of annual infant deaths[6]. In a recent 2018 meta-analysis, the pooled prevalence of EBF in Ethiopia was 59.3%[6]. This is higher than the average for EBF in LMIC and Sub-Sahara Africa. Extensive work needs to be done within EBF to reach the WHO 2030 goal of achieving a 70% EBF rate[18].

Breastfeeding in Ethiopia

The breastfeeding rates among premature infants in Addis Ababa and Ethiopia (and globally) are considerably lower than term infants[9]. Timely initiation of breastfeeding within one hour of delivery can prevent 22% of neonatal deaths[57]. The Ethiopian Demographic and Health Survey 2016 (DHS) has shown that only approximately 51.5% of newborns are initiated to breastfeeding within one hour of delivery[57]. It has been shown that the place of delivery has a significant association with the timely initiation of breastfeeding. Women who delivered their infant at a health facility were 3.5 times more likely to practice timely initiation of breastfeeding than women who did not deliver at a health facility in Ethiopia[57].

For the past decade, there has been a solid push for incorporating Kangaroo Mother Care, providing skin-to-skin contact between a mother and newborn with frequent, or exclusive, breastfeeding[27], (KMC) in health facilities worldwide. In an Ethiopia meta-analysis study, KMC has shown that preterm and LBW infants who received KMC interventions initiated

breastfeeding 2 days 14 hours and 24 minutes earlier than preterm and LBW infants who received traditional care through a radiant warmer incubator[27]. The preterm and LBW infants receiving KMC intervention also gain more weight per day and had better heart rate and breathing regulations[27].

In a recent breastfeeding study done in the Amhara region of Ethiopia, there was an elevated belief among women that they should discard the colostrum human breast milk as it was seen as dirty or causing the infant abdominal pain[9]. This is especially true for women of sick, LBW, or premature infants leading to prelacteal feeding for the first few days.

Prelacteal feeding is the practice of giving newborns food before breastfeeding is established[58]. This practice is more common in rural areas and for women who lack breastfeeding support in their community[9]. In Ethiopia, an average of 27% (three in ten children) are given prelacteal feeds within the first three days of life[58]. Infants exposed to prelacteal feeding practices are 16 times more likely to have diarrhea or pneumonia[59].

There are many reasons women will participate in prelacteal feeds. One thought is that prelacteal feeds provide a laxative effect and provide the infant with clean meconium, even though this type of stool makes the infant prone to contamination and diarrhea[58]. Another reason for prelacteal feeds is colostrum is thought to be dirty, cause gastrointestinal issues, and harm the infant [6,8,29,33,58]. In a 2017 study, the most common prelacteal foods in Southern Ethiopia were plain water, cow's milk, water and "natra" (a type of sugar), and butter[58].

Colostrum avoidance is common in Amhara, Ethiopia, with less than half (44.8%) of infants receiving colostrum[60]. Traditional birth attendants have been quoted as telling pregnant and breastfeeding women that "breastmilk should not be given until the placenta has passed,

which could take as long as three days" [60]. In addition to this, Ethiopian women have a traditional thought of the first milk as being bad milk[60], also resulting in higher incidences of prelacteal feeds. Thus, the Federal Democratic Republic of Ethiopia Ministry of Health has implemented programs to reduce this belief.

In 2016, the Federal Democratic Republic of Ethiopia Ministry of Health released a pediatric hospital pocketbook that included breastfeeding neonates' management and care guidelines. It outlines the basic guidelines for breastfeeding each infant, including guides for the LBW, VLBW, and ELBW neonate, as well as preterm infants. Specifically, looking at the various health facilities, community health supports, and ministry guidance on breastfeeding and neonatal feeding supports helps understand ways to lower neonatal mortality in Amhara, Ethiopia. In addition to these guidelines, it states with the strong recommendation that every health facility that provides antenatal, maternity, and care for newborns should:

1. *Have a written breastfeeding policy that is routinely communicated to all healthcare staff.*
2. *Train all healthcare staff in the skills necessary to implement this policy.*
3. *Inform all pregnant women about the benefits and management of breastfeeding.*
4. *Help mothers initiate breastfeeding within half an hour of birth.*
5. *Show mothers how to breastfeed and how to maintain lactation even if they are separated from their infants.*
6. *Give newborns no food or drink other than breast milk unless medically indicated.*
7. *Encourage rooming-in is a hospital arrangement where the mother and baby stay in the same room day and night.*
8. *Encourage breastfeeding on-demand.*

9. *Give no artificial feeds or pacifiers to breastfeeding babies.*
10. *The key to breastfeeding practices is continued day-to-day support for the breastfeeding mother within her home and community.* [61]

These guidelines are very similar to the Baby-Friendly Hospital Initiative (BFHI) by the WHO and UNICEF. They are provided on the next page and are part of a program to help achieve the 70% goal of EBF by 2030. Countries are challenged to do the following and implement the ten steps to scale up breastfeeding promotion within facilities and beyond to ensure successful breastfeeding.

Figure 2:1 10 Steps to Successful Breastfeeding

Baby-Friendly Hospital Initiative:

1. *Establish or strengthen a national breastfeeding coordination body.*
2. *Integrate the Ten Steps into relevant national policy documents and professional standards of care.*
3. *Ensure the competency of health professionals and managers in the implementation of the Ten Steps.*
4. *Utilize external assessment systems to evaluate adherence to the Ten Steps regularly.*
5. *Develop and implement incentives for compliance and/or sanctions for non-compliance with the Ten Steps (see figure above).*
6. *Provide technical assistance to facilities that are making changes to adopt the Ten Steps.*
7. *Monitor implementation of the initiative.*
8. *Advocate for the BFHI to relevant audiences.*
9. *Identify and allocate sufficient resources to ensure the ongoing funding of the initiative.*[1]

Gaps

To reduce neonatal and infant mortality, exclusive breastfeeding rates need to increase. Identifying the factors associated with EBF is an essential aspect of reducing these deaths, especially when a widely accessible approach can quickly achieve it. Multiple studies have recently come out around EBF within the six-month timeline, but few examine the neonatal time frame, especially with regards to sick neonates. Understanding EBF within this time frame in Ethiopia will provide a tool to reduce neonatal mortality and improve childhood outcomes.

Chapter 3: Methods

Performance Monitoring for Action and Maternal Newborn Health Survey Overview

The 2016 Ethiopia Performance Monitoring for Action (PMA) dataset is used to gather women for the Maternal and Newborn Health Survey in Ethiopia to understand the determinants of exclusive breastfeeding the first six weeks after birth. PMA Ethiopia is a five-year project partnership between Addis Ababa University, John Hopkins University, and the Federal Ministry of Health [62]. From August 2016 through July 2017, a longitudinal household survey was designed to collect data on 331 women identified as pregnant to participate in this study out of the 100,000 identified households to be screened[63]. Follow-up interviews were done seven days, six weeks, and six months after delivery.

The Ethiopia PMA is a cross-sectional household and service delivery point survey. Women aged 15-49 who live in randomly selected households within the enumeration areas are eligible for this survey. Ethiopia PMA measures family planning, female empowerment, reproductive decision-making, and fertility intentions at the survey time. In addition to women aged 15-49, health facilities that provide services to women 15-49 are also surveyed. The final sample size for the 2015 PMA survey was 7,643 households (7,545 females and 446 service delivery points).

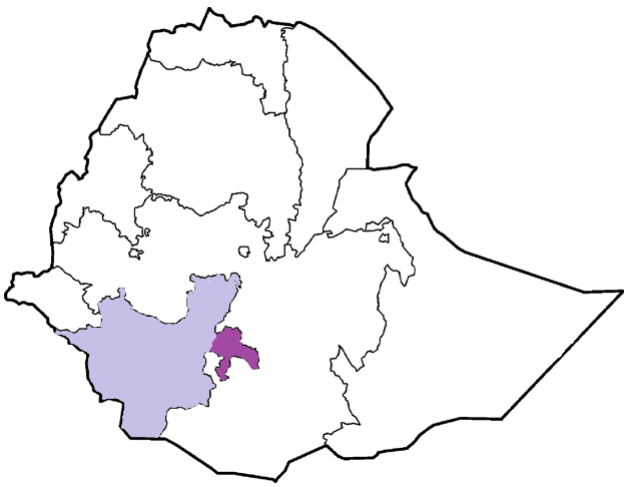

Figure3: Map of Ethiopia

For this study, the survey team used 44 enumeration areas in four different PMA Core 2020 study rounds. The PMA 2016 was used as a screening tool to determine

eligibility, women currently at least six months pregnant and willing to participate, to identify for the longitudinal study[62]. The Maternal and Newborn Health Survey was administered by trained surveyors using mobile technology[63] in two regions on Ethiopia of Southern Nations Nationalities and People (SNNP) and Sidama (colored regions in Figure 3).

To examine the determinants of exclusive breastfeeding for infants six weeks after delivery, the analysis will be done on the Maternal and Newborn Health Survey dataset to see which variables have been statistically significant in the odds of EBF (figure 4). Emory IRB has determined there is no need for an IRB. See appendix to read the IRB decision.

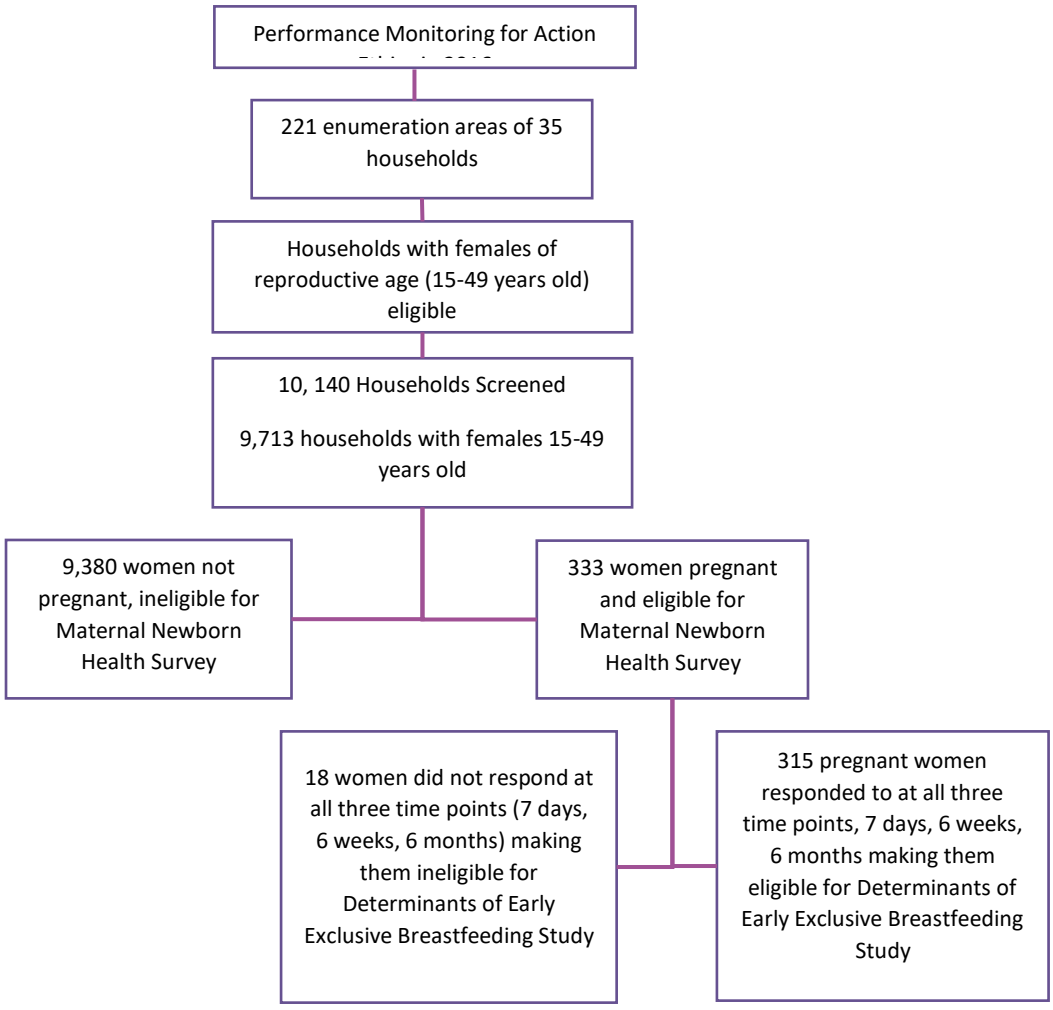

Figure 4: Methodology of Study

Variables

It was necessary to clean the data and then create exposure and outcome variables. Variables were created for exclusive breastfeeding total at each time point (seven days, six weeks, and six months), exclusive breastfeeding in the last 24 hours at each time point (seven days, six weeks, and six months), age categories on whether the mother is classified as being an adult or adolescent, education status, early initiation of breastfeeding within the first hour of delivery, seeing a skilled antenatal care provider during pregnancy, the length of pregnancy, pregnancy problems, delivery problems, delivery assistance provided by a skilled provider, and if the infant was sick.

Outcome Variables

The primary outcome for this study is early exclusive breastfeeding, breastfeeding for six weeks, in Ethiopian women. To create this variable, we combined all feeding information to have a variable that shows the longitudinal outcome of exclusive breastfeeding. This bivariate variable requires respondents to state they have exclusively breastfed from birth at each visit (seven days, six weeks, and six months) after delivery. Also, the respondent had to respond that they have not given their infant any other type of supplemental liquid such as water, cow milk, an herbal tonic, or formula.

The secondary outcomes are exclusive breastfeeding at the seven-day time-point and the six-week time-point of participants. These variables were made the same way as the six-week exclusive breastfeeding variable. All of these variables are known as Exclusive Breastfeeding Total. In this dataset, variables around exclusively breastfeeding in the last 24 hours were collected. Those variables are known as Exclusive Breastfeeding-24 hours.

Exposure Variables

To understand what factors, increase or decrease the odds of Ethiopian women exclusively breastfeeding, we examined multiple exposure variables. Age was continuous in the MNH dataset; thus, to categorize women into two age groups, minors were women under 18 and younger, and adults were women 19 years and older. The education variables in the MNH dataset had six categories; for this research study, we wanted to examine if any education level played a role in determining early exclusive breastfeeding. For that, we combined education into two categories: women who report no education and women who reported having primary or higher level of education.

Early initiation of breastfeeding (EIBF) was done using two different questions in the MNH questionnaire. It was broken down into time by seconds, minutes, and hours and then by days. To create an EIBF variable, we combined the two variables into one with the cut-off point of one hour to be considered EIBF. To examine if seeing skilled antenatal care provided impacted our exclusive breastfeeding outcome, we combined all skilled providers (doctors, nurses, midwives, and trained birth attendants) into one variable: having a skilled antenatal care provider during pregnancy. The same method was used for the delivery assistance variable to see if having a skilled provider at delivery impacted the odds of exclusive breastfeeding.

To examine if the pregnant women had any pregnancy complications, such as headache, bleeding, cramps, high blood pressure, edema, or convulsions, we combined all complications into a bivariate variable of yes or no. This method was also done for women who had delivery problems such as hemorrhage, prolonged delivery, or poor infant positioning during delivery.

Infant sickness in our study is defined as an infant whose mothers reported if their infant experienced illness through a fever, cough, diarrhea, fast breathing, not emptying bladder

through urination or no fecal output. To create this variable, the bivariate responses were combined into one more significant variable. If the mother reported any illness at any time point, the infant was considered sick. If the mother reported that they did not experience any of these symptoms (cough, fever, diarrhea, fast breathing, no urination, or no stool), the infant was not sick. The mother was asked these questions at seven days, six weeks, and six months' time points, asking if, since the last survey visit if the infant experienced any of the symptoms, we use to define our infant sick variable.

Participants

This study includes data on 333 mother-infant pairs from the Maternal and Newborn Health Survey. Within these parameters, variables are used with a minimum of 30 respondents in each categorical outcome. This study examines which variables impact the likelihood of an infant being exclusively breastfed for six weeks after delivery.

Chapter 4: Results

Demographic Analysis

In this study, 333 mother and infant pairs were enrolled to assess the determinants of exclusive breastfeeding an infant for the first six weeks after delivery. Most participants lived in urban areas (Table 1). 89.2% of mothers were aged 19 years and older, and 209 (63.0%) lived in households with the highest wealth index level (Table 1). 50.8% were Christian, 39.9% Orthodox, and 16.3% Muslim (Table 1). Additionally, 49.8% of infants were sick and about 80% of pregnant women saw a skilled prenatal care provider during pregnancy (Table 1). As seen in Table 2, most newborns started early breastfeeding initiation within the first hour after delivery (64.3%). When comparing exclusive breastfeeding (EBF) at three different time

Table 1: Descriptive Demographics of 2016-2017 Ethiopian Maternal and Newborn Survey from Performance Monitoring for Action Survey

	Overall (N=333)
Urbanicity	
Urban	191 (57.4%)
Age	
Adult (> 18 years)	297 (89.2%)
Religion	
Christian	165 (50.8%)
Muslim	53 (16.3%)
Orthodox	107 (39.9%)
Education	
Primary or higher education	237 (71.2%)
Married	
Yes	322 (96.7%)
Wealth Index	
Highest	209 (63.0%)
Lowest	62 (18.7%)
Middle	61 (18.4%)
Vaginal Delivery	
Yes	196 (85.2%)
Delivery Problem	
Yes	117 (35.9%)
ANC Provided by Skilled Provider	
Yes	202 (79.8%)
Length of Pregnancy	
Term	180 (54.1%)
Baby Sex	
Boy	169 (52.6%)
Baby Sick	
Yes	156 (49.8%)

Table 2: Infant Feeding Demographics of 2016-2017 Ethiopian Maternal and Newborn Survey from Performance Monitoring for Action Survey

	Overall (N=333)
Early Initiation of Breastfeeding	
Yes	214 (64.3%)
Baby Fed Any Breastfed in Last 24 hours at 7 days	
Yes	311 (98.4%)
Baby Fed Any Breastfed in Last 24 hours at Six Weeks	
Yes	308 (99.0%)
Baby Fed Any Breastfed in Last 24 hours at 6 Months	
Yes	56 (18.12)
Baby Given Water at 7 Days	
Yes	24 (7.59%)
Baby Given Water at 6 Weeks	
Yes	47 (15.1%)
Baby Given Herbal Tonic at 7 Days	
Yes	14 (4.44%)
Baby Given Herbal Tonic 6 Weeks	
Yes	28 (9%)
Exclusively Breastfed for 7 Days	
Yes	271 (86.03%)
Exclusively Breastfed for 6 Weeks	
Yes	220 (70.5%)
Exclusively Breastfed for 6 Months	
Yes	50 (16.1%)

points (seven days, six weeks, and six months), there is a visible decline in EBF; 86.03% of infants were exclusively breastfed for the first seven days after birth, 70.5% of infants were exclusively breastfed for six weeks after delivery, and 16.53% of infants were exclusively breastfed for six months (Table 2).

Infant Feeding Practices

When examining the difference of those infants who were given breastmilk during the last 24 hours at the three-time points of seven days, six weeks, and six months after delivery to infants who are exclusively breastfed at the same time periods (EBF total at seven days, six weeks, and six months), we see most infants were given breastmilk; however they were supplemented with additional water, formula, tonic, other animal milk, or some mixture of supplemental liquids (Figure 5).

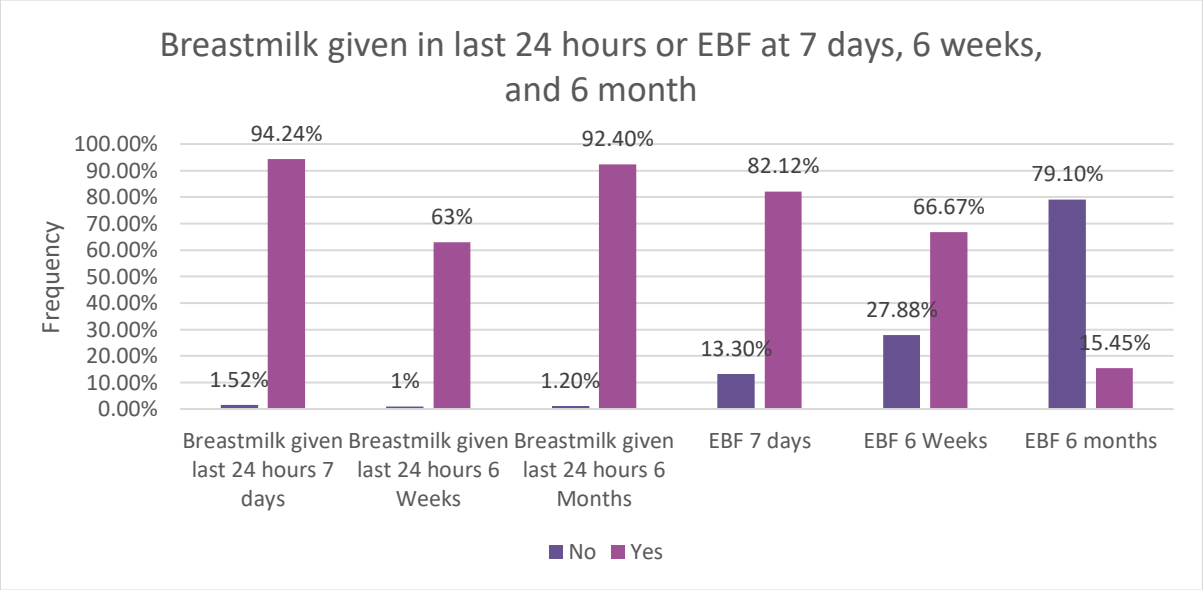

Figure 5: Infant Breastfeeding Practices

A small percentage of infants were supplemented with other liquids in addition to breastmilk at the seven-day and 6-week survey points. About 14% of infants were not EBF for the first seven days after birth. Of these 44 infants, 52.6% of infants were given water, and 26.3% were given an herbal tonic mixture. At the six-week time point, 92 infants were not EBF (29.5%). Of these 92 infants, 52.1% were supplemented with water and 25.4% with herbal tonic. There is a drastic change when looking at the six-month time point; 178 infants were receiving other liquids outside of breastmilk. For 75 of the infants, the mothers responded to not exclusively breastfeeding and did not respond to what types of liquids or foods they are giving their child (Figure 6).

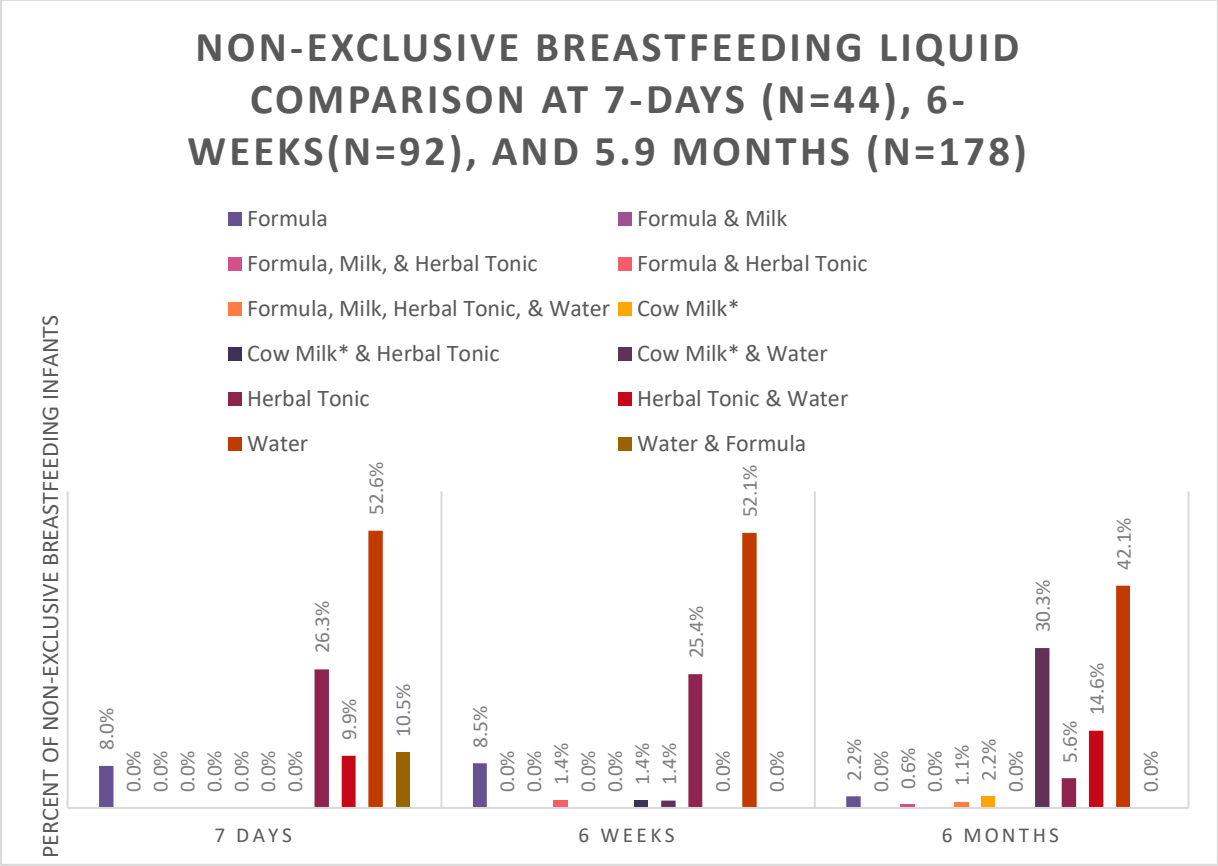

Figure 6: Non-exclusive Breastfeeding Liquids

Infants who start exclusive breastfeeding within the first hour after delivery, known as early breastfeeding initiation (EIBF), continue to breastfeed at 49.8% exclusively. 20.8% of infants who are not early initiation of breastfeeding do exclusively breastfeed for six weeks. When looking out at the impact of EIBF on EBF for six months, we see that 26.7% of exclusively breastfeeding infants were started on early initiation of breastfeeding (figure 7).

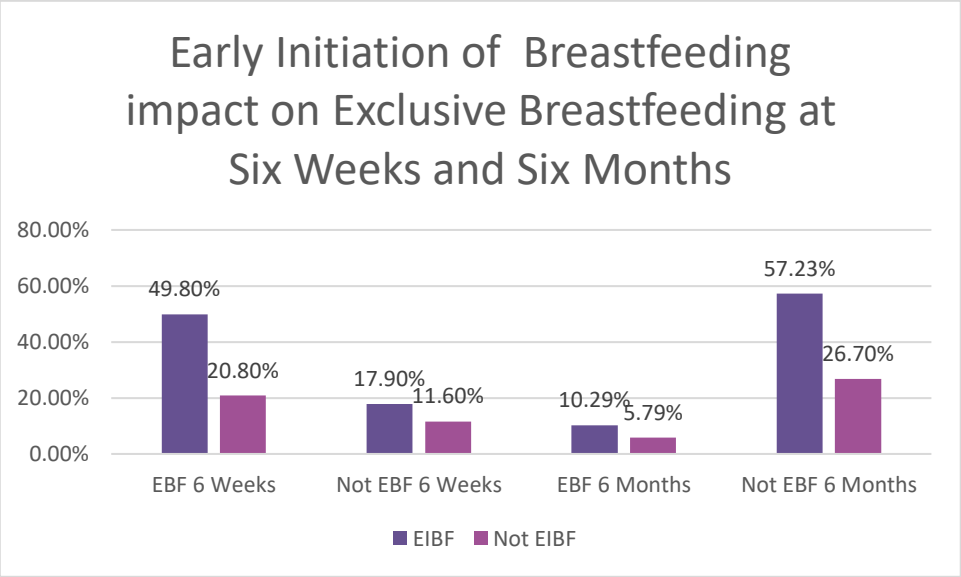

Figure 7: EBF and EIBF at Six Weeks and Six Months

Bivariate Analysis

Unadjusted odds ratios were calculated to determine the association between independent variables and EBF for six weeks after delivery (Table 3). Mother and infant pairs who live rurally were significantly lower for six weeks of EBF (OR= 0.52, 95% CI= 0.32-0.85). Mothers who identify as Muslim had significantly higher EBF rates than other religions (OR=4.02, 95% CI=1.62-12.34). Mothers in the lowest wealth index have significantly lower rates of EBF for six

Table 3: Bivariate Odds of Exclusive Breastfeeding at seven days, six weeks, and six months of 2016-2017 Ethiopian Maternal and Newborn Survey from Performance Monitoring for Action Survey

	7 Days		6 Weeks		6 Months	
Variable	**OR**	**95% CI**	**OR**	**95% CI**	**OR**	**95% CI**
Urbanicity						
Rural	0.81	(0.42, 1.54)	**0.52**	**(0.32, 0.85)**	1.29	(0.70, 2.37)
Age						
Adult	1.32	(0.42, 3.52)	1.56	(0.73, 3.26)	2.02	(0.68, 9.00)
Religion						
Muslim	2.17	(0.78, 7.85)	**4.02**	**(1.62, 12.34)**	0.96	(0.38, 2.23)
Orthodox	1.15	(0.57, 2.41)	0.78	(0.46, 1.34)	1.08	(0.54, 2.11)
Education						
Primary or higher	1.03	(0.49, 2.03)	1.23	(0.72, 2.08)	**0.38**	**(0.20, 0.70)**
Married						
Yes	2.75	(0.44, 12.64)	1.64	(0.39, 6.05)	1.56	(0.28, 39.46)
Wealth Index						
Lowest	1.01	(0.46, 2.41)	**0.45**	**(0.25, 0.84)**	2.05	(0.94,4.31)
Middle	1.87	(0.74, 5.80)	1.02	(0.53, 2.04)	2.05	(0.94,4.31)
Skilled Provider During Delivery						
Yes	0.39	(0.14, 1.21)	0.46	(0.21, 1.02)	0.2	(0.04, 1.70)
Delivery Problems						
Yes	0.92	(0.48, 1.83)	0.7	(0.42, 1.17)	0.69	(0.34, 1.31)
ANC Skilled Provider						
Yes	1.87	(0.79, 4.17)	**3.96**	**(2.05, 7.80)**	2.77	(0.93, 12.37)
Gestation Length						
8+ months	1.02	(0.53, 1.94)	1.46	(0.89, 2.49)	1.08	(0.59, 2.01)
Baby Sex						
Boy	0.99	(0.50, 1.97)	0.87	(0.52, 1.46)	0.92	(0.48, 1.76)
Early Initiation of Breastfeeding						
Yes	1.69	(0.83, 3.39)	1.53	(0.92, 2.55)	0.83	0.42, 1.66
Baby Sick						
Yes	**0.32**	**(0.14,0.65)**	**0.29**	**(0.17, 0.49)**	**0.41**	**(0.20, 0.74)**

weeks (OR=0.45, 95% CI=0.25-0.84). Mothers who saw a skilled health care provider for antenatal care had significantly increased odds of EBF for six weeks (OR=3.96, 95%CI=2.05-7.80). Infants who are sick have a statistically significant decreased odds of exclusively breastfeeding for six weeks (OR=0.29, 95% CI=0.17-0.49). The only variable statistically significant at all three-time points for impacting EBF is if the infant is sick. At all three time points, if the infant is sick, the odds of being EBF are significantly decreased: at seven days (OR=0.32, 95% CI=0.14-0.65), at six weeks (OR=0.29, 95% CI=0.17-0.49), and at six months (OR=0.41, 95% CI= 0.20-0.72).

Multivariate Analysis

Predictors significant in unadjusted bivariate analysis were entered together into a final multivariate model. When adjusting for wealth index, religion, age,

Table 4: Determinants of EBF* Among Ethiopian Infants at; 7-days, 6-weeks, and 6-months 2016-2017 PMA

	7-days		6-weeks		6-months	
	AOR	95% CI	AOR	95% CI	AOR	95% CI
Age						
Adult	2.04	(0.53,6.68)	2.55	(0.91,7.11)	0.72	(0.23, 2.57)
Education**						
Primary or Higher	1.44	(0.50,3.87)	1.14	(0.50,2.52)	0.5	(0.20, 1.24)
Wealth Index						
Lowest	2.48	(0.72, 10.69)	0.7	(0.27, 1.84)	2.08	(0.66,6.24)
Middle	3.33	(0.93,16.32)	1.43	(0.56, 3.95)	3.52	(1.21, 10.26)
Religion***						
Muslim	1.82	(0.59, 6.95)	4.09	(1.49, 13.39)	4.09	(1.49, 13.39)
Orthodox	1.26	(0.55, 2.93)	0.98	(0.51, 1.89)	0.98	(0.51, 1.89)
ANC Skill Provider						
Yes	2.94	(0.87, 6.43)	3.61	(1.63, 8.16)	5.89	(1.69, 28.81)
Baby Sick						
Yes	0.26	(0.09, 0.63)	0.34	(0.17, 0.64)	0.43	(0.19, 0.91)

*EBF: feeding only breastmilk to the infant except for medication and vitamins as directed by a doctor.
**Primary education up to higher learning
***Christianity is reference group

education, a skilled antenatal care provider, and infant being sick at seven days and between seven days and six weeks after delivery, seeing a skilled antenatal care provider (AOR= 3.61, 95% CI=1.63- 8.16), identifying as Muslim (AOR=4.09,95% CI=1.49-13.39), and infant being sick (AOR=0.34 , 95% CI=0.17-0.64) remained significant predictors of odds of EBF for six weeks (Table 4). When looking at our model for the EBF at seven days since birth (Table 4), being sick is the only significant variable (AOR=0.26 , 95% CI=0.09-0.6). When using our model to look at EBF at six months since birth (Table 4), being in the middle wealth index become statically significant, increasing the odds of EBF (AOR= 3.52, 95% CI=1.21-10.26), seeing skilled antenatal care provided stays significant and increases the odds of EBF (AOR=5.89, 95% CI=1.69-28.81), and being sick decreases the odds of EBF (AOR=0.43, 95% CI=0.19-0.91).

Chapter 5: Discussion and Conclusion

Our study provided insight into the early feeding practices and EBF determinants for the first six weeks of life. Most mothers EBF their infants during the first six weeks; however, we see a sharp decline in EBF at the six-month mark (16%). Women being Muslim and seeing a skilled antenatal care provider were protective factors, increasing the odds of exclusive breastfeeding (EBF) significantly. Whereas, if the infant is sick, we see a decrease in the odds of EBF significantly.

Our estimates of EBF at six months are much lower than in previous studies. Previous data show that EBF rates at six months in Ethiopia are closer to 59.3%[6]. Our data shows that approximately 16% of infants are exclusively breastfed for six months. There are multiple possible reasons why our data shows such a low percentage of EBF at six months. One could be our sample size of 333 mother-infant pairs. Another reason could be that most participants are in the "highest" wealth index. This could mean that the mothers are working. Working mothers might need to supplemental feed so they can continue to work. When looking at what six-month-old infants are being fed other than breastmilk, we see cow milk being given more frequently than the 1.4% of infants at six weeks.

A prior study shows infants less than four months old are exclusively breastfed with a sharp drop in exclusive breastfeeding after[8,64]. Another study has shown that infants who are two months or younger have statistically higher odds of EBF[8], which our study confirms this with approximately 82% of infants being EBF at six weeks. There could be cultural factors regarding this outcome as women who return to their family home are helped by their mothers during the first 40 days[17]. Mothers might have received more encouragement and help with EBF during this time. Additionally, educational status could impact the likelihood of EBF. In our bivariate

analysis at the six months show that higher education reduces the odds of EBF. Women who have a higher education level might be working, which can create barriers to EBF.

Few studies explore the relationship between EBF and if the infant experienced any illness (coughing, diarrhea, fever, fast breathing, not urinating, no fecal output). A study done in Egypt showed infants who had jaundice were more likely to be mixed-fed than exclusively breastfed[65]. Another study out of Ethiopia showed that any infant comorbidity (diarrhea, cough, fever, and shortness of breath) had a 66% less likely odds of EBF compared to infants who were healthy[66]. Both studies verify our findings that infants who are sick have a reduced odd of being exclusively breastfed.

Infants who are sick might have to spend time away from their mother, which could be why they are not EBF, even though breastmilk has been shown to have healing properties[53]. Mothers could also be afraid to breastfeed while the infant is sick. Some qualitative studies have shown fear on the mothers part of spreading HIV through breastmilk[67]. Additional studies have shown that; women not wanting to breastfeed in public, intergenerational approaches, and finical status have been called barriers to EBF in Ethiopia[68]. This data and our study show the importance of furthering research into why infants in Ethiopia who are sick have a reduced likelihood of being exclusively breastfed.

Our study shows that at six weeks, being a breastfeeding Muslim woman is a protective factor; however, this is not so at the six-month mark. This could be due to the overall study size or the sharp drop of only 50 women EBF their infants at the six-month mark. Interestingly, in the 2016 Ethiopian DHS, 31% of women identified as Muslim, and 22% identified as Protestant Christian[69]. Our dataset has 50% identified as Protestant Christian and 16% identified as Muslim.

Our study is in line with other studies showing that seeing a skilled antenatal care provider during pregnancy increases the odds of EBF[8,11,12,16,17]. One study shows a 2.25 increased odds of exclusively breastfeeding when skilled antenatal care was provided during pregnancy[66]. Our study shows 3.61 times odds increased in EBF when seeing a skilled antenatal care provider at the six-week mark and 5.89 times odds increased in EBF when seeing a skilled antenatal care provider at the six-month mark.

Surprisingly, age and education do not impact an infant being EBF for the first six weeks after birth in our study. In other studies, age has been identified as a factor impacting EBF [11,12,14,15]. Similarly, education has been shown in previous studies to impact the odds of EBF2,70,71 significantly. Our study has age and education as bivariate variables, whereas other studies have more categorical options due to higher sample volumes. Most studies showing age and education being significant variables use the Ethiopia DHS data, which has a much larger sample size than the MNH data set.

When examining what supplements or replaces breastmilk, 52.6% of Ethiopian women reported giving their infant water during the first seven days of life, 52.1% reported giving water during the first six weeks of life, and 42.1% reported giving water during the first six months. An herbal tonic mixture was the second most frequently used supplement or replacement to breast milk given to the infant at the first two time points, seven days (26.3%) and six weeks (25.4%). However, the cow's milk and water combination were the second most frequently used (30.3%) at the six-month time point. Herbal tonic, a type of herbal tea that varies by infant depending on what the family has access to, is given more frequently at the seven-day and six-week time points than the six-month time point. An herbal tonic mixture and water is the third most reported at the seven-day marker. Herbal tonics have been widely studied during the first few

days of a child's life as a supplement for those avoiding colostrum and doing prelacteal feeds[60,70]. Many reasons have been reported for colostrum avoidance in Ethiopia, mainly because it is believed to cause the infant abdominal distress[9,70].

Strengths

The 2016 Ethiopian Maternal and Newborn Health survey (MNH) has many strengths. The MNH is a longitudinal study that followed pregnant women through pregnancy until the child was six months old. This is a considerable strength, as asked both recall questions and in-the-moment questions. This is especially useful when assessing exclusive breastfeeding practices. Most studies looking at EBF ask if the mother has EBF during the last 24 hours. The MNH asked both if the mother EBF in the last 24 hours as well as since birth. Because of how the MNH collected breastfeeding data, we were able to run our model at the three different periods to see how our model would examine the odds of exclusive breastfeeding for seven days, six weeks, and six months since birth.

Additionally, this allowed us to look at if the mother reported exclusively breastfeeding in the last 24 hours impacted the outcome of exclusively breastfeeding since birth. Additionally, this survey asked questions about when the infant was first put to the breast. This allowed assessment if early initiation of breastfeeding (EIBF) was a determinant of EBF and the rate of EIBF in Ethiopian infants.

Limitations

There are multiple limitations to this study, mainly because only secondary data was available. This survey was designed specifically to look at antenatal care services and how they impact pregnancy and infant outcomes. This study uses secondary data collection from Performance Monitoring for Action (PMA) for the Maternal Newborn Health (MNH) survey,

thus, bringing multiple limitations. In our sub-analysis, 63% of the women in this study are classified in the highest wealth index. We were able to run an analysis on both the PMA and the MNH datasets, and it showed that a majority of the respondents to both surveys were in the highest wealth index. Upon further research, it was unexplainable why both surveys had such high wealth tertiles. It is unknown if these tertiles were premade and were using a reference population to make these tertiles.; traditionally, each category of the wealth index should be a third of the population. Having the highest wealth index makeup two-thirds of the study is questionable and could indicate bias. When examining this issue further, it shows a similar spread of wealth index among the PMA study. It begs to question how the survey designers created this wealth index score being provided in the survey. The wealth index in the 2016 DHS Ethiopia report shows that the highest wealth index level has a median average of 3.7 months of exclusive breastfeeding, which is just barely more than the poorest (3.0) and poor (3.6) wealth levels. Each of the DHS wealth index quartiles is 20% of their sample population[69].

Another limitation is that the survey asked if an infant was weighed after birth, but it did not record any weight categories. Many studies have shown a connection between birth weight and EBF. Using such a variable in this model and analysis is a gap that cannot be addressed in this study. Other studies have shown that providing counseling on the benefits of EBF to the mothers increases the odds for infants to be EBF[8,9,16,17]. Our dataset only has 25 out of the 333 MNH survey participants providing an answer for if the mother received EBF counseling before the seven-day postpartum care visit. Because of the low response rate, this variable was unable to be analyzed.

Multiple variables that have been shown to determine if an infant is exclusively breastfed were not collected in this survey. Low birth weight or premature infants have been shown to

benefit significantly from early breastfeeding initiation and the continuation of exclusive breastfeeding[22,23,25]. This survey did not collect birth weight information, and thus we were unable to use it in our analysis. When looking at an infant's prematurity, this data showed that 45.9% of infants were born at seven months. This is an unusually high rate of premature infants: the overall pooled prevalence of preterm birth in Ethiopia was 10.48% between 2009-2019[71]. Due to this, the use of gestational length was not used in this analysis. The MNH survey collected data on if the infant was sick. However, it did not collect data on if the mother was sick; this limited our ability to look at the mothers' health and its impact on EBF.

Chapter 6: Public Health Implications and Recommendations

While this study was able to assess determinates of EBF among Ethiopian infants between religion, skilled antenatal care, and if the infant was sick significant determinates of EBF; vital variables are missing in this study that needs further examination. In the next round of MNH surveys, it is recommended that survey questions include birth weight or birth weight categories, information regarding EBF counseling, a truer spread of wealth index participants, and what kind of breastfeeding support was provided to the women.

By understanding the determinants of EBF, Ethiopia can implement policies that increase the odds of EBF in their communities. Implementing supports to increase EBF rates will lower neonatal, infant, and under-five mortality and morbidity rates, increasing Ethiopia’s health overall. Further research and advocacy around exclusively breastfeeding the sick infant to increase those odds.

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Appendix

EMORY UNIVERSITY
Institutional Review Board

NON-HUMAN SUBJECTS RESEARCH DETERMINATION FORM

Emory does not require IRB review of studies that do not meet the definitions of "human subjects research" (DHHS) or "clinical investigation" (FDA). This tool is to help you define your project and to ensure proper review and regulatory requirements are met.

If the tool results in an outcome of "no IRB review required," this form will serve as your documentation of that determination. Please keep the completed copy in your records.

AUDIT: The IRB will periodically audit completed forms and your written proposal to ensure that the tool is providing accurate results.

NOTE: this tool should only be used for projects completed by Emory/EHC affiliates doing work for Emory purposes. When answering the questions in this determination tool, consider only the project activities performed by Emory/EHC affiliates in the current proposed project (e.g. if your study is a secondary data analysis, do not include the primary data collection activities when considering your responses.) Emory/EHC affiliates who are completing a project for academic credit at a different institution should seek a determination from that institution's IRB.

1

Project Title *

Determinants of Exclusive Breastfeeding of Ethiopian Neonates

2

PROJECT LEADER (not necessarily the person filling in this form) *

Nastassia Donoho

3

FUNDING *

Will these activities be supported by a DHHS award (e.g., NIH, NSF, DoE, DoD) through a grant, contract, subaward/subcontract, or cooperative agreement?

NOTE: If Emory is the prime recipient of a DHHS award and the funding application indicates that human subjects will be involved, IRB submission is required.

Also, if Emory is the prime recipient of a DHHS award, but contracting with another site to carry out all non-exempt human subjects research activities for that award, please contact the Emory IRB for guidance instead of using this form.
If Emory is the subrecipient, only the activities done by Emory should be considered for this form, even if other sites are performing human subjects research.

- ( ) Yes
- (•) No

4

SHARING DATA OUTSIDE OF EMORY *

Will you be sharing data (identified or de-identified) outside of Emory? If yes, you need to contact OTT (ott.emory.edu) to determine if a Data Use Agreement is needed.

- ( ) Yes
- (•) No

5

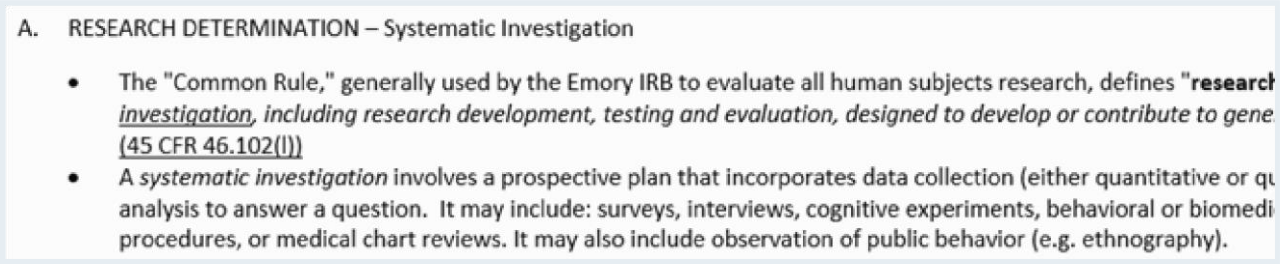
Does the project involve Veterans Affairs?
(e.g. study site, data source, researcher's affiliation) *

- ( ) Yes
- (•) No

6

RESEARCH DETERMINATION- Systematic Investigation *

Is the proposed project a "systematic investigation?" For example: are you conducting online or inperson surveys, focus group discussions, or data analysis?



A. RESEARCH DETERMINATION – Systematic Investigation

- The "Common Rule," generally used by the Emory IRB to evaluate all human subjects research, defines "**research** *investigation, including research development, testing and evaluation, designed to develop or contribute to gene* (45 CFR 46.102(l))
- A *systematic investigation* involves a prospective plan that incorporates data collection (either quantitative or qu analysis to answer a question. It may include: surveys, interviews, cognitive experiments, behavioral or biomedi procedures, or medical chart reviews. It may also include observation of public behavior (e.g. ethnography).

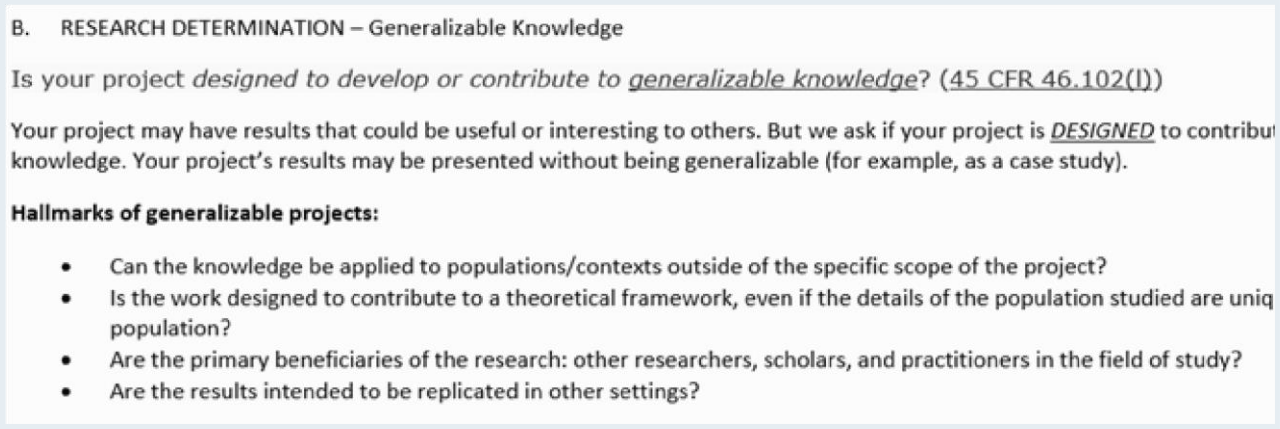
- (•) Yes
- ( ) No

7

RESEARCH DETERMINATION- Generalizable Knowledge

Is the proposed project "designed to develop or contribute to generalizable knowledge?" *

Review these links if your project falls into one of the following categories:
Case Studies/Series (http://irb.emory.edu/forms/review/casestudy.html)
Classroom Activities (http://irb.emory.edu/forms/review/classroom.html)
Public Health Practice (http://irb.emory.edu/forms/review/PH.html)
Program Evaluations (http://irb.emory.edu/forms/review/programeval.html)
Quality Improvement (http://irb.emory.edu/forms/review/QI.html)
Sociobehavioral research: Oral History/Journalism and Ethnography/Anthropology (http://irb.emory.edu/forms/socio.html)
If you still have questions, you can call our office for clarification at (404) 712-0720.



B. RESEARCH DETERMINATION – Generalizable Knowledge

Is your project *designed to develop or contribute to generalizable knowledge*? (45 CFR 46.102(l))

Your project may have results that could be useful or interesting to others. But we ask if your project is *DESIGNED* to contribu knowledge. Your project's results may be presented without being generalizable (for example, as a case study).

Hallmarks of generalizable projects:

- Can the knowledge be applied to populations/contexts outside of the specific scope of the project?
- Is the work designed to contribute to a theoretical framework, even if the details of the population studied are uniq population?
- Are the primary beneficiaries of the research: other researchers, scholars, and practitioners in the field of study?
- Are the results intended to be replicated in other settings?

( ) Yes

( ) No

8

HUMAN SUBJECTS DETERMINATION *

Does this study involve obtaining information about living individuals? Answer "yes" if you're obtaining de-identified data or anonymous survey results if the results contain information about living people.

( ) Yes

( )

No

9

If yes, does the study involve intervention or interaction with the individuals (e.g., online or in-person surveys [even if generating anonymous results], prospective collection of specimens, scans, etc.)?

- ○ Yes
- ◉ No

10

Do the activities involve accessing or generating individually identifiable and private information about living individuals?

Please review the list of identifiers for more information (http://www.irb.emory.edu/documents/phi_identifiers.pdf)

- ○ Yes
- ◉ No

11

Does the study involve analysis of existing data/specimens, where ALL data and/or specimens already exist prior to the start of the study? (Important: all parts of this question must apply if answering Yes.)

- ◉ Yes
- ○ No

12

If yes, would ANY member of the research team be able to reidentify the data/specimens, either directly, or via a code and key?
* If anyone on the newly-proposed study team took part in the original collection of the existing specimens or data, your should answer Yes. * If there are codes on the data, but no one on the study team has access to a link: you may answer "No" to this question only if you have a documented agreement with the data/specimen providers that prohibits your team from having access to the link.

- ( ) Yes
- (•) No

13

HUMAN SUBJECTS RESEARCH DETERMINATION - FDA

Will any individual be a recipient of any test article (i.e., drug, medical device) or be used as a control?

FDA 21 CFR 56.102 (23c&e)

Human Subject- an individual who is or becomes a participant in research, either as a recipient of the test article or
Clinical Investigation- any experiment that involves a test article and one or more human subjects.

- ( ) Yes
- (•) No

14

Will any device be tested (including software, apps, in-vitro assays) using any individual's specimens or data, even if completely deidentified?

- ( ) Yes
- (•) No

15

This project does not require IRB review because it is not research with "human subjects", nor is it a "clinical investigation" as defined in the federal regulations. Please use the Microsoft Print to PDF or Microsoft XPS Document Writer option to save a copy of your responses to this form. *

- (•) There is no eIRB submission necessary. I will protect the confidentiality of information accessed or obtained in this project. I will keep a copy of my responses to this form for my records.