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Lisetta Del Castillo Date

Prevalence and Risk Factors of Anemia in the Mother-Infant Population from Apartadó, Colombia

By

Lisetta Del Castillo
Masters of Public Health

Hubert Department of Global Health

_____

Dr. Juan Leon, PhD MPH
Committee Chair

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By

Lisetta Del Castillo
B. A.
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Thesis Committee Chair: Dr. Juan Leon, PhD MPH

An abstract of
A thesis submitted to the Faculty of the
Rollins School of Public Health of Emory University
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Abstract

Prevalence and Risk Factors of Anemia in the Mother-Infant Population from Apartadó, Colombia

By Lisetta Del Castillo

Iron deficiency is the most common cause of anemia in developing countries and a major contributor of infant mortality deaths worldwide (WHO, 2017a). In Apartadó, Colombia, there are limited data on anemia status in young children and mothers (ENSIN, 2010). The study aimed to quantify the prevalence and the risk factors of anemia in a cohort of Colombian children and their mothers. 198 healthy mother-infant pairs were recruited from one post-natal health facility in Apartadó. Children were between the ages of 6 to 60 months and the ages of the mothers ranged from 15 to 46 years old. A blood test was performed in 135 children and 102 mothers using HemoCue® to determine the level of hemoglobin, from which anemia was diagnosed in the mother and infant. About 50% of the children and mothers in the study had anemia. Additionally, a health characterization survey was conducted to identify the health conditions of the mother infant pair that included diarrhea diseases, respiratory problems, stunting and wasting in order to determine risk factors associated with anemia. Bivariate correlations between health outcomes and anemia were assessed using logistic regression models. Through a multiple logistic regression model, it was found that age was a significant risk factor of anemia (OR: 0.196; 95% CI: 0.083, 0.463; P = 0.0002). Older children were 80% less likely to develop anemia than younger children. The prevalence of anemia in children and mothers was 15.5 and 17.2 percentage points higher than the Colombian national prevalence accordingly. The high prevalence of anemia in this cohort of Colombian children and mothers suggests an immediate need for interventions in order to address the impact of anemia in Apartadó.

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Chapter 1: Literature Review

Global Burden of Iron Deficiency

Iron deficiency is the most common and widespread nutritional disorder in the world and is the most common cause of anemia (WHO, 2017a). According to the World Health Organization, over 2 billion people – roughly 30% of the world's population – are anemic, primarily due to iron deficiency. Iron deficiency disproportionally affects a large number of pregnant women and children under five years old in developing countries. Globally, 41% of pregnant women and 27% of children under five years old have iron deficiency anemia (ENSIN, 2010). In developing countries, the primary cause of anemia is iron deficiency (Kassebaum, 2016; WHO, 2017a). Iron deficiency anemia impairs cognitive development, growth, immune function as well as physical work capacity (Crawley, 2004; Haas & Brownlie, 2001; WHO, 2017a).

According to the World Health Organization (WHO), micronutrients including iron, iodine and vitamin A enable the body to produce substances essential for proper growth and development. An absence of these micronutrients affects the nutrition of populations and represents a major public health threat. Iron deficiency is one of the primary causes of anemia because iron is necessary to produce hemoglobin, a key molecule responsible for the transport of oxygen in the human system (WHO, 2011).

WHO defines iron deficiency anemia as having hemoglobin concentrations below 110 grams per liter (gl) in pregnant women and children under five (WHO, 2011). The cut-off point for non-pregnant women is having hemoglobin below 120 gl. Hemoglobin levels below 70 gl are considered as severe iron-deficiency anemia, which is strongly associated with an increased risk of infant mortality deaths (Scott et al., 2014). Additionally, evidence suggests that moderate and

mild iron-deficiency anemia contributes to mortality risk among children under five years old (Scott et al., 2014).

Risk Factors Associated with Iron Deficiency Anemia

Exclusive Breastfeeding & Iron Deficiency Anemia

Risk of iron-deficiency anemia in children has been linked to prolonged and exclusive breastfeeding in prospective studies (Calvo et al., 1992; Dewey et al., 2004; Meinzen-Derr et al., 2005; Monterrosa et al., 2008). The study "Iron Status in Exclusively Breast-fed Infants" concluded that prevalence of iron-deficiency anemia increased as children continued breast-feeding. The study indicated that at nine months of age, iron-deficiency anemia was at 27.8% among exclusively breast-fed (EBF) group and 7.1% among the formula-fed group (Dewey et al., 2004). Similarly, in this study (Meinzen-Derr et al., 2005), 7% of children who EBF for less than 4 months had iron-deficiency anemia at 9 months of age, followed by 18% of children who EBF from 4-6 months, and 60% of children who EBF for more than 6 months. Additionally, Dewey found that iron deficiency was higher among exclusively breast-fed infants from 4-6 months than among partially breastfed infants (Dewey et al., 2004). This suggests that exclusive and prolonged breastfeeding protects infants from iron-deficiency anemia only during the first four months. After four months, in accordance with the literature above, iron-deficiency anemia increases with exclusive breastfeeding (Dalili et al., 2015; Marques et al., 2014; Wang et al., 2016).

Moreover, evidence from a clinical trial and a retrospective study suggested that prolonged breastfeeding without iron fortification is a risk factor for iron-deficiency anemia among infants with a low birth weight of less than 2,500 grams (Dewey et al., 1998; Joo et al, 2016). In this study, partially breastfed children and exclusively breastfed children were given

iron supplementation from 4-6 months. Iron nutrients increased in both groups but it was higher among the partially breastfed group, suggesting that exclusively breastfed children were at a higher risk for iron deficiency than partially breastfed children even if provided with iron supplements. Therefore, the study recommends providing exclusively breastfed children iron supplements in order to protect the nutrition of the child.

While the studies above suggest that prolonged and exclusive breastfeeding may increase risk for iron-deficiency anemia, cross sectional studies found that prolonged and exclusive breastfeeding correlated to higher hemoglobin concentrations and improved iron-status among children and that complementary breastfeeding may increase risk for iron-deficiency anemia (Eneroth et al. 2009; Uyoga et al., 2016).

Maternal Anemia & Iron Deficiency Anemia

Studies examining risk factors associated with iron deficiencies among exclusively breastfed children found that a history of maternal anemia was associated with childhood iron-deficiency anemia (Mhanna et al., 2016). Additionally, a study on maternal anemia in a Mexican cohort found that children born to anemic mothers were at higher risk of low hemoglobin levels than children born to non-anemic mothers (Meinzen-Derr et al., 2005). Similarly, a study examining iron deficiency found that maternal iron deficiency during pregnancy can put their infants at risk for iron deficiency during infancy (Burke et al., 2014). Maternal anemia also contributed to infant's low birth weight, which increases the risk of iron deficiency (de Pee et al., 2002).

Stunting/Wasting & Iron Deficiency Anemia

Scientific literature indicated that stunting is significantly associated with iron-deficiency anemia. According to the WHO, stunting – as an established marker of poor child development –

is defined as a height that is more than two standard deviations below the WHO child growth guidelines (WHO, 2017b). Stunting was linked to anemia among children aged 6 to 23 months in cross-sectional studies (Woldie et al., 2015; Kuziga et al., 2017). The studies revealed that children between 6 to 23 months were more likely to have iron deficiency anemia if stunting was a present or pre-existing condition. In addition to this, a study in Burkina Faso among school children ages 8 to14 years found that stunting was associated with moderate and severe iron-deficiency anemia (Erismann et al., 2017). Furthermore, a study focused on determining significant causes of iron-deficiency anemia among disadvantaged communities revealed that the incidence of wasting among an indigenous community in Malaysia was associated with mild iron-deficiency anemia (Rajoo et al., 2017). The study also highlighted that low household income was a risk factor of stunting. These findings suggests that public health programs should focus on improving socioeconomic status among marginalized populations in order to prevent poor health conditions related to stunting and wasting.

Diseases and Iron Deficiency Anemia

Studies revealed that a presence of infectious and chronic diseases affected the nutrition and hemoglobin levels of children and adults. Diseases impair the immune system thereby affecting nutrient absorption and leading to iron deficiency (Leathers & Foster, 2004; Gasche et al., 2004). Most common diseases have a detrimental impact on a child's nutritional status given that children have weaker immune systems to fight off diseases. Diseases such as HIV, tuberculosis, malaria and intestinal parasites can cause iron-deficiency anemia at a faster pace in children than in adults (Kruger et al., 2013; Spottiswoode et al., 2012). Additionally, gastrointestinal infection can cause regular diarrhea and thus nutrient deficiency (Schaible & Kaufmann, 2007).

Body Mass Index (BMI) & Iron Deficiency Anemia

The literature was limited in identifying significant associations between the mother's body max index status (BMI) and infant iron-deficiency anemia. However, cross sectional studies examining the determinants of iron-deficiency anemia among women revealed that BMI played a role in hemoglobin levels among women (Bentley & Griffiths, 2003; Goetz & Valeggia, 2017). Prevalence of iron-deficiency anemia was higher among underweight and normal weight women than in overweight women. Differences in iron-deficiency anemia were also associated with social economic status and urban and rural locations. Women living in rural locations were more likely to be underweight and had a higher prevalence of iron-deficiency anemia compared to urban women (Bentley & Griffiths, 2003). Other relevant studies found that underweight pregnant women had a higher risk of iron-deficiency anemia than non-pregnant women, suggesting that pregnancy status was an additional risk factor for maternal anemia (Fazio Ede et al., 2011; Uno et al., 2016).

Lack of Education & Iron Deficiency Anemia

There is a strong association between poor nutrition status and poor education levels among mothers (Gupta et al., 1991; Kassouf et al., 1996). According to the Pan American Health Organization (PAHO, 2012), poor nutrition in women and children under five years old is higher among women with no education than among those in which the mother had a primary education (PAHO, 2012; DHS, 2009; World Bank, 2016). For example, chronic malnutrition is at 10.8% among children whose mothers do not have education and 1.6% among children whose mothers had primary education (PAHO, 2012). This suggests that education plays a significant role in helping the mother-child population stay healthy. If parents or caretakers lack knowledge on the importance of a nutritious and balanced diet, then it is likely that the children will not consume

the necessary daily micronutrients including iron. This in turn affects the iron status and overall health of the child. However, it is important to recognize that it is very difficult to attain healthy lifestyles even if parents had the knowledge of proper iron foods for children without resources to purchase food. Additionally, it is likely that mothers with no education have minimum wage jobs or no jobs at all, making it difficult for them and their families to maintain well-balanced diets in the household (DHS, 2009; PAHO, 2012).

Burden of Iron Deficiency in Colombia

Public health institutions in Colombia are primarily concerned with iron deficiency because it is the dominant cause of anemia and disproportionally affects the health of vulnerable populations (Leathers & Foster, 2004; MINSALUD, 2015; Müller & Krawinkel, 2005; WHO, 2017a). According to the report, "Global Burden of Disease (GBD)," iron deficiency accounts for 3% of the burden of disease in Colombia (GBD, 2010). A diet lacking iron impacts physical growth and brain development during early childhood and this has long-term consequences for the health and well-being of the child and adult population. Iron deficiency is the main underlying cause of anemia in Colombia and continues to disproportionally affect the health of vulnerable populations.

The National Nutritional Survey in Colombia (ENSIN) reported in 2010 that 33.2% of children aged 1-4 years old had anemia (ENSIN, 2010). Additionally, at the national level 53.2% of children between the ages of 12-23 months had anemia and nearly 33% of mothers aged 13-49 years old had anemia (ENSIN, 2010). According to the Ministry of Health in Colombia, the prevalence of iron deficiency anemia varies across the country. The rates of iron-deficiency anemia is exorbitantly higher among marginalized populations that include indigenous populations (32.6%) and Afro-Colombians (33.7%) in the Caribbean region (MINSALUD,

2015). In Urabá, the study site in the northwest region of the country in the Caribbean, about 49% to 79% of indigenous and Afro-Colombian children have iron-deficiency anemia, depending upon the age (Correa & Carmona-Fonseca, 2014). In this region, income inequality prevails and living conditions are challenging with high unemployment, violence, and severe poverty (Correa & Carmona-Fonseca, 2014).

Root Causes of Iron Deficiency in Colombia

Poverty & Iron Deficiency Anemia

Iron-deficiency anemia in Colombia is often linked to poverty that leads to poor nutrition (Dekker et al., 2010; Hackett et al., 2009; WFP, 2017). Although Colombia is classified as a middle-income country, in 2014, 29% of Colombians were poor and 6 million people lived below the poverty line of $3.50 (USD) per day (Graham, 2016). Poverty is higher in rural regions (Corbett, 2014; FSP, 2012). According to the ENSIN, impoverished people suffering from iron-deficiency anemia did not have the necessary resources to buy iron-rich food consistently for themselves and their families (ENSIN, 2010). Therefore, it is likely that impoverished people are vulnerable to iron-deficiency anemia given their poor-in-nutrients diets. About 43% of Colombians living in rural regions consider themselves food insecure due to poverty (WFP, 2017). Additionally, studies examining the implications for food insecurity revealed that the absence of iron nutrients impacts cognitive development and impairs productivity level, condemning people to a vicious cycle of poverty (Hackett et al., 2009).

Internal Armed Conflict & Iron Deficiency Anemia

Colombia's civil conflict and internal displacement had a profound impact on poor nutrition and iron-deficiency anemia in the Colombia. After Syria, Colombia has the largest internally displaced population in the world (DHS, 2009; Edwards, 2016; WFP, 2017). Although the

government and the Revolutionary Armed Forces of Colombia (FARC) have come closer to ending the internal armed conflict, violence and crime continue to be prevalent throughout the country particularly in rural regions (IDMC, 2014; WFP, 2017). According to research studies, internal conflict and displacement have a direct association to poor nutrition in countries that experience wars, violence and political instability (Messer & Cohen, 2007). In Colombia, armed conflict disrupted farming and food production throughout most of the rural regions (Amazon Watch, 2002; WFP, 2017). The conflict forced millions of people to flee their homes, leading to hunger emergencies and severe poverty as the displaced were left without any means to fend for themselves and their families.

The principal health problem in Colombia affecting displaced populations is protein malnutrition, which leads to micronutrient deficiencies that include iron deficiency (PAHO, 2012; WFP, 2017). Protein malnutrition among displaced children is double the national average of 13% (WFP, 2017). Given the problems associated with protein malnutrition and micronutrient deficiencies, populations affected by displacement are at an increased risk for iron-deficiency anemia. In the displaced indigenous and Afro-Colombian communities of the Caribbean, 6 out of 10 households live without access to iron-rich food and proper housing including water and sanitation (PAHO, 2012; WFP, 2017).

Urabá, Colombia

Urabá in the Caribbean, is a region in the Colombian Department of Antioquia. This region is highly affected by the internal armed conflict (Correa & Carmona-Fonseca, 2014; Frundt, 2009; Giugale et al., 2003). In this region, violence prevails and living conditions are extremely poor for most of the population (Carmona-Fonseca et al., 2011; Correa & Carmona-Fonseca, 2014). About 19.2% of children under eight years old have anemia (Álvarez et al., 2007). Apartadó,

near the Gulf of Urabá, is the biggest municipality of Urabá. The municipality has a history of violence and displacement especially after illegal armed groups got involved in drug trafficking and saw the municipality as a crucial route for trafficking illegal drugs (El Tiempo, 2013). Despite being the most populated municipality in Urabá, there are limited studies examining iron deficiency anemia in the mother-infant population of Apartadó due to its remote location and violent history (Correa & Carmona-Fonseca, 2014).

Conclusion & Significance

Conclusion

The goal of the study is to identify the prevalence and the risk factors of anemia in the mother-infant population in Apartadó, Colombia. Scholarship included in the literature review indicated that complementary breastfeeding could be a risk factor for anemia. Therefore, this study aims to test this hypothesis. The literature also showed that diarrheal diseases predicted anemia in children and adults. Based on the limited information on the topic, the study aimed to test this hypothesis. Given the limited research on iron deficiency in Apartadó, the study will address an important need for the region.

Significance

Anemia is a health problem that significantly impacts the health of vulnerable populations including women and children, but the prevention of anemia remains a public health challenge given that Anemia is overlooked in the municipality of Apartadó. Identifying the prevalence and risks factors of anemia in the mother-infant population in Apartadó will provide valuable insight to conducting effective public health interventions to reduce the impact of anemia in the region. The scientific knowledge gained from this study will lead to reduced rates of anemia and mortality in children and mothers of this region. In addition to this, other

research studies will be able to use the findings of this study as a framework for conducting larger studies examining anemia in vulnerable communities.

Chapter 2: Methods

Study Approval & Location

This study Emory IRB 00088473 was approved by Emory and Colombia IRB and was conducted in the municipality of Apartadó in the Caribbean region of Urabá. The rural region of Urabá is located in northwestern Colombia near the Panama border, with a population of 676,356 people (Piñeros-Jiménez et al., 2011). Afro-Colombian, indigenous and mestizo populations live in the region. The majority of the population is Afrodescendant (51.5%) and under 25 years old (59%) (Piñeros-Jiménez et al., 2011). The main economic activities are banana growing and cattle ranching (Uribe et al., 2005).

Sample Size

As part of the parent study, in order to identify the health status of the mother-infant pair in Apartadó, the study recruited a sample of N=198 mother-infant pairs in order to obtain a precision of 0.061 based on an alpha level of 0.05, a response rate of 99%, and a 25% prevalence of stunting among children under 15 years old from Urabá, without adjusting for Finite Population Correction (FPC) given that the study population of 676,356 was greater than 25,000 (Álvarez et al., 2007). For this specific investigation, the study obtained data and samples from within the study population of the parent study and collected a sample size of N=135 of children in order to identify anemia prevalence. The sample size was calculated based on a precision of 6.7%, an iron-deficiency prevalence of 19.2% among children under 8 years old in Urabá, an alpha of 0.05, and a response rate of 99% (Álvarez et al., 2007).

Study Design & Study Population

Mothers and infants between 6 and 60 months of age were recruited in the waiting room during their post-natal visit to the health facility *Pueblo Nuevo* (New Town) in Apartadó while waiting for their appointment with health professionals. A total of 198 mother-infant pairs

were recruited to participate in the study. Inclusion criteria for mother-infants participation included 1) mother of at least 15 years old; 2) a healthy child aged 6 to 60 months old; 3) registered to attend post-natal visits and 4) fluency in Spanish. If the mother met the inclusion criteria and verbally expressed interest in participating in the study, the informed consent process was carried out verbally and in writing and documented (See Appendix A). Mothers who were not registered to attend post-natal visits were excluded from the study. The study used Quota sampling, a nonprobability sampling technique (Ruel et al., 2016). Quota sampling, as opposed to random sampling, required choosing the target population out of the specific subgroup of individuals (Ruel et al., 2016).

Data Collection Tools & Study Activities

Data was collected using pre-tested and structured health surveys through interviews with mothers or caretakers of the child (See Appendix B). Mothers or caretakers documented information about them and their children related to the history of diseases, susceptibility to infections, frequency of breastfeeding, feeding practices, vaccination coverage, sociodemographic status, and household conditions. Photographs were taken of vaccination cards and the civil registries for later data entry.

After mothers or caretakers were surveyed, the anthropometry of the mother and the child were performed based on the World Health Organization (WHO) guidelines. Height and weight were measured in order to identify height-for-age, weight-for-age, and weight-for-height anthropometric parameters using a digital SECA scale and a Shorrboard® (WHO, 2017c). Additionally, individual Z-scores were calculated using AnthroPlus software, developed by the WHO (WHO, 2009). Weight-for-height, height-for-age and weight-for-age were interpreted by using the Z-scores classification system (WHO, 2017c). A Z-score below 2 indicated that there

was a health condition affecting the growth of the child and this included undernutrition, stunting and wasting. Moreover, in the mother, height and weight measures were used to calculate Body Mass Index (BMI) based on guidelines from the National Institute of Health in order to identify the mother's health conditions (NIH, 2017).

Subsequently, a blood test was performed using HemoCue® to determine the level of hemoglobin of the mother and child, from which iron-deficiency anemia was diagnosed in mothers and children. HemoCue® is a non-invasive standard test to measure hemoglobin concentrations from a finger prick (Pagliaro et al., 2014). A single drop of blood from a finger prick was taken and placed into the HemoCue® to quantify hemoglobin serum levels. Iron-deficiency anemia was diagnosed based on hemoglobin concentrations. According to WHO guidelines for iron deficiency, pregnant mothers and children aged 6 to 60 months who have hemoglobin levels <11 g/dL are considered anemic, 10.0–10.9 g/dL as mildly anemic, 7–9.9 g/dL moderately anemic, and <7 g/dL as severely anemic. The cut-off point for iron-deficiency among non-pregnant women is having hemoglobin levels < 120 g/dL (WHO, 2011).

At the end of the procedure, the mother was given a form with the results of her hemoglobin levels and BMI, in addition to the hemoglobin value and anthropometric parameters of her child. A referral to see a doctor was given to mothers and children with hemoglobin levels below their cut-off points. Referrals were also provided for children who had Z-score values less than 2 and for mothers with BMI values greater than 25. Additional counseling by the study team was provided to encourage healthy eating habits and exercise. Upon the completion of the study activities, the team provided the mother with a small token gift of food and a toy for the child to express gratitude for their participation in the study. Activities took nearly forty-five minutes to complete.

Database Design

A database was developed for the study. In the initial stage of developing the database, all of the variables from the survey and the number of answer choices for each variable were included in the top rows of the database. Variables were arranged by topic into group sections, which made it easier to locate. Following this procedure, the study team developed a data dictionary for coding the answers choices into the database. All answer choices were assigned a numeric value, date or short text.

Data Entry and Data Quality

Data quality was assured through double data entry. Double data entry is a standard method for transferring paper-based survey data to an electronic format because it ensures the quality of the daya by entering information twice (Aksel & Lausitsen, 2012). Statistical Analysis Software (SAS) was used to compare both databases in order to address discrepancies related to duplicate entries, missing values, or data errors. Discrepancies were addressed using the original survey forms to verify correct inputs and corrections were made in the original database. The reconciliation process was documented in a monitoring log in order to ensure data quality. Additionally, standard diagnostic procedures such as checking for outliers in the data graphs were used to detect data errors.

Data Analysis

Descriptive analysis was used to characterize the basic features of the study population. Socio-demographic and health characteristics of the study population were described using (SAS). Tables were developed in order to provide summaries of the socio-demographic and health characteristics of the mother-infant pair. In addition to describing socio-demographics and health characteristics, two logistic regression models were used to test risk factors associated

with iron-deficiency anemia and to calculate the odds ratios and 95% Confidence Intervals. The first logistic regression model tested whether anemia differed in children who were complementary breastfed versus children who were not complementary breastfeed, adjusting for covariates. Previous research from the literature review indicated that complementary breastfeeding was associated with anemia among children under five years old. Therefore, the study aimed to test this hypothesis. Given the limited research in risks factors associated with anemia in the region, the second model tested whether anemia differed in children who had suffered from diarrhea in the past two weeks and those who did not experience a diarrhea related condition, adjusting for covariates.

Chapter 3: Results

Socio-Demographic Characteristics of the Mother-Infant Pair

Table 1 provides the socio-demographic characteristics of 198 mother-infant pairs. The study consisted of children between 6 and 60 months and mothers aged 15 to 46 years old. Based on the following socio-demographic table (Table 1), more than half of the children were under two years old and about one third of the children were between the ages of two and five years old. In the parent study, more than half of the mothers were between the ages of 15 to 24. The majority of the mothers were Afro-Colombian, of low socio economic status, and cohabitating with partner or single. Only a few mothers finished their high school degree or attended college. Additionally, despite the challenging living conditions related to poverty, most of the mothers reported having access to safe water in the households.

Table 1. Socio-Demographic Characteristics of the Mother-Infant Pair

	N (%)
Child (month)	**(N=198)**
6-24 months	137 (69)
25 - 60 months	61 (31)
Mother (years)	**(N=198)**
15 – 24	108 (55)
25 – 34	59 (30)
35 – 46	31 (15)
Race	**(N=198)**
Afro-Colombian	88 (44)
Mestiza (Mix-Race)	66 (33)
White	15 (8)
Indigenous	4 (2)
Missing	25 (13)
Socio-economic status	**(N=198)**
Low social class	146 (74)
Middle social class	33 (17)
Upper middle class	2 (1)
Missing	17 (8)
Marital Status	**(N=198)**

Married	20 (10)
Cohabitating	106 (54)
Single	68 (34)
Missing	4 (2)
Education Level	**(N=198)**
Primary School Incomplete	11 (6)
Primary School Complete	12 (6)
High School Incomplete	79 (40)
High School Complete	68 (34)
College or Higher Education	26 (13)
Missing	2 (1)
Access to Water	**(N=198)**
Connection in the house	161 (81.5)
Connection outside the house	1 (0.5)
Mechanical well pump	7 (4)
Manually operated well pump	8 (4)
Stream, river, or creek	12 (5)
Other	2 (1)
Missing	7 (4)

Health Characteristics of Children

Further analysis was conducted in Table 2 in order to identify the prevalence of anemia and other health conditions among the children population. The final analysis in Table 2 includes 198 children. Male and female children were evenly recruited for the study. Half of the children in the study were anemic and had respiratory illnesses. A quarter of the children in the study experienced diarrhea episodes and nearly half experienced fever symptoms in the last two weeks. Almost all of the children received the first and second dose of rotavirus vaccines. Unlike other health conditions, stunting and wasting were not predominantly prevalent in the study population, with prevalence rates between 7% and 3%. Stunting significantly differed by gender ($p=0.0183$). Males had an increased risk of stunting than females based on (OR: 6.276; 95% CI: 1.365, 28.853).

Table 2. Health Characteristics of Children

	6-60 months N (%)	P value	OR	95% Confidence Interval
Child (month)	**198**	–	–	–
Female	95 (48)			
Male	103 (52)			
Anemia[1] (<11 HB)	**98 (49)**	**0.3996**	**1.386**	**0.649, 2.959**
Female	45 (47)	Ref		
Male	53 (51)			
Respiratory Diseases	**102(52)**	**0.7628**	**0.918**	**0.525, 1.603**
Female	50 (53)	Ref		
Male	52 (50)			
Diarrhea Past 2 Weeks	**49 (25)**	**0.2486**	**1.470**	**0.764, 2.826**
Female	20 (21)	Ref		
Male	29 (28)			
Fever (>37C)	**81 (41)**	**0.4077**	**1.272**	**0.720, 2.246**
Female	36 (38)	Ref		
Male	45 (44)			
Rotavirus 1	**167 (84)**	**0.8055**	**0.867**	**0.280, 2.690**
Female	83 (87)	Ref		
Male	84 (82)			
Rotavirus 2	**163 (82)**	**0.9440**	**1.038**	**0.372, 2.897**
Female	80 (84)	Ref		
Male	83 (81)			
Stunting (<2 STD)	**14 (7)**	**0.0183***	**6.276**	**1.365, 28,853**
Female	2 (2)	Ref		
Male	12 (12)			
Wasting (- 2STD)	**6 (3)**	**0.4592**	**1.916**	**0.343, 10.715**
Female	2 (2)	Ref		
Male	4 (4)			

[1]Iron-deficiency anemia was tested in 135 children out of 198
*Significant association based on an alpha level of 0.05 ($p<0.05$)

Health Characteristics of Children by Gender and Age Group

Table 3 provides analysis on the health conditions of children by age group and by gender. It was observed that there were widespread health differences by age group, even when stratified by gender, based on an alpha level of 0.05. Overall older children were 80% less likely

to develop anemia than younger children (OR: 0.196; 95% CI: 0.083, 0.463; P=0.0002). Older males had a 90% decrease risk of anemia than younger males. Older females were 61% less likely to experience fever than younger females (OR: 0.389; 95% CI: 0.152, 0.995; P=0.0488). The risk of diarrhea was also significant higher in younger children even when stratified by gender with older children being 85% less likely to report diarrhea (OR: 0.143; 95% CI: 0.049, 0.420, P=0.0004). Additionally, older children were 75% less likely to complete rotavirus 1 and 70% less likely to get the second rotavirus dose. The difference by age group in vaccine coverage was significant when pooled and not significant when stratified by gender.

Table 3. Health Characteristics of Children by Gender and Age Group

	6 -24 months N (%)[1]	**25-60 months N (%)**	**P value**	**OR**	**95% Confidence Interval**
Child (month)	**137**	**61**	–	–	–
Female	62 (45)	33 (54)	–	–	–
Male	75 (55)	28 (46)	–	–	–
Anemia[2] (<11 HB)	**84 (61)**	**14 (23)**	**0.0002***	**0.196**	**0.083, 0.463**
Female	37 (60)	8 (24)	0.0607	0.324	0.100, 1.052
Male	47 (63)	6 (21)	0.0008*	0.113	0.032, 0.407
Fever (>37C)[3]	**60 (44)**	**21 (34)**	**0.2169**	**0.674**	**0.360, 1.261**
Female	28 (45)	8 (24)	0.0488*	0.389	0.152, 0.995
Male	32 (43)	13 (47)	0.7321	1.165	0.487, 2.786
Diarrhea[4]	**45 (33)**	**4 (7)**	**0.0004***	**0.143**	**0.049, 0.420**
Female	19 (31)	1 (3)	0.0118*	0.071	0.009, 0.556
Male	26 (35)	3 (11)	0.0237*	0.226	0.062, 0.820
Stunting (<2 STD)	**11 (8)**	**3 (5)**	**0.4614**	**0.610**	**0.164, 2.273**
Female	2 (3)	0 (0)	0.9536	<0.001	<0.001, >999.999
Male	9 (12)	3 (11)	0.9156	0.928	0.231, 3.727
Rotavirus 1	**120(88)**	**47 (77)**	**0.0181***	**0.245**	**0.076, 0.786**
Female	55 (89)	28 (84)	0.1270	0.255	0.044, 1.475
Male	65 (87)	19 (68)	0.0600	0.219	0.045, 1.066
Rotavirus 2	**117(85)**	**46 (75)**	**0.0263***	**0.306**	**0.108, 0.869**
Female	53 (85)	27 (81)	0.1226	0.306	0.068, 1.376
Male	64 (85)	19 (68)	0.1071	0.297	0.068, 1.301

Wasting (- 2STD)	**4 (3)**	**2 (3)**	**0.8656**	**1.161**	**0.207, 6.521**
Female	0 (0)	2 (6)	0.955	>999.999	<0.001, >999.999
Male	4 (5)	0 (0)	0.9624	<0.001	<0.001, >999.999
Respiratory Diseases	**70 (51)**	**32 (52)**	**0.8593**	**1.056**	**0.577, 1.932**
Female	34 (55)	16 (48)	0.5552	0.775	0.333, 1.807
Male	36 (48)	16 (57)	0.4101	1.444	0.602, 3.465

[1]Younger children are the reference group
[2]Iron-deficiency anemia was tested in 135 children out of 198
[3]Fever experienced in the last two weeks
[4]Diarrhea episodes in the last two weeks
[*]Significant association based on an alpha level of 0.05 ($p<0.05$)

Health Characteristics of Mothers

Table 4 describes the health characteristics of the mother population in the study. The study population consisted of 198 mothers between the ages of 15 to 46 years old. However, anemia was only tested in 102 mothers out of 198. Out of the mothers tested for hemoglobin, half of the mothers had anemia. About half of the mothers who had anemia were aged 35 to 46 years old. Furthermore, based on body mass index data of 194 mothers, about half of the mothers had a normal weight, while 31% were overweight, 20% obese, and 7% underweight.

Table 4. Mother Health Characteristics

Anemia (<12 HB)	**(N=102)** [1]
15 – 24	26 (22)
25 – 34	13 (22)
35 – 46	12 (44)
Total	51 (50)
Body Mass Index (BMI)	**(N=194)**
Underweight (<18.5)	13 (7)
Normal weight (18.5 -24.9)	81 (42)
Overweight (25-29.9)	60 (31)
Obesity (>30)	40 (20)

[1]Anemia was tested in 102 mothers out of 198.
[2] 118 women in the study
[3] 59 women in the study
[4] 27 women in the study
[5]BMI was measured in 194 out of 198 mothers

Risk Factors Associated with Anemia

Given the high rates of anemia in children, it was crucial to conduct multiple logistic regression models in order to understand risk factors associated with anemia. Two multiple logistic regression models were used to test if anemia differed by exposure. The first model tested if anemia in children had an association with complementary breastfeeding, adjusting for covariates (Table 5). Controlling for socio-demographic covariates, no significant association was found between anemia and complementary breastfeeding (p=0.2803). Furthermore, among the studied socio-demographic factors, only children's age and mother's race were significantly associated with anemia. Based on the analysis, children's age was significantly associated with anemia (p= 0.0009). Older children were about 85% less likely to develop anemia than younger children (OR: 0.164; 95% CI 0.056, 0.476). Additionally, there was a significant difference in risk of anemia between children whose mothers were mix-raced and Afro-Colombian. The odds ratio for developing anemia was 3.501 greater for children whose mother's were mixed raced than for children whose mother's were Afro-Colombian.

Table 5. Complementary Breastfeeding Significant Predictor of Anemia

	OR	95% Confidence Interval	P value
Complementary Breastfeeding	2.798	0.432, 18.114	0.2803
Socio Economic Status	1.143	0.302, 4.316	0.8442
Mother's Age	0.969	0.904, 1.038	0.8624
Mother's Race "White Vs. Afro"	0.970	0.184, 5.101	0.9711
Mother's Race "Mix Vs. Afro"	3.501	1.096, 11.186	0.0345*
Child's Gender	1.103	0.366, 3.323	0.8767
Child's Age[1]	0.164	0.056, 0.476	0.0009*

*Significant association based on an alpha level of 0.05
[1]Younger children (6-24 months) are the reference group

The second model tested if anemia has an association with diarrhea related conditions, adjusting for covariates (Table 6). Further analysis was conducted using a second multiple logistic regression model to examine if diarrheal related conditions predicted anemia in children, adjusting for socio-demographic covariates (Table 6). Based on an alpha of 0.05, there was no significant association between diarrhea and anemia (p=0.3793). Similarly to the previous logistic model, there was no statistical significance between anemia and the socio-demographic covariates with the exception of children's age (p=0.0008). In this model, older children were about 85% less likely to developing anemia than younger children.

Table 6 Diarrhea Significant Predictor of Anemia

	OR	95% Confidence Interval	P-value
Diarrhea Illness	1.762	0.498, 6.234	0.3793
Race Mix Vs. Afro	2.957	0.958, 0.127	0.0594
Race White Vs. Afro	0.550	0.279, 10.751	0.5551
Access to Water	0.916	0.594, 1.413	0.6927
Socio Economic Status	1.209	0.323, 4.521	0.7784
Child's Gender	1.270	0.432, 3.730	0.6636
Child's Age[1]	0.160	0.055, 0.468	0.0008*

*Significant association based on an alpha level of 0.05
[1]Younger children (6-24 months) are the reference group in this model

Chapter 5: Discussion

Introduction & Findings

The goal of the study is to describe the prevalence and the risk factors of anemia among the mother-infant population in Apartadó, Colombia. Anemia was the most prevalent health condition in the mother-infant population. Overall, 49% of the children, and 50% percent of the mothers had anemia in the study. The study also observed, in a multiple logistic regression model, that age was significantly associated with anemia. Additionally, the study concluded that complementary breastfeeding and diarrhea were not associated with an increased risk in anemia.

Anemia Prevalence

The high prevalence of anemia in the study population of Apartadó is concerning given that it is higher than the national prevalence of 33.2% for children and 32.8% for mothers. According to the WHO guidelines on prevention and control of anemia, the prevalence of anemia globally should be less than 5% and it is defined as a severe public health problem when anemia is higher than 40% (WHO, 2001). Therefore, by definition, Apartadó has a public health emergency. High rates of anemia in the region could be the result of socio-economic barriers preventing individuals from accessing nutritious diets for healthy life styles (ENSIN, 2010).

Several studies demonstrated that poverty, violence, and lack of education are all leading factors contributing to the risk of iron deficiency anemia in Colombia (ENSIN, 2010; Hackett et al., 2009; Messer & Cohen, 2007; WFP, 2017). Impoverished individuals in Colombia suffering from anemia reported not having the necessary resources to buy iron-rich food (ENSIN, 2010). Additionally, the armed conflict in Colombia forced millions of people to flee their homes, leading to hunger emergencies and severe poverty as the displaced were left without any means to fend for themselves and their families (Amazon Watch, 2002; WFP, 2017). Apartadó suffered

from the consequences of the internal armed conflict. Therefore, it is likely that people living in Apartadó are vulnerable to anemia and other health conditions due to the precarious living conditions.

Age and Anemia

The data analysis suggested that younger children between the ages of six months and two years old had a higher risk of anemia than older children. It is possible that younger children are at an increased risk of anemia than older children because younger children are more likely to exclusively breastfeed than older children. Exclusively breastfeed children do not benefit from the various sources of iron-rich foods, whereas older children are more likely to consume various sources of iron-rich foods, making them less susceptible to anemia. Most cross-sectional, cohort and clinical trials observed that iron deficiency anemia in young children was associated with exclusive and prolonged breastfeeding practices (Calvo et al., 1992; Dewey et al., 2004; Meinzen-Derr et al., 2005; Monterrosa et al., 2008). Thus, it is likely that younger children are more vulnerable to anemia than older children. These findings suggest that greater attention should be paid to how breastfeeding practices play a role in the health status of children.

Complementary Breastfeeding and Anemia

The study did not find a relationship between complementary breastfeeding and anemia based on an alpha level of 0.05 and ($p=0.2803$). It is likely that complementary breastfeeding is not a risk factor for developing anemia because children benefit from various sources of iron-rich nutrients and are therefore less susceptible to iron deficiencies. The study's findings are in line with existing evidence indicating that complementary breastfeeding is not a risk factor for iron deficiency anemia (Dewey et al., 1998; Jonsdottir et al., 2012; Qasem et al., 2015). In order to evaluate the risk of complementary breastfeeding on iron status, prior clinical trials randomly

assigned children to either continue exclusive breastfeeding or to receive iron-fortified foods in addition to breast milk (Dewey et al., 1998; Jonsdottir et al., 2012). Based on follow-up data, complementary breastfeed children had higher hemoglobin levels than exclusively breastfeed children and no significant correlation was found between complementary breastfed children and iron deficiency anemia (Dewey et al., 1998; Jonsdottir et al., 2012). Furthermore, systematic studies conducted electronic searched publications on randomized controlled trials and found no significant risk of anemia in complementary breastfeed children (Montel & Giugliani, 2004; Qasem et al., 2015).

Diarrhea and Anemia

Similarly, there was no relationship between diarrhea and anemia (p=0.3793). There were no studies examining this association in the scientific literature. It is likely that there is no correlation between diarrhea and anemia because the condition of diarrhea does not biologically impair the iron status of individuals but it is rather a condition of other illnesses (Mayo Clinic, 2017). The study also relied on self report to quantify cases of diarrhea in the target population and this might have had an impact in the results of the study as diarrhea cases were not confirmed in the laboratory.

Strengths and Limitations

The study recruited its intended sample size based on a 95% Confidence Interval and a precision of less than 10% for the research questions that examined health characteristics of the mother-infant population and anemia prevalence, as well as the risks factors associated with anemia. Recruiting the desired sample size guaranteed reliable results and provided the findings with sufficient power to identify associations. A limitation of the study was the non-probability sampling design, quota sampling (Ruel et al., 2016). Quota sampling, as opposed to random

sampling, required choosing the target population out of the specific subgroup of individuals, limiting broad generalizations in the population (Ruel et al., 2016).

Implications

Based on the limited research on the prevalence of anemia in Apartadó, the studies findings will help health care providers develop evidence-based interventions in order to address this public health issue in Apartadó . Moreover, understanding that age is significantly associated with anemia could help tailor programs designed to improve the iron status of childrenbetween six and 24 months old , before they become iron deficient, given that they are a high risk group for developing anemia. Finally, while diarrhea is not associated with anemia,it is still a prevalent condition in Apartadó . This information could help with the development of preventive programs at the hospital designed to control the spread of diarrheal diseases in the municipality.

Conclusion

Anemia is a public health challenge in Apartadó given its disproportionally high prevalence in the region, as well as the health consequences it has for women and children. Despite the research findings in identifying the prevalence of anemia and finding that age is a risk factor of anemia, gaps in knowledge still remain. Given that the study design limits generalizations in the broader population, larger randomized design studies are needed in order to identify the prevalence of anemia for the municipality. Furthermore, it was identified that younger children had a higher risk of anemia than older children . However, in order to prioritize public health interventions, more studies are needed to identify which specific groups are at higher risk of anemia within the subgroup of children under two years old . Further research is also needed to identify which specific diseases increase the risk of anemia in the mother-infant

population of Apartadó. These research interventions will help develop evidence-based strategies designed to effectively address and reduce the impact of anemia in Apartadó and Uraba.

Chapter 6: Public Health Implications

- The study found that the mother-infant pairs had an anemia prevalence of about 50%. Given the disproportionally high prevalence of anemia, local public health programs should develop strategies to help reduce the prevalence of Anemia among the study population that attends post-natal care visits at the local clinic.
- The study showed that young children are more likely to develop anemia than older children . This suggests that prevention programs should prioritize younger children because they are at greater risk of anemia.
- Analysis from the study determined that children who had mix-raced mother's had a higher risk of anemia than children whose mothers were Afro-Colombian. Health care providers should consider identifying the reasons why children born in mix-raced families are at a greater risk of developing anemia than other groups of children in order to prevent anemia.
- About half of the children had respiratory problems including allergies and influenza. Therefore, influenza vaccinations should be encouraged during post-natal visits as part of the required patient care.
- The study showed that a quarter of children had diarrhea. This suggests that mothers or caretakers in the study are not keeping adequate and consistent hygiene in the their dietary practices. The importance of hygiene and sanitary practices should be encouraged to mothers and caretakers during post natal visits.
- The study found that about 7% of the children were stunted. This finding was lower than the national stunting prevalence of 13% (DHS, 2009). Future programs in the post-natal facility should continue their excellent work in maintaining low rates of stunting.

- The study indicated that only 3% of children were wasted. However, this prevalence is higher than the national prevalence of 1% (DHS, 2009). Future programs in the post-natal facility should include interventions to help address this issue.
- The study found that younger children are more likely to complete rotavirus vaccinations in a timely manner than older children. More efforts in the public health sector need to be conducted in order to ensure that all children get the full rotavirus coverage in a timely manner.
- The study revelaed that about one third of the mothers in the study were overweight. This is lower than the national overweight prevalence of 45% in mothers aged 15 to 49 years old (DHS, 2009). While, the finding is better than the national rates, post-natal programs at the clinic should encourage the importance of exercise and a balanced diet in order to prevent chronic conditions in the future.

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Appendix A:

INFORMACION PARA LOS PARTICIPANTES Y CONSENTIMIENTO INFORMADO

Proyecto: "Inmunidad a patógenos virales que causan diarrea aguda: transferencia de inmunidad materno-infantil en Urabá, Colombia: Estudio Inicial"

Estimada participante,
Somos del Instituto Colombiano de Medicina Tropical ICMT - Universidad CES, la Universidad de Emory en Estados Unidos y estamos realizando una investigación que se llama: **"Inmunidad a patógenos virales que causan diarrea aguda: transferencia de inmunidad materno-infantil en Urabá, Colombia: Estudio Inicial".**

Este proyecto quiere determinar las tasas de diarrea, crecimiento deficiente, anemia y acceso a los servicios de salud y cobertura de vacunación y caracterizar la práctica de la lactancia materna en la población de madres y bebés de Urabá.

¿Qué le pedimos?
Se le está pidiendo que participe voluntariamente en este proyecto. Su participación en este proyecto no tiene nada que ver con la atención médica que usted o su hijo(a) reciben en este hospital. La participación de su hijo(a) en esta investigación es completamente voluntaria, no es obligatoria. Usted puede retirarse del proyecto cuando quiera. Las muestras que se queden después de los análisis se van a utilizar en futuras investigaciones. Si usted está interesada en participar voluntariamente en este proyecto, se le solicitará que firme este documento. En agradecimiento por su tiempo y participación, se le entregará un obsequio.

Si usted decide participar, habrá una entrevista individual y/o grupal, así como las actividades descritas abajo. Si no terminamos, podemos agendar con usted un segundo encuentro para concluir las actividades. Las actividades durarán aproximadamente una a dos horas. Después de obtener su permiso, el personal del proyecto realizará lo siguiente:

a) Se le hará preguntas de su nutrición y la de su hijo, la lactancia materna, las vacunas que su hijo recibió, posibles diarreas de su hijo(a), y como accede a servicios de salud.
b) Para evaluar el retraso del crecimiento y la nutrición de su hijo(a), se tomará medidas de talla, peso y el tamaño de su cabeza. Esta información y recomendaciones se le entregará inmediatamente.
c) Para determinar su peso y talla, se le tomará medidas a usted también. Esta información y recomendaciones se le entregará inmediatamente.
d) Se le pedirá si podemos tomar un poco de la popó de su bebe de su pañal para ver si tiene microbios. Se le dará otro pañal a cambio. No se le podrá dar esta información pronto porque nos demorará más de un año en tener esta información.
e) Se le pedirá si podemos tomar saliva de usted y de su hijo para ver si es resistente a microbios que causan diarrea. No se le podrá dar esta información pronto porque nos demorará más de un año en tener esta información.
f) Para ver si usted o su hijo(a) tiene anemia, se le tomará a usted y su futuro hijo(a) unas gotas de sangre de su dedo (madre) o dedo o talón (niño). Esta información y recomendaciones se le entregarán inmediatamente.

¿Qué beneficios y riesgos tendrá al participar de este proyecto.

Se beneficiaran su hijo(a) y usted gratuitamente.

Toma de sangre: Con este resultado puede saber si usted o su hijo(a) tienen o no anemia, una enfermedad en la que la sangre que disminuye los glóbulos rojos. Es muy importante identificar y tratar la anemia porque la anemia puede llevar a otros problemas de salud en la madre y niño. Si usted o su hijo tienen anemia se les remitirá a su servicio médico.

Medidas de antropometría: Con el resultado de las mediciones de talla y peso, puede saber si usted o su hijo(a) tienen un buen estado nutricional. Al finalizar la visita, si se llega a encontrar que usted o su hijo(a) tiene problemas de

desnutrición o sobrepeso, o diarrea, se le referirá a servicios médicos para que les evalúen, y de ser necesario, se les dé tratamiento.

Entrevistas: la información obtenida en estas entrevistas contribuirá a orientar acciones de salud encaminadas a la detección precoz de diarrea y problemas nutricionales de madres y niñas/os.

Los posibles riesgos pueden incluir para la toma de sangre un moretón o dolor en el sitio del pinchazo. Para disminuir estos riesgos, el material utilizado para la punción de dedo o talón, será estéril y desechable, y la recolección siempre se llevará por personal de salud capacitado. También tomaremos su tiempo para estas actividades. El equipo hará todo lo posible para reducir el tiempo de realización de los procedimientos del estudio, sin sacrificar el tiempo y su seguridad o la de su niño. En caso de que el tiempo que usted tenga que dedicar al estudio no le sea aceptable, se le hará otra cita (ya sea en el Hospital o en el hogar), y así lograr disminuir la interferencia en sus actividades personales.

¿Qué harán con mi información?
Toda la información que usted dé es confidencial. El nombre de usted y de su hijo(a) solo será utilizado para la entrega de los resultados en la ficha clínica del hospital. Información personal como dirección y teléfono, únicamente se utilizará durante la duración del proyecto para poder recordarla y localizarla para la segunda entrevista.

Si usted tiene alguna duda sobre este proyecto, puede consultar a:

Dra. Margarita Arboleda, ICMT Apartadó: cel 3006529199
Dra. Nora Cardona, ICMT Medellín: cel 3108987451

Se me ha informado de mi derecho de rechazar o no participar en esta investigación, sin que esto tenga consecuencias para mi estado de salud, y la posibilidad y libertad de retirarme en el momento que así lo considere. Se me ha dado la oportunidad de preguntar y aclarar las dudas generales acerca del procedimiento y objetivos de la investigación, he recibido la información a satisfacción sobre el proyecto y puedo contactar a las investigadoras a los teléfonos que me han brindado.

Yo _____ cc# _____ acepto voluntariamente participar en el proyecto: **"Inmunidad a patógenos virales que causan diarrea aguda: transferencia de inmunidad materno-infantil en Urabá, Colombia: Estudio Inicial"** conociendo previamente el estudio, teniendo libertad para mi retiro y sabiendo cuál es mi papel en el.

Firma del participante	Firma del Profesional encargado
Fecha	Fecha
Firma del testigo	Firma de testigo
Fecha	Fecha

Appendix B:

Sección A: Encuesta Sociodemográfica (Madre) Cuidadora?___ Vive con madre?___

Información Personal Muchas gracias por su participación en nuestro estudio. ¿Le importaría si le hiciera unas preguntas sobre usted, su hogar y su bebé? Esta información será utilizada para mejorar nuestro conocimiento de los participantes del estudio.
ID_____Fecha de nacimiento de la madre (según el documento de identidad): Día (_ _) Mes (__ __) Año (__ __ ___ __)
Fecha de hoy: Día (_ _) Mes (__ __) Año (__ __ ___ __) Sexo: niño (___) niña (___) Encuestador:_____Edad niño (meses)_____

Nro	*Pregunta*	*Respuesta con Códigos*	*Comentarios adicionales*
1.	¿Usted se considera de qué raza?	1.) Afrodescendiente 2.) Mestiza 3.) Blanca 4.) Indígena 5.) Otra _____ 99 NS/NR	No indígena -> Pregunta 3; Respuesta única
2.	Si es indígena, ¿a qué comunidad pertenece?	1.) Las playas 2.) La coquera 3.) Las palmas 4.) Otro_____	Respuesta única, si no indígena=0
3.	¿Hasta qué año estudió? *(¿Hasta que año del colegio hizo?)*	1.) Sin educación 2.) Primaria incompleta 3.) Primaria completa 4.) Secundaria incompleta 5.) Secundaria completa 6.) Superior y más 99 NS/NR	Respuesta única
4.	¿Cuál es su estado civil?	1.) Casada y vive junto con su esposo 2.) Unión libre y vive con compañero 3.) Separada/Divorciada o vive sola 99 NS/NR	Respuesta única
5.	¿Cuántas personas viven en la casa?	_____ (número de personas) 99 La madre no sabe	

Información sobre el Trabajo Con su permiso, le voy a preguntar acerca de su trabajo.

Nro.	*Pregunta*	*Respuesta con Códigos*	*Comentarios adicionales*
6.	¿Usted tiene un trabajo?	1.) Sí 0.) No **(Ir a pregunta 9)** 99 NS/NR	
7.	¿Es usted cabeza de la familia?	1.) Sí 0.) No 99 NS/NR	Si pregunta 6=0, 0 aquí
8.	¿Qué tipo de trabajo tiene?	1.) Trabajador bananero 2.) Trabajador independiente 3.) Empleada 4.) Ama de casa 5.) Oficios varios 6.) Ventas y servicios (en una tienda) 7.) Vendedor Ambulante 8.) Manual calificado (técnico) 9.) Manual no calificado 10.) Agricultura 11.) Estudiante	Respuesta única; Si pregunta 6=0, 0 aquí

		12.) Otro_____ 99 NS/NR	

Información sobre su hogar Ahora voy a hacerle algunas preguntas sobre su hogar.

Nro.	*Pregunta*	*Respuesta con Códigos*	*Comentarios adicionales*
9.	¿Usted vive en la ciudad de Apartadó?	0.) No **(Pregunta 11)** 1.) Sí	
10.	¿Hace cuánto tiempo vive en Apartadó? (en niños)	_____ (#) 99 La madre no sabe años	Respuesta libre
11.	¿A qué estrato socioeconómico pertenece? Pregunta a la persona si tiene factura de servicios públicos para confirmar el estrato.	_____(número 1 a 6) 99 La madre no sabe	Respuesta libre
12.	¿De dónde saca el agua para tomar o cocinar?	1.) Por conexión intra-domiciliario (acueducto/grifo/llave) 2.) Por conexión fuera de la vivienda 3.) Pozo con motobomba 4.) Pozo sin motobomba 5.) Quebrada, río, vertiente o acequia 6.) Otro: _____ 99 NS/NR	Respuesta única
13.	¿El agua se va durante el día o la noche o varios días?	1.) Todo el tiempo 2.) Unas pocas horas diarias 3.) Lunes a viernes, pero no los sáb., dom. 4.) Algunos días de la semana 5.) Casi no se va	
14.	¿El agua que consume es tratada?	0.) No 1.) Sí 99 NS/NR	Si pregunta 15=2, se asume 1 aquí
15.	¿Cómo trata su agua, o que tratamiento hace con su agua? **No lea las opciones listadas en voz alta.** *Pregunte por el método MÁS usado*	1.) Hervir 2.) Agua del municipio 3.) Usar filtro (cerámica/ arena/ otro) 4.) La deja reposar 5.) Otro _____ 99 NS/NR	Respuesta única;
16.	¿Con qué cocina usted? *Pregunte por el método MAS usado*	1.) Leña 2.) Pipa de gas 3.) Gas domiciliario 4.) Electricidad 5.) Otro _____ 99 NS/NR	Respuesta única
17.	¿Tiene un servicio sanitario (ej. baño o letrina)? *(¿Tiene baño o letrina en su casa?)*	0.) No **(Pasa a pregunta 19)** 1.) Sí 99 NS/NR	
18.	¿Usted tiene baño en su casa o lo comparte con sus vecinos? *(¿Tiene que compartirlo con vecinos?)*	1.) Privado del hogar 2.) Compartido con otros hogares 99 NS/NR	En caso de pregunta 17=0, 0 aquí
19.	¿El desagüe del servicio sanitario se realiza por…….? *(¿Por dónde sale el agua contaminada de la*	1.) Alcantarillado o tubería 2.) Pozo séptico 3.) A la superficie (a campo abierto) 4.) Otro _____	

	casa?)	99 NS/NR	
20.	¿Cuál es el material más utilizado en los pisos de su vivienda? *(¿De qué está hecho el piso de su casa?)*	1.) Tierra 2.) Madera 3.) Cemento 4.) Mosaico/Baldosa/Cerámica 5.) Ladrillo 6.) Otro _____ 99 NS/NR	Respuesta única

Sección B: Encuesta de Morbilidad Materna

Ahora, quisiera hacerle unas preguntas acerca de su salud en las últimas dos semanas.

Nro.	**Preguntas para la madre o acudiente**	Respuesta	*Comentarios adicionales*
1.	¿Ha tenido algún problema de salud en las últimas dos semanas? (*Si dice que no, clarifica con "*tales como diarrea, tos o fiebre"?)	0.) No **(Pasar a siguiente sección)** 1.) Sí	En caso de pregunta 1=0, toda la sección=0
2.	En las últimas dos semanas, ¿ha tenido diarrea?	0.) No 1.) Sí 99 NS/NR	
3.	En las últimas dos semanas, ¿ha tenido tos o problemas respiratorios?	0.) No 1.) Sí 99 NS/NR	
4.	En las últimas dos semanas, ¿ha tenido fiebre?	0.) No 1.) Sí 99 NS/NR	
5.	En las últimas dos semanas, ¿ha estado Ud. hospitalizada?	0.) No **(Pasar a pregunta 8)** 1.) Sí 99 NS/NR	
6.	¿Por cuantos días estuvo hospitalizada?	_____ días 99 La madre no sabe	
7.	¿Por qué estuvo usted hospitalizada?	1.) Problemas respiratorios 2.) Diarrea 3.) Otro _____ 99 NS/NR	
8.	En las últimas dos semanas, ¿ha tenido algunos otros problemas de salud?	0.) No **(Pasar a siguiente sección)** 1.) Sí 99 NS/NR	
9.	¿Cuáles son los otros problemas de salud que ha tenido?	1. 2. 3.	

Sección C: Encuesta de Morbilidad y Diarrea Infantil

1.	En las últimas dos semanas ¿El niño ha estado enfermo? (*Si dice que no, clarifica con "*tales como tos o fiebre"?)	0.) No **(Pasar a siguiente sección)** 1.) Sí	
2.	En las últimas dos semanas, ¿El niño ha tenido tos o problemas respiratorios?	0.) No 1.) Sí	En caso de pregunta 1=0,

		99 NS/NR	preguntas 2 hasta 8 =0
3.	En las últimas dos semanas, ¿ha tenido fiebre?	0.) No 1.) Sí 99 NS/NR	
4.	En las últimas dos semanas, ¿ha estado Hospitalizado su bebé?	0.) No 1.) Sí 99. NS/NR	
5.	¿Por cuantos días estuvo hospitalizado?	_____ días 99 La madre no sabe	
6.	¿Por qué estuvo el niño(a) hospitalizado?	0.) Problemas respiratorios 1.) Diarrea 2.) Otro _____ 99 NS/NR	
7.	En las últimas dos semanas, ¿ha tenido algunos otros problemas de salud?	0.)No 1.) Sí 99 NS/NR	
8.	¿Cuáles son los otros problemas de salud que ha tenido?	1. 2. 3.	

Acerca de las diarreas

La diarrea infantil se define como más que tres deposiciones líquidas para un bebé en un periodo de 24 horas. (**Verificar si la mamá sabe lo que es diarrea)**

Nro.	*Pregunta*	*Respuesta*	*Saltos*
9.	¿Cuándo está saludable el bebé, cuántas deposiciones diarias es normal para él/ella? Si no recuerda o no responde, ponga "99" *(¿Cuántas veces hace el bebé popó en el día?)*	____ ____ deposiciones	
10.	En las últimas dos semanas, ¿ha tenido diarrea su bebé?	0.) No **(Ir a Pregunta 18)** 1.) Sí 99 NS/NR	En caso de 0, preguntas 11 hasta 17 =0
11.	¿Hace cuántos días empezó la diarrea?	____ ____ días	
12.	¿Le ha dado un nuevo alimento al bebé, o ha cambiado la dieta en las últimas dos semanas?	0.) No 1.) Sí 99 NS/NR	
13.	¿Hace cuántos días terminó la diarrea, o todavía sigue? **Si todavía sigue, escribe "99"**	____ ____ días	
14.	¿En el peor día de su diarrea, cuántas deposiciones tuvo el bebé? Si no recuerda o no responde, ponga "99" *(¿Cuántas veces hizo popó en el peor día?)*	____ ____ veces	
15.	¿Cuando tuvo diarrea esta vez, hubo sangre en su caquita?	0.) No 1.) Sí 99 NS/NR	

16.	¿Cuando tuvo diarrea esta vez, hubo vómitos?	0.) No 1.) Sí	
17.	¿En el peor día de su diarrea cuantas veces vomitó?	_____ _____ veces	
18.	¿Qué hizo para que el bebé mejorara? **No lea las opciones listadas. Marque todas que apliquen** *Si NO tiene diarrea, Preguntar igual que hacen para manejarla*	a.) Llevarlo a la consulta b.) Líquidos caseros (agua de arroz, panela, etc.) c.) Solución casera (agua con sal y azúcar) d.) Sales de rehidratación oral e.) Medicamento contra la diarrea (Ej. jarabe de zinc) f.) Antibiótico/Antiparasitario g.) Remedio de hierbas h.) No hizo nada i.) nunca ha tenido diarrea j.) Otro: _____	*Respuestas múltiples* Cada respuesta es una columna (Sí=1, No=0) **(Si no dice a, salta hasta 20)**
19.	Si llevó a su niño a la consulta, ¿qué le indicó el médico?	a.) Sales de rehidratación oral b.) Medicamento contra la diarrea (Ej. jarabe de zinc) c.) Antibiótico/Antiparasitario d.) Otro: _____	*Respuestas múltiples* Cada respuesta es una columna (Sí=1, No=0)
20.	¿Alguien más en su casa ha tenido diarrea en las últimas dos semanas?	0.) No **(Ir a siguiente sección)** 1.) Sí 99 NS/NR	
21.	¿Quién(es) ha(n) tenido diarrea? **No lea las opciones listadas. Marque todas que apliquen**	a.) Otro niño/a en la vivienda b.) Padre del niño c.) Otro adulto en la casa	*Respuestas múltiples*

Sección D: Datos Clínicos (Madre)

Historia Clínica de la Madre

Nro.	*Pregunta*	*Respuesta con Códigos*	*Comentarios adicionales*
1.	¿Cuántos embarazos ha tenido usted?	_____ # de gestas 99 La madre no sabe	
2.	¿Cuántos partos ha tenido, incluidos cesáreas?	_____ # de partos 99 La madre no sabe	
3.	¿Cuántos partos de nacidos vivos ha tenido?	_____ # de partos de nacidos vivos 99 La madre no sabe	
4.	¿Cuál fue la edad gestacional al parto? *(¿Cuántas semanas tenía cuando nació el niño?)*	_____ (semanas) y _____ (días) 99 La madre no sabe	
5.	¿Qué tipo de parto fue? *¿Cómo tuvo el/la niño/a? ¿Normal o por cesárea?*	1.) Espontaneo (vaginal) 2.) Cesárea	

6.	¿Cuántos gramos pesó el bebé al nacer?	☐☐☐☐ gr 99 La madre no sabe	
7.	¿Hubo alguna complicación durante el parto?	0.) No **(Ir a pregunta 9)** 1.) Sí 99 NS/NR	
8.	¿Qué tipo de complicaciones hubo? No lea las opciones listadas en voz alta. Marque todas que aplican.	a.) Sangrado excesivo b.) Trabajo prolongado del parto c.) Sufrimiento fetal d.) Infección o fiebre materna e.) Otra _____	*Respuestas múltiples* Cada respuesta es una columna (Sí=1, No=0)
9. .	¿Qué edad tienen sus hijos vivos (años, meses y días)? Incluir todos los hijos empezando por el mayor. Poner todas las edades en años. Si tiene solo unos meses, dividir por 12 y poner hasta 4 decimales.	Hijo 1_____Hijo 6_____ Hijo 2_____Hijo 7 _____ Hijo 3 _____Hijo 8 _____ Hijo 4 _____Hijo 9 _____ Hijo 5 _____Hijo 10 _____99 La madre no sabe o no tiene un hijo de esa edad	*Respuestas múltiples* Cada respuesta es una columna (Sí=1, No=0)

Sección E: Encuesta Evaluación de la práctica de lactancia materna

Alimentación del bebé

Nombre del *Encuestador*_____

Explique que quisiera hacerle unas preguntas acerca de la práctica de lactancia materna y alimentación complementaria del bebé.

Nro.	*Pregunta*	*Respuesta con Códigos*	*Comentarios adicionales*
1.	¿Cuándo se le dio al bebé pecho por primera vez después del nacimiento? **No lea las opciones listadas en voz alta.** Marque la que corresponde con la respuesta de la madre.	1.) < 1 hora 2.) 1 hora -3 horas 3.) >3 horas 99 NS/NR	
2.	¿El bebé recibió alimentación materna? *(¿Se le da el seno al niño?)*	0.) No 1.) Sí	
3.	¿En las últimas 24 horas, le ha dado pecho a su bebé? *(¿Usted le da seno a su bebé?)*	0.) No **(Ir a Pregunta 5)** 1.) Sí	
4.	¿Cuántas veces le ha dado pecho a su bebé en las últimas 24 horas? **NO hace falta leer las opciones listadas en voz alta.**	_____ 99 NS/NR	Respuesta libre
5.	¿Hasta el día de hoy, le ha dado al bebé algún líquido además de la leche materna?	0.) No **(Fin de encuesta)** 1.) Sí	

6.	¿Qué líquido le ha dado al bebé además de la leche materna? **NO lea las opciones listadas en voz alta.** *Marque todas que apliquen.*	a.) Leche de tarro b.) Leche de vaca c.) Agua d.) Té en polvo e.) Jugo f.) Gaseosa g.) Suplementos (nutrientes, ensure, tarrito rojo, zbec) h.) Otro _____	*Respuestas múltiples*
7.	Si le ha dado al bebé leche de tarro, ¿cuál era? *Marque todas que apliquen.*	a.) KLIM b.) Nestógeno c.) NAN d.) Enfamil e.) Similac f.) S26 g.) Otro_____	*Respuestas múltiples*
8.	¿Cuántas veces le dio **líquido(s)**, que no sea leche materna, al bebé en las últimas 24 horas?	_____(#) veces 99 La madre no sabe	
9.	¿Hasta el día de hoy, le ha dado al bebé alguna alimentación complementaria además de la leche materna?	0.) No **(Fin de encuesta)** 1.) Sí 99 NS/NR	
10.	¿Cuántos meses tenía el bebé cuando le dio **alimentación complementaria** por la primera vez?	0.) Desde nacimiento 0.5) Con menos de un mes 1.) 1 mes 2.) 2 meses 3.) 3 meses 4.) 4 meses 5.) 5 meses 6.) 6 meses 7.) 7 meses 8.) 8 meses 9.) 9 meses 10.) 10 meses 11.) 11 meses 12.) 12 meses Otro _____	
11.	¿Cuántos meses tenía el bebé cuando le dio alimentación complementaria por la última vez? *¿Cuándo empezó el bebé a comer lo mismo que los otros miembros de la familia?*	0.) Con menos de un mes 1.) 1 mes 2.) 2 meses 3.) 3 meses 4.) 4 meses 5.) 5 meses 6.) 6 meses 7.) 7 meses 8.) 8 meses 9.) 9 meses 10.) 10 meses 11.) 11 meses 12.) 12 meses Otro _____	

12.	¿Qué alimentación complementaria le ha dado al bebé además de la leche materna? No lea las opciones listadas en voz alta. Marque todas que apliquen.	a.) Yogur b.) Papilla c.) Cereales d.) Cereales fortificadas e.) Sopa f.) Fruta g.) Carne h.) Otro _____	*Respuestas múltiples* Cada respuesta es una columna (Sí=1, No=0)
13.	¿Cuántas veces le dio esta(s) alimentación(es) complementaria(s) al bebé en las últimas 24 horas?	_____(#) veces 99 La madre no sabe	Respuesta libre

Sección F: Antropometría (Niño)

Medidas Antropométricas del bebé

Nombre del *Encuestador*_____

Nro.	*Pregunta*	*Respuesta con Códigos*	*Comentarios adicionales*
1.	Obtenga el carné de crecimiento y desarrollo y anote la fecha del nacimiento del niño.	__ ___-___ _ _-___ ___ ___ ___ (dd– mm -aa) 99 La madre no sabe	
2.	Usando la fecha del nacimiento del niño, anote la edad del niño en días y meses	_____meses	
3.	Anote el género del niño desde el carne de vacunas.	0.) Niña 1.) Niño	
4.	¿Hay popó en el pañal del bebé?	0.) No 1.) Sí	
5.	¿Nos podría dar el pañal sucio del bebé para que le podamos hacer una prueba para ver si tiene gérmenes/virus? A cambio, le daré un pañal nuevo. En caso de sí, pedirle el pañal al fin de la entrevista y complete página 1 del "Formulario de Recolección de Heces"	0.) No 1.) Sí	
6.	Peso del niño(a) (kg) **Sin pañal** También marque el peso	□□.□kg 99 No medida	
7.	Longitud del niño (a)(cm)	□□□ . □cm 99 No medida	
8.	Perímetro cefálico del niño(a) (cm)	□□.□cm 99 No medida	
9.	Examine el área de la tibia o cerca del tobillo, para la presencia de edema en ambas piernas ¿Él bebé tiene edema bilateral?	0.) No 1.) Sí	
10.	Hubo algún problema al tomar las medidas o durante el examen?	0.) No 1.) Sí Observaciones (ropa):_____	

11.	En base a las tablas de referencia del software de la Organización Mundial de la Salud (OMS) "WHO Anthro", ¿el niño tiene baja talla para la edad (=<-2 puntaje Z)?	0.) No 1.) Sí	
12.	En base a las tablas de referencia del software de la Organización Mundial de la Salud (OMS) "WHO Anthro", ¿el niño tiene bajo peso para la talla (=<-2 puntaje Z)?	0.) No 1.) Sí	

Antropometría (Madre)

Medidas Antropométricas de la Madre

Nro.	*Pregunta*	*Respuesta con Códigos*	*Comentarios adicionales*
13.	Talla de la madre (cm)	☐☐☐.☐cm 99 No medida	
14.	Peso de la madre (kg)	☐☐.☐kg 99 No medida	
15.	¿Está embarazada la mama?	0.) No 1.) Si 99 NS/NR	
16.	Índice Masa Corporal de la madre	☐☐.☐ kg/m^2	
17.	¿Hubo algún problema al tomar las medidas o durante el examen?	0.) No 1.) Sí 99 NS/NR Observaciones: _____	

Sección G: MADRE Toma de muestra de sangre a través de punción capilar

Nombre de *Encuestador* _____

Nro.	*Pregunta*	*Respuesta con Códigos*	*Comentarios adicionales*
1.	Hora de la toma de muestra *(hora militar 24h)*	__ __: __ __ h h : m m 99 NS/NR	
2.	Hemoglobina (g/dL) (nivel bruto/observado)	☐☐.☐g/dL *Marque el resultado de Hb también en la boleta de resultados de la madre* 99.9Medida no tomada	
3.	¿Hubo algún problema al tomar las medidas?	0.) No 1.) Sí, observaciones: _____ _____	
4.	¿Actualmente está embarazada?	0.) No 1.) Sí 99 NS/NR	
5.	¿Ha tenido fiebre en las últimas 48 horas?	0.) No 1.) Sí 99 NS/NR	
6.	¿A qué hora comió su último alimento? (formato 24 horas/hora militar) Si la hora es tarde (por ejemplo 21:00, asumimos que es ayer si no se especifica)	__ __: __ __ h h : m m 99 NS/NR	
7.	¿Es fumadora?	0.) No 1.) Sí 99 NS/NR	
8.	¿Tiene anemia la madre?	0.) No 1.) Sí (Apuntar en la boleta de resultados)	
9.	Grupo sanguíneo según historia clínica o documento de identidad:	1.) A 2.) B 3.) AB 4.) O	

Con el resultado obtenido determinar la presencia de anemia según la Tabla 1 debajo.

Población	**Anemia**
Mujeres NO embarazadas	Hb menos de 12g/dL
Mujeres embarazadas	Hb menos de 11g/dL

Pregunta 9: Camine con la paciente hasta la sala de espera. Pregunte si se siente bien. ¿El paciente presenta alguno de los siguientes síntomas?

	Sí	**No**
Moretón en el sitio de extracción de la sangre	○	○
Inflamación en el sitio de extracción de la sangre	○	○
Sangrado excesivo en el sitio de extracción de la sangre	○	○
Desmayo	○	○
Otro problema posiblemente relacionado con la toma de sangre:	○	○

_____

Si alguna de las complicaciones mencionados ocurrieron a una madre o al niño(a) después de la extracción de sangre(excepto moretón):

1. **Refiérase la madre a un médico para atención con el boleto de referencia.**
2. **Anote el evento adverso usando la encuesta y registro de Eventos Adversos.**

Diga a la mama del participante que puede irse. Instrúyale que si tiene complicaciones o problemas durante los próximos días, que llame a la coordinadora del proyecto, cuya nombre y número está en el carnet del estudio ID les dimos.

Sección H: NIÑO Toma de muestra de sangre

Nro.	*Pregunta*	*Respuesta*	*Comentarios adicionales*
1.	Hora de la toma de muestra *(hora militar 24h)*	__ __: __ __ h h : m m	
2.	Hemoglobina (g/dL)	☐☐.☐g/dL 99.9 No medida Marque el resultado de Hb también en la boleta de resultados	
3.	¿Hubo alguna injerencia con las medidas?	0.) No 1.) Sí, observaciones: _____ _____	
4.	¿Ha tenido el niño fiebre en las últimas 48 horas?	0.) No 1.) Sí 99.) NS/NR	
5.	¿A qué hora le dio pecho o comió por última vez el niño? (formato 24 horas/hora militar) Si la hora es tarde (por ejemplo 21:00, asumimos que es ayer si no se especifica)	__ __: __ __ h h : m m 99 La madre no sabe	
6.	¿Tiene anemia el niño?	0.) No 1.) Sí (Apuntar en la boleta de resultados)	
7.	Grupo sanguíneo según historia clínica o documento de identidad:	1.) A 2.) B 3.) AB 4.) O	

Use el nivel bruto de Hemoglobina para determinar la presencia de anemia según la Tabla 1 debajo.

Tabla 1. Puntos de corte de hemoglobina (g/dL) para diagnóstico de anemia en el niño

Población	**Sin anemia**	**Con anemia**
Niños (0–59 meses)	>11.0 g/dLo más	<11.0g/dL o menos

Camine con la paciente hasta la sala de espera. Pregunte si se siente bien. ¿El paciente presenta alguno de los siguientes síntomas?

	Sí	**No**
Moretón en el sitio de extracción de la sangre	○	○
Inflamación en el sitio de extracción de la sangre	○	○
Sangrado excesivo en el sitio de extracción de la sangre	○	○
Otro problema posiblemente relacionado con la toma de sangre:	○	○

_____

Si alguna de las complicaciones mencionados ocurrieron al niño(a) después de la extracción de sangre:

1. Refiérase a el/la niño(a) a un médico para atención con la boleta de referencia
2. Anote el evento adverso usando la encuesta y registro de Eventos Adversos.

Dígale a la mama del participante que puede irse. Instrúyale que si tiene complicaciones o problemas durante los próximos días, que llame a la coordinadora del proyecto, cuya nombre y número está en el carnet del estudio ID les dimos.

Sección I: Actividades Misceláneas

Nro.	*Pregunta*	*Respuesta*	*Comentarios adicionales*
1.	¿Has tomado una foto del carné de vacunación?	0.) No hay carné de vacunación 1.) Sí 2.) Otro _____	
2.	¿Has dado la boleta de resultados a la madre?	0.) No 1.) Sí _____	
3.	¿Estaba referido el niño al personal de salud por alguna anormalidad?	0.) No 1.) Sí _____	
4.	¿Has tomado una muestra de saliva de la madre?	0.) No 1.) Sí _____	
5.	¿Has tomado una muestra de saliva del niño?	0.) No 1.) Sí _____	
6.	¿Tienes una muestra de heces del niño?	0.) No 1.) Sí _____	
7.	¿Has compartido la información (resultados) con el personal de salud?	0.) No 1.) Sí _____	

Apartadó
Edificio ICMT
Tel.: 8281708
Fax: 8285606

Envigado
Calle 36 D Sur Km 4
Tel.: 336 0260 Ext. 126
Fax.: 336 0260 Ext. 1119

Sabaneta
Carrera 43 A # 52 Sur 99
Tel.: 3053500 Ext.: 2343
Fax: 3014258

Instituto Colombiano de Medicina Tropical

Sabaneta, 29 de julio de 2016

Doctora
NORA CARDONA CASTRO
Investigadora
Instituto Colombiano de Medicina Tropical

Respetada Doctora Cardona:

El Comité de Bioética del Instituto Colombiano de Medicina Tropical, se reunió el 29 de julio de 2016, como consta en el Acta 56 de este Comité, para evaluar las consideraciones éticas del proyecto titulado: **Enfermedad diarreica aguda y desnutrición en niños de 6 a 60 meses en Apartadó (Urabá antioqueño),** presentado por John Paul Builes, investigador. La investigación cumplirá con los aspectos éticos que figuran en la resolución 008430 de 1993 emanada del Ministerio de Salud en la cual en el Título II Capítulo 1, se establecen las normas éticas para la investigación en seres humanos.

- La presente investigación se considera de RIESGO MÍNIMO, porque se hará toma de muestra de sangre.
- Se conservará la confidencialidad de la información.
- Se solicitará el consentimiento informado escrito para la participación en el estudio de las madres voluntarias y de sus hijos.
- Los participantes tendrán la libertad de retirarse en el momento que quieran.
- Prevalecerán los beneficios sobre los riesgos en este proyecto.
- No se dará remuneración por su participación
- Se conservará la confidencialidad de los participantes.

El Comité, aprobó las consideraciones éticas del proyecto.

Atentamente,

LUIS ERNESTO LÓPEZ ROJAS
Presidente del Comité de Bioética

INFORMED CONSENT FOR STUDY PARTICIPANTS

Project: Immunity to viral pathogens that cause acute diarrhea: transmission of immunity status amongst the mother-infant population in Urabá, Colombia: Pilot Study
(Back-translated from the Spanish Informed Consent entitled "Consentimiento Informado Estudio Inicial")

Dear participant,

We are from the Colombian Institute of Tropical Medicine (ICMT) - CES University and Emory University from the United States and we are conducting a study called: "Immunity to viral pathogens that cause acute diarrhea: transmission of immunity status amongst the mother-infant population in Urabá., Colombia: Pilot Study".

The project intends to determine the rates of diarrhea, growth deficiency, anemic status, and access to health services as well as immunization coverage. In addition to this, the project also aims to investigate breastfeeding practices of 200 mother-infant pairs in Urabá.

What are we asking from you?

To join the research study voluntarily. The decision to join or not to join will not affect the medical care services you or your child receive at the hospital. Your child's participation in this study is also completely voluntarily—it is not obligatory. You can withdraw from the study at any time. The samples that remain after the analyses will be used for future research. If you are interested in voluntarily participating in this project, we ask that you sign this document. In appreciation of your time and participation, you will receive a small token of appreciation.

If you decide to participate in the study, there will be an individual or group interview. We will also perform the following activities described below. If we do not finish, we could schedule a second encounter with you in order to conclude all the proposed activities. All the activities will last approximately 1-2 hours. To complement these activities, we will ask your permission to look in your medical records and your child's nutrition status, diarrhea status, and vaccine status. After you consent to participate, the researchers will perform the following:

a) We will ask you questions in the form of a survey, regarding your child's nutrition, breastfeeding practices, vaccination and diarrhea status of your child as well as access to health services.
b) In order to assess deficient growth and malnutrition of your child, we will measure your child's height, weight and head circumference. This information and recommendations will be provided immediately after completion.
c) We will also measure your height and weight to calculate your BMI. We will provide you with this information and recommendations immediately.
d) We will ask you if it would be possible to take some of the feces in your infant's diaper to identify if the child has microbes. If so, we will request to have the diaper and provide you with a clean diaper in exchange. Unfortunately, we would not be able to provide the information on this, as it will take about a year to gather and analyze this information.
e) We will request to take saliva from you and your child to assess susceptibility to diarrheal infections. We would not be able to provide the information on this, as it will take about a year to gather and analyze this information.
f) In order to determine anemia status, we will collect a blood sample from you and your child via finger-prick or heel-stick. Results from the blood samples will be provided immediately along with recommendations.

What are the benefits and risks of participating in the study?

You and your child will benefit for free from participating in the study.

Blood sample: With a blood sample result you will be able to know if you or your child have anemia, a disease that decreases your blood cell count. It is very important to identify and treat anemia at an early stage because anemia can lead to other severe health problems for the mother and child. If you or your child have anemia, we will direct you to the appropriate medical service.

Anthropometry measurements: the results of these measurements will allow you to determine if you and your child have a good nutritional status. After the visit, if you find that you or your child have anemia, malnutrition, problems with obesity, or diarrhea, the study researchers will refer you or your child to appropriate medical services for further evaluation and if necessary treatment will be provided.

Interviews: The information obtained in the interviews will contribute to activities aimed at early detection of diarrhea and nutritional problems in mothers and infants.

Potential risks with collecting blood samples may include a small bruise or temporary pain in the location of the blood-draw. Fainting or infection may occur, but would be extremely rare as we are only drawing a very small drop of blood. However, in order to minimize risks, trained staff at the clinic will make sure to use sterile and disposable equipment at all times. In addition to this, the process will always be carried out by trained health professionals.

The study will also need your time to complete the activities mentioned above. The team will do everything possible to reduce the time of completion of the study procedures without sacrificing the mother and child in regards to time and security. At times, when you cannot stay for the entire encounter, the staff will schedule another appointment (at the hospital or at home) to finish the interview. This way, the study will not interfere with the personal activities.

What is going to happen with my information?

All of the information is confidential. Your name and your child's name will only be used for sharing results in your medical chart. In addition to this, contact information such as telephone number and address provided will only be used throughout the duration of the project to remind you about the second encounter.

There is a minimal risk of a breach of confidentiality of your information. To avoid this, we will ensure that our staff upholds the highest ethical standards and keeps all personal identifiers out of anyone else's reach. Furthermore, our staff have no incentive to disclose any information as it would jeopardize our study. Only identification numbers, without names or addresses will be returned to the U.S. for research and data analysis purposes.

If you have any questions or concerns about the study, please contact the following representatives:

Dra. Margarita Arboleda, ICMT Apartadó: cell phone 3006529199
Dra. Nora Cardona, ICMT Medellín: cell phone 3108987451

I have been informed of my right to participate or decline participating in this study with the understanding that my response will not have consequences for my health. I have also been informed that my decision will not affect my ability to withdraw from the study at any time. I was given the opportunity to ask questions and request clarifications regarding general concerns about the study's objectives. I also received the necessary information about the study and contact information for any future communications with the project representative.

I_____ accept voluntarily to participate in the research study: "Immunity to viral pathogens that cause acute diarrhea: transmission of immunity status amongst the mother-infant population in Urabá., Colombia: Pilot Study". I understand the objectives of the study. I also understand that I have the right to withdraw from the study at any given time or can refrain from participating in the study.

ID #:_____

Participant's Signature	Staff Signature
Date	Date
Witness' Signature	Witness' Signature
Date	Date