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The main objectives of this study are: 1) Examine the prevalence of early introduction to solids and adding cereal into the formula practice among low-income and mainly minority infants, and: 2) Examine how adding cereal into the formula is associated with daily calorie and macronutrient intake among low-income and mainly minority infants.

This study was approved by the IRB of the University of North Carolina at Greensboro. A longitudinal study of 3 years was carried out to investigate infant feeding practices focusing on a population of individuals from a minority and low-income background. Interviews and 24-hour dietary recalls were performed to collect information on infants feeding patterns when the infant was 2, 4, 6, 9, and 12 months old.

Results indicated that 29.4% of 4 month old infants had been introduced to complementary foods and that 29.9% of 6 month infants had received infant cereal in the bottle at 6 months and 14.4% at 9 months. At 6 months infants who received cereal in their bottle consumed 165 additional calories, had an additional 33.28 grams of total carbohydrate intake and an additional 3.75 grams of protein compared to infants who did not receive cereal in their bottle. At 9 months similar trends were observed. Infants who received cereal in their bottle at 9 months consumed an additional 158 calories per day and had an additional 27.61 grams compared to 9 month infants who did not receive cereal in the bottle. In conclusion, introducing infants to complementary foods before the recommended age is a common practice with about 30% of infants being introduced to complementary foods at 4 months. Adding infant cereal into the bottle was also a common practice with around 30% of 6 months participants carrying out this practice. The addition of infant cereal into the infants bottle was associated with an increase in

daily caloric intake and macronutrient intake among 6 and 9 month low-income and mainly minority infants.

HOW IS ADDING CEREAL INTO THE BOTTLE ASSOCIATED WITH DAILY MACRONUTRIENT INTAKE AMONG LOW-INCOME INFANTS?

by

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APPROVAL PAGE

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CHAPTER I: INTRODUCTION

Obesity has been on the rise over the past decades with rates gradually increasing (*Childhood Obesity Facts | Overweight & Obesity | CDC*, 2022a). Childhood obesity has been following the same trend (*Products - Health E Stats - Prevalence of Overweight, Obesity, and Severe Obesity Among Children and Adolescents Aged 2–19 Years*, 2021). Childhood obesity is related to many disorders later in life including type 2 diabetes, high blood pressure, and other metabolic disorders (Bleich et al., 2011; Estabrooks et al., 2008; Weihrauch-Blüher & Wiegand, 2018). The rate of childhood obesity differs by socioeconomic status in the U.S. To combat childhood obesity, the focus has been made on the first 1,000 days of life, since there is strong evidence that weight status during pregnancy, infancy, and toddlerhood is a significant predictor of weight status during adulthood (Taveras, 2016). In fact, for the first time, USDA dietary guidelines published in 2020 include recommendations for pregnancy and lactation during infancy and toddlerhood (*Dietary Guidelines for Americans, 2020-2025*, n.d.-a). Breastfeeding for the first six months of life has been one of the key recommendations in infant feeding. Breastfeeding has been linked to many health benefits for both the infant and the mother including a reduction in risks of illnesses like respiratory illnesses for infants and ovarian and breast cancers for mothers (CDC, 2022d). Despite the many benefits, according to the 2020 Breastfeeding Report Card, only 58.3% of infants were breastfeeding at 6 months and only 25.6% of the infants were exclusively breastfed through 6 months of age ("Breastfeeding Report Card United States, 2020," n.d.). Significant differences in breastfeeding rates are seen by income, race, and ethnicity, with rates being significantly lower among low-income and minority birth parents.

In other feeding practices, the age of introduction to complementary foods has been found to be critical in predicting weight status during infancy. Introduction of complementary foods before 4 months of age, has been associated with obesity compared to infants who are introduced to complementary foods after 4 months of age (Pearce et al., 2013; Wang et al., 2016; Weihrauch-Blüher & Wiegand, 2018). Reasoning for parents to introduce infants to complementary foods before what is recommended by the Dietary Guideline, as indicated by Clayton et. al. are being provided misinformation from health professionals or assuming the infant is old enough (Clayton et al., 2013). When infants begin to be introduced to complementary foods a variety of choices are at hand for parents. Popular/common foods include pureed foods and infant cereal, which are both safe options once the infant shows signs of being ready for consumption of these foods without any harm.

As infant cereal is a common food that is first introduced to infants, a common practice among parents has been observed to be adding infant cereal into the infants bottle of formula. This specific practice is not a recommendation by the Dietary Guidelines and is generally a practice that is recommended to be avoided for routine use (*Dietary Guidelines for Americans, 2020-2025*, n.d.-a; Milanaik et al., 2019). Studies have observed and collected information as to why parents add infant cereal into the bottle with reasonings including that the infant needs more food to sustain their hunger and the addition of cereal into their bottle can assist with that (Savage & Birch, 2017). As it is observed how there are differences in infants who start to be introduced to complementary foods before and after 4 months, there are differences observed in infants who consumed formula with the addition of infant cereal and those who did not have infant cereal in their bottle. Considering, the disparity in childhood obesity by income, it is critical to examine feeding choices and predictors of different feeding practices, specifically the addition of infant cereal into the bottle among low-income households.

The specific aims of my thesis are to:

1) Examine the prevalence of early introduction to solids and adding cereal into the formula practice among low-income and mainly minority infants.
    - Hypothesis: Overall early introduction to solids will be common among the study population and will be positively related to the practice of adding cereal into the formula.
2) Examine adding cereal into the formula is associated with daily calorie and macronutrient intake among low-income and mainly minority infants.
    - Hypothesis: Adding cereal into the formula will be associated with higher intake of calories and other macronutrients among low-income, mainly minority infants.

CHAPTER II: LITERATURE REVIEW

First 1,000 Days of Life

The first 1000 days of life which begins from the first day of pregnancy and goes through until the child is 2 years old, is recognized as a very crucial period for child development including in predicting weight status during childhood and later in life (Blake-Lamb et al., 2016; Taveras, 2016). For instance, gestational weight gain has been associated with obesity among children (Perez-Escamilla et al., 2018). A study by Fraser et. al. found that not only does a greater gestational weight gain increase the offspring's odds of obesity, but the timing of the weight gained during the pregnancy is important as well (Fraser et al., 2010). Women who gained weight of around 500g/week had higher odds of developing a greater gestational weight gain and offspring odds of obesity compared to women who lost weight or did not gain any weight during early pregnancy (Fraser et al., 2010). Another study found that among women who had greater than average gestational weight gain, about 50% of the children were overweight at 3 years old (Olson et al., 2009). In addition to prenatal condition, infant feeding practices have gained a lot of attention by predicting growth rate during infancy and thereby obesity risk in childhood (CDC, 2022d; Perrine et al., 2014).

The Medical Cost of Obesity

Not only a social burden but overweight and obesity also put an economic burden on society. A recent estimate indicates that obesity costs the US about $147 billion per year in medical expenses (CDC, 2022b; *Fast Facts – Costs of Obesity | STOP Obesity Alliance | Milken Institute School of Public Health | The George Washington University*, n.d.). Even with a high BMI range, the health cost of an obese individual is estimated to be 15 times more compared to an individual with an overweight BMI. Finkelstein et. al examined 6 studies and found that the average lifetime medical cost for a child who experiences obesity is around $19,000 compared to $12,000 for a child who does not experience obesity in their childhood irrespective of any excess weight gain throughout their life (Finkelstein et al., 2014).

Childhood Obesity

Obesity has been an ongoing problem among children in the US. The national trend data indicated that the number of children with obesity has overall significantly increased in the past few decades with the rate increasing from 10% in 1988-1994 to the current childhood obesity rate of 19.3% among the 2 to 19-year age group (Estabrooks et al., 2008; *Products - Health E Stats - Prevalence of Overweight, Obesity, and Severe Obesity Among Children and Adolescents Aged 2–19 Years*, 2021). Obesity puts children at risk for poor health outcomes in the short and long term. Overweight and obese children are more likely to have respiratory health problems, such as asthma and sleep disorders (CDC, 2022b; Estabrooks et al., 2008). Excess body weight among children is also associated with low self-esteem and social problems such as depression, bullying, and stigma (Bleich et al., 2011; CDC, 2022b). In the long-term, children who are overweight or obese are more likely to become adults with a high BMI, which in turn is associated with type 2 diabetes, high blood pressure, chronic respiratory disorders, and other types of metabolic disorders (Bleich et al., 2011; CDC, 2022b; Estabrooks et al., 2008; Weihrauch-Blüher & Wiegand, 2018).

Causes of Childhood Obesity

In understanding the causes, it is noted that multiple factors at the genetic, behavioral, and environmental levels play a role in childhood obesity. Especially, it is argued that even though genetic/biological factors play a part in predicting obesity among children, the current epidemic increase is attributed mainly to the positive energy balance (Estabrooks et al., 2008). It is estimated that the changes in one's lifestyle, environment, and behavioral factors can cause an increase in calorie intake and a decrease in energy expenditure among children in recent decades.

In a systematic review by Bleich et. al 27 studies were examined assessing nutrition and physical activity among children and concluded that both the factors that are calorie intake and expenditure play significant roles in predicting obesity among children (Bleich et al., 2011). Specifically, in the case of energy intake, sugar-sweetened beverages (SSB) have been identified as a significant contributor to increased energy intake among children (Bleich et al., 2011; Estabrooks et al., 2008; Pan et al., 2014). Especially the link between SSB and weight gain has been seen in the non-Hispanic Black and Hispanic youth population compared to other ethnicities (Bleich et al., 2011). Many of the total calories that children consume are from SSBs (Bleich et al., 2011; Kay et al., 2018; Pan et al., 2014). The national-level data shows that 6 in 10 youths (63%) drink a SSB averaging about 143 calories from it on a given day, intake of SSB has also increased among young children (Rosinger et al., 2017). Further, consumption of SSBs during infancy was associated with a higher prevalence of obesity at 6 years of age compared to children who did not consume any SSB during infancy (Pan et al., 2014). Barrera et. al. found that the odds of obesity were higher among infants who were introduced to solids before 4 months of age compared to those introduced at 4-6 months (Barrera et al., 2016). However, this trend was not significant after controlling for maternal and infant characteristics such as maternal race/ethnicity, education, and infant's birth weight. The different duration times of breastfeeding were also found to have inverse results with SSB intake and obesity prevalence. Infants who were breastfed for less than 6 months showed a higher prevalence in SSB intake (31%) during infancy and a higher prevalence of obesity when the child was 6 years old compared to children who were breastfed for 6 or more months during infancy (Pan et al., 2014). The findings from the

6-year follow-up from The Infant Feeding Practices Study II (IFPS II) present results indicating that actions made during infancy can affect the child's health later in life.

Racial/socioeconomic Status Disparities

In comparison, obesity is disproportionately higher among minority children and those living in low-income households (*Childhood Obesity Facts | Overweight & Obesity | CDC*, 2022b; Estabrooks et al., 2008; Taveras, 2016). For instance, the rate of childhood obesity is 25.6% and 24.2% among Hispanic and African American children respectively, compared to 16.1% among non-Hispanic white children (*Childhood Obesity Facts | Overweight & Obesity | CDC*, 2022b). This difference is mainly driven by socioeconomic status since racial/ethnic minority groups are disproportionately represented in the low-income group. Results of the NHANES study by Ogden et. al. indicated that low-income children or children living in households with income ≤130% federal poverty level were 2 times at a higher risk of being obese compared to children living in households with income of >350% of federal poverty level (Ogden, 2017). IFPS II assessed the weight status of 1,189 infants (2005-2007) at a 6-year follow-up (2012). Results of this study indicated that the obesity rate at 6 years of age was 15% among infants from low-income households (<185% federal poverty level), while the prevalence of obesity among children at 6 years of age was 9.3% and 7.7% among middle and higher income (185%-349%, ≥350% federal poverty level) households, respectively (Pan et al., 2014).

Similarly, based on education levels, it was observed that obesity prevalence was highest among individuals with a lower level of education and inversely among individuals with a higher level of education i.e., 19.8% of children at year 6 were obese from mothers who had a high school education or less, while obesity among 6-year old's was 11.9% and 7% from mothers with some college and college degree, respectively (*Childhood Obesity Facts | Overweight & Obesity | CDC*, 2022b; Pan et al., 2014).

Recommended Infant Feeding Practices

The 2020-2025 USDA Dietary Guidelines provided recommendations on infant feeding practices, and following are some of the key feeding recommendations provided (*Dietary Guidelines for Americans, 2020-2025*, n.d.-a). Exclusive breastfeeding for the first 6 months of life. However, if breastfeeding is not a possible option then formula feeding is recommended. Once the infant is around 6 months of age, adding complementary foods into the diet is recommended. Complementary foods include a variety of nutrient dense foods like, fruits, vegetables, whole grains, proteins. Introduction to new foods should be spread out to be aware of allergens.

Certain foods and beverages are recommended to be avoided during infancy. An example of beverages to be avoided are sugar sweetened beverages like fruit juices or sport drinks. These beverages tend to be high in added sugars and can therefore make up a big portion of a child's caloric intake (Bleich et al., 2011; Estabrooks et al., 2008; Pan et al., 2014). Another beverage that is recommended to be avoided is cow milk until the infant is 12 months old. Introducing cow milk to an infant before 12 months can cause disturbances to their digestive system (CDC, 2022c; *Dietary Guidelines for Americans, 2020-2025*, n.d.-a).

A more specific option and common practice that is recommended to be avoided for routine use is the addition of infant cereal into the bottle (CDC, 2021; Milanaik et al., 2019). Infant cereal is one of the most common complementary foods to be introduced to infants when being introduced to solids (Milanaik et al., 2019).

Age of Introduction to Solids

According to the Dietary Guidelines, there are significant signs to watch out for to know if an infant is developmentally ready to start eating solid foods (*Dietary Guidelines for Americans, 2020-2025*, n.d.-a). Being able to sit up and hold their head up on their own and being able to grab food and direct it into their mouth are all good signs indicating that the infant could be ready to start on solid foods. Considering the developmental readiness and ensuring proper nutrition, it is recommended that the nutrient-dense complementary food should begin around 6 months of age (*Dietary Guidelines for Americans, 2020-2025*, n.d.-a). Especially, the timing of when solid foods are introduced to infants can affect daily energy intake and growth trajectory during infancy.

Other feeding choices

Along with the guidelines on the age of introduction to solids, the Dietary Guidelines recommends overall variation in complementary foods to meet nutritional and energy needs during infancy. Feeding choices including a variety of vegetables, fruits, whole grains, lean protein, and plant protein, are recommended. Foods high in omega-3 and omega-6 such as specific oils, seeds, and the introduction of iron and zinc-rich foods are also highly recommended to be included in the complementary foods. The recommendation to the introduction of a variety of foods is also endorsed to allow infants to be exposed to different textures and flavors (*Dietary Guidelines for Americans, 2020-2025*, n.d.-a). In the usual nutrient intake assessment among the national sample 6 to 23 months old infants and toddlers (n = 897), results of two 24-hour feeding recalls indicated that the infants were adequate for most nutrients; however, 10% had an iron intake below the daily requirement while only 21% had a vitamin D intake that met or exceeded the recommended amount. Among toddlers, inadequate intake of vitamin E and D was common.

By food groups, the IFPS II study showed that about 17% of infants consumed fruits and vegetables at 4 months and 40% were consuming infant cereal and less than 1% of the infants were consuming meats at that age (Grummer-Strawn et al., 2008). In examining complementary feeding practices, differences by income level and race/ethnicity have been identified (Roess et al., 2018). In comparison feeding practices between the special Supplemental Nutrition Program for Women, Infants, and Children (WIC) and non-WIC participants are also examined (Guthrie et al., 2018). Particularly, infants enrolled in WIC representing household income of 185% or below the federal poverty line, were significantly more likely to consume SSBs compared to the non-WIC infants or high-income group (Guthrie et al., 2018). In an examination of racial/ethnic differences, the result of the Perrin et. al study with 863 infants found that adding cereal in the bottle was more common among non-Hispanic Black (24%) and non-Hispanic White (16%) families when compared with Hispanic families (4%) (Perrin et al., 2014). Similar results were found in the study by Thompson et al. with a little under 50% of low-income mothers reporting adding infant cereal in the formula and/or breastmilk bottle at 3 months of infant age (Thompson & Bentley, 2013).

Timing of Solid Food Introduction

In the recent NHANES study, it was found that 43.5% of infants were fed other drinks and solids such as juice, sugar water, and baby food before 4 months of age (Orozco et al., 2020). Complementary foods that would typically be consumed during the first 6 months consist mostly of infant cereal regardless of the type of grain and pureed baby foods consisting of fruits, vegetables, or meats. The FITS 2016 study shows that infants under the age of 4 months who had consumed any formula had more infants consuming solid foods compared to infants who had not consumed any formula (Roess et al., 2018). About one-third of infants in the US who were introduced to complementary foods before 4 months of age were receiving infant formula or a mixed feeding of formula and breastmilk (*Dietary Guidelines for Americans, 2020-2025*, n.d.-a). A study by Fåk et al. examined ghrelin, a hormone that promotes appetite, concerning the introduction of solid foods in mice (Fåk et al., 2007). Mice in the study that had delayed weaning presented reduced amounts of gastric and plasma ghrelin and lower body weight compared to the mice who did not delay weaning. Several studies have found that introduction to complementary foods before the age of 4 months is associated with an increased risk of obesity later in life (Pearce et al., 2013; Wang et al., 2016). It is argued that early introduction to solids can lead to excess energy intake affecting growth rate during infancy. Huh et. al. conducted a prospective cohort study with 847 children to examine the association between timing of introduction to solids and obesity at 3 years of age (Huh et al., 2011). The timing of solid food introduction was not associated with odds of obesity among breastfed infants, but among formula-fed infants, the introduction of solids before 4 months was associated with a six times higher likelihood of obesity at 3 years of age. The possible explanation provided for the high obesity risk specifically among formula-fed infants was that formula-fed infants may increase their energy intake when solids are introduced, while breastfeeding may allow a mother to recognize infant's hunger and satiety cues compared to in formula feeding. Perrin et al., who majority of infants in their study were formula fed, found feeding styles that are commonly associated with obesity later in life (Perrin et al., 2014). For example, putting an infant to bed with a bottle, propping the bottle when they were being fed, encouraging the infant to finish their bottle and to immediately feed infants when they began to cry were common practices among some infants.

Addition of Cereal into the Bottle

With introducing solid foods as early as 4 months being relatively common, infant cereal tends to be a popular choice and one of the most common solid foods among 6 month old infants (Orozco et al., 2020; Smith et al., 2019). In a study by Barrera et al., (n= 1482) 16.3% of infants were introduced to solids before 4 months of age and 54.6% were introduced to solids before 6 months of age. Infants who were not breastfed for more than 4 months or at all had significantly greater odds of being introduced to solids early (Barrera et al., 2018). A national study, (n= 1334) observed possible reasons as to why mothers would introduce solids to infants earlier than the recommended age. For this study 40.4% of infants were introduced to solids early. Infants only fed formula (52.7%) were more likely to be introduced to solids early compared to infants only fed breastmilk (24.3%). The top indicated reasons as to why mothers decided to introduce solids early to their infants were, "My baby was old enough to begin to eat solid food"(88.9%), " my baby seemed hungry a lot of the time" (71.4%), and "a doctor or other health care professional said my baby should begin eating solid foods" (55.5%) to name a few (Clayton et al., 2013). Barrera et al. and Clayton et al. had similarities in the demographics of the mothers who introduced solids early to their infants, generally the mothers were receiving WIC benefits, and were younger compared to the mothers who were not introducing solids early.

Overall, optimal nutrition during infancy is critical in growth and development and feeding practices during this period can influence short- and long-term health. Infancy is marked by high nutrient needs and includes critical transitions from breastmilk or formula feeding in early infancy to adding variety of complementary foods in later infancy. Especially, early introduction to solids and feeding practice such as adding cereal into the bottle is not recommended. However, it is not clear how are these practices interrelate and how it relates to daily nutrient intake among infants, especially among high-risk group of low-income and mainly minority infants.

CHAPTER III: RESEARCH ARTICLE

Early Introduction to Solids and Adding Cereal into the Bottle: The Relationship and Association with Daily Macronutrient Intake among Low-income Infants.

Abstract

Objectives: To examine 1) prevalence of early introduction to solids and its association with sociodemographic characteristics and food security status, 2) how early introduction to solids is associated with adding cereal into the bottle later in infancy, 3) how adding cereal into the bottle contributes to daily calorie and macronutrient intake later in infancy.

Design: Longitudinal data from 201 interviews and 24-h feeding recalls conducted with mothers-infant dyads at 4, 6, and 9 months of infants age.

Participants: Low-income, mothers $\geq$18 years old and their full-term, singleton infants.

Main Outcome Measure(s): If introduced early to solids, if breastfeeding at 4 months and differences in total energy and macronutrient intake between cereal in the bottle vs not (6 and 9 months).

Analysis: Descriptive statistics, chi-square, ANOVA and logistic regression.

Results: Early introduction to solids for 29% of infants. Significantly more common among employed and moderate to very low food secure mothers. Early introduction to solids was negatively associated with breastfeeding at 4 months. Infants fed cereal in the bottle were consuming significantly more calories compared to counterparts.

Conclusions and Implications: Early introduction to solids is associated with poor feeding. Further investigation is needed to understand if food insecurity promotes early introduction to solids. Nutrition education programs on infant feeding practices is critical.

Key words- Infant, Cereals, Food insecurity, Infant food, Nutrient intake

Introduction

Infancy is a critical stage for establishing healthy dietary patterns, supported by the addition of feeding recommendations for infants and toddlers in the 2020–2025 U.S Department of Agriculture (USDA) Dietary Guidelines (*Dietary Guidelines for Americans, 2020-2025,* n.d.-b). Recommendations for the first six months of age are exclusive breastfeeding or iron-fortified formula if breastfeeding is not feasible, followed by an introduction to complementary foods at six months (*Dietary Guidelines for Americans, 2020-2025*, n.d.-b).

The Recommendation is to avoid complementary foods before four months because gastrointestinal, immunological, and renal systems are still developing (Naylor & Morrow, 2001). In addition, early introduction to complementary foods and beverages has been associated with discontinued breastfeeding, early transition to formula feeding, and non-responsive feeding styles, which are practices that may increase the risk for poor dietary habits and childhood obesity (Perez-Escamilla et al., 2017; Woo Baidal et al., 2016).

Food insecurity can have a powerful effect on the feeding practices parents may provide to their infants. Food insecurity is defined by the USDA as an individual or household reporting little to no access or availability to a variety of quality food. There are two levels of food insecurity that indicate food insecurity, low food security and very low food security. The latest data from the USDA shows that 14.8% of households including children were food insecure in 2020. Of the 14.8% of households, 7.6% of those households include both adults and children being food insecure (*USDA ERS - Food Security and Nutrition Assistance*, n.d.).

Programs in the United States are in place to reduce the percentage of households with any level of food insecurity. The Supplemental Nutrition Assistance Program (SNAP) assists approximately 42 million Americans as of 2021 (*SNAPsummary-8.Pdf*, n.d.). The Special

Supplemental Nutrition Program for Women, Infants, and Children (WIC) also helps around 6.3 million individuals as of 2019. The Hispanic community had the highest number of individuals participating in WIC and the highest number of infants and children participating in the program (*WIC 2019 Eligibility and Coverage Rates | Food and Nutrition Service*, n.d.).

Specific feeding practices like adding infant cereal to the bottle are typically more common among low-income, single-parent, and racial/ethnic minority households (Barrera et al., 2018; Orozco et al., 2020; Perez-Escamilla et al., 2017). Adding infant cereal to a bottle is not recommended for routine use as it can cause overfeeding and dysregulation of infants' hunger and satiety cues (CDC, 2021; Milanaik et al., 2019). However, there is a lack of understanding on how this practice contributes to caloric and nutrient intake.

The addition of infant cereal to formula or breastmilk bottles is a typical initial complementary food. About half of the 4 to 6 month old infants in the United States receive cereal daily and giving it through the bottle is a very usual practice (Roess et al., 2018; Smith et al., 2019). For instance, a study among parents from a low-income, predominantly African American community found that 78% of the infants were given cereal at 3 months of age, with 85% receiving it through the formula bottle (Thompson & Bentley, 2013). In addition to misperceptions about cereal in the bottle increasing infants' sleep, this practice is also common when infant fussiness is viewed as a sign of hunger (Lucas et al., 2017; Savage & Birch, 2017; Vilar-Compte et al., 2022).

This study aims to understand how early introduction of complementary food before 4 months is associated with socio-demographic characteristics and food security status in a sample of mother–infant dyads from low-income, racial/ethnic minority backgrounds. Further, the second and third objectives are to: determine how early introduction to complementary foods is associated with adding cereal into the bottle later in infancy at 6 and 9 months; and examine how adding infant cereal into the bottle relates to daily calorie and macronutrient intake at 6 and 9 months of infancy.

Methods

The Office of Research Integrity at XX-XXXX and a partnering pediatric clinic approved this longitudinal study involving mother-infant dyads. Data was collected from March 2019 to March 2022. The partnering pediatric clinic, located in the piedmont triad in North Carolina, mainly served minority and low-income families, with around 85% of patients enrolled in Medicaid, representing a household income of < 210% below the federal poverty line (NC Medicaid and Health Choice Outreach and Public Health, Health and Human Services, n.d). Participant selection criteria included: biological mother of at least 18 years of age, fluent in English or Spanish, Medicaid recipient, and singleton infant born at full-term, defined as 37 weeks or longer gestation.

In-person recruitment was done by approaching potential participants in the clinic's waiting area. The study staff approached mothers of infants aged 2 months or younger during their well-child appointments, as confirmed by the clinic's appointment schedule. Information about the study was explained and the staff would assess their interest in study participation. Upon interest and confirmation of eligibility, mothers were asked to provide contact information and to sign the consent forms for permission to conduct interviews at regular intervals. Interviews were conducted during a 10-day window before or after the infants' age at 4, 6, and 9 months.

Prior to COVID-19 restrictions in March 2020, the interviews were conducted in person or over the phone based on participants' preferences. However, in response to the pandemic, in-person recruitment was halted from March 2020 - July 2020, and all interviews were conducted over the phone from March 2020 onwards. Post-July 2020, in-person recruitment resumed using the COVID safety guidelines of wearing masks, face shields, and completing a daily COVID symptom and exposure screening.

For the analyses and to address the study objectives related to the early introduction of complementary feeding, the sample was restricted to 201 infants who were formula-fed (partially or exclusively) at 4 months out of the total 247 participants recruited. Participants received e-gift cards or physical gift cards for grocery stores at each interview.

Interviews and Measures

The interviews were conducted by well-trained bilingual research assistants fluent in English and Spanish. Each interview lasted approximately 30 minutes using the secure electronic data capture tool REDCAP hosted at XXXX. Data was gathered on socio-demographic characteristics, age of complementary food introduction, breastfeeding status during the 4 month interviews, and household food security status. Household food security status was collected and measured using the USDA U.S Household Food Security Survey using the prior 30 days reference period (Coleman-Jensen & Nord, n.d.). Information on adding cereal into the bottle and nutrient intake was based on the 24-hour diet recall at 6 and 9 months of infant's age.

Questions from the Infant Feeding Practices Study (IFPS II), conducted by the Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC), were used to collect information on feeding practices (Fein et al., 2008). For breastfeeding, the following question was asked at the 4 month interview, "are you currently breastfeeding or feeding baby your pumped milk?"; yielding a 'yes' or 'no' response which was used to calculate the breastfeeding rate at 4 months. To determine early introduction to complementary foods, we asked, “Is your baby fed any solid foods (like baby cereal, rice puffs, crackers, mashed potato, etc.) through formula or on its own?”, yielding a ‘yes’ or ‘no’ response. The IFPS II frequency questionnaire also assessed complementary feeding prior to 4 months, including giving any of the following items in the past week: baby cereal; other cereals and starches; fruit; vegetables; french fries; meat, chicken, combination dinners; peanut butter or nut foods; eggs; sweet foods like cookies, cake. As the paper focused on how early introduction of complementary foods is related to giving cereal in the bottle later in infancy, liquids including water, sugar water, herbal teas, or fruit juices were not counted toward defining early introduction.

Information on adding cereal to the bottle was retrieved from 24-hour diet recalls conducted at 6 and 9 months of infant’s age. The recalls were performed using the multiple pass method, utilizing the Nutrition Data System for Research (NDSR) software developed by the Nutrition Coordinating Center (NCC), University of Minnesota, Minneapolis, MN. The NDSR database includes more than 1,000 baby products, including dairy and non-dairy formulas, fruit and vegetable pouches, and jar foods. A day before the recall, participants were sent pictures of standard sippy cups, formula bottles, and spoons to help them more accurately report portion sizes. Each research assistant involved in doing recalls completed a 2-day NDSR Certification training and completed a minimum of ten practice 24-hour recalls.

Adjustments were made on direct breastmilk intake since we do not have an exact amount of how much was consumed by infants compared to formula where the amount made and consumed was recorded. The adjusted mL/day for direct breastmilk intake was based on adjustments made in previous literature (Haisma et al., 2003; Tongchom et al., 2020; Wells et al., 2012). To adjust at 6 months of infants age, total milk volume was adjusted to 675 mL/day for infants who were consuming any complementary foods. The total milk volume was adjusted to

835 mL/day for those who were only consuming direct breastmilk and formula. At 9 months, the total milk volume was adjusted was 600 mL/day. The total milk volume included both breastmilk and formula. No adjustments were made for pumped milk feeding since the participants could report the specific amount. Before the analyses, 10% of the total 6 and 9 month 24-hour diet recalls were randomly selected for a line-by-line quality check. Only the completed recalls with a high-quality rating by the interviewer were selected for the analyses resulting in a sample size of 201 participants after selecting participants who were formula feeding exclusively or partially at 4 months and whose completed recalls at 6 and 9 months were of high quality. Quality of interviews were measured by the interviewer at the end of the 24-hour recall by selecting if the interview was reliable, unreliable because the participant was unable to recall on one or more meals or unreliable for other reasons.

Statistical Analyses

We began by testing for outliers and homogeneity of variance to confirm mean differences were not due to extreme values between groups. Descriptive statistics were used to examine socio-demographic characteristics, breastfeeding rate, and other feeding practices over time. Multivariable logistic regression analyses were conducted to estimate how socio-demographic variables and food security status was related to early complementary feeding. Bivariate Chi-square tests was used to estimate differences in rates of breastfeeding and adding cereal into the bottle between those who gave complementary foods prior to 4 months and those who did not. To explore how adding cereal into the bottle related to total calorie and macronutrient intake, after controlling for infant's sex, we used analysis of variance (ANOVA) comparing infants who did and did not receive added cereal in formula bottles. The analyses were conducted using a pre-specified statistical plan with SPSS software (IBM SPSS Statistics for Windows, Version 21.0. Armonk, NY: IBM Corp.) with statistical significance set at $p < .05$.

Results

As shown in Table 1, most participants were African American (42.8%) or Latinx origin (35.3%). Mothers' average age was 29.8, average household size was 4.5, and the average monthly household income was $1700. Most mothers (83.6%) participated in the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), and 49.8% received Supplemental Nutrition Assistance Program (SNAP). Less than half (38.1%) of mothers were employed part-time or full-time, and 57.7% had a high school or equivalent level of education. Over one-third (37.3%) reported marginal to very low food security. By study design, all infants were receiving formula at 4 months of age; 29.4% had received complementary foods and 42.8% were partially breastfed. At 6 and 9 months, 29.9% and 14.4% of the infants had received formula with cereal in the bottle, respectively.

Using the non-Hispanic white group as a reference, the Latinx group had a lower likelihood of feeding infants anything other than formula or breastmilk before 4 months (β: -2.08, OR:0.12, 95% CI: 0.03, 0.49; $p = 0.00$) (Table 2). The odds of giving complementary foods before 4 months (β: -1.20, OR:0.30, 95% CI: 0.13, 0.65; $p = 0.00$) were 20% lower among mothers who were non-employed compared to mothers who were employed. When mothers were experiencing moderate to very low food insecurity, the odds of an early introduction to complementary foods were 149% higher compared to mothers who reported they were food-secure (β: 0.91, OR 2.49, 95% CI: 1.09, 5.68; $p = 0.03$). Among mothers who introduced complementary foods before 4 months, infant cereal was the most common item (78%), followed by fruits and vegetables in a puree, mash, or pouch form (48%).

In examining the association between early introduction to complementary foods with other feeding practices, it was found that breastfeeding was significantly lower (*p*=0.01) while adding cereal into the bottle at 6 months was significantly higher (*p*<0.01) (Figure 1). No significant association was found between early introduction to solids and adding cereal into the bottle at 9 months.

When observing the average intake of calories and macronutrients among study participants, it was found that at 6 months infants consumed 771 kcals/day, 97g of carbohydrate per day, 36g of fat per day, and 17g of protein per day, respectively. At 9 months, infants consumed 939 kcals/day, 125g of carbohydrate per day, 39g of fat per day, and 25g of protein per day, respectively. When comparing the average intake of study participants to the recommended energy and macronutrient intake, study participant intake was on average higher than the recommended intake (Table 3).

At 6 months, adding cereal to the bottle was associated with increased caloric and carbohydrate intake. Based on the 24-hour recall analyses, infants who received formula with added infant cereal consumed 165 more calories per day than infants who received formula with no infant cereal ($F(2, 199) = 15.51$, $p < .001$). The total carbohydrate intake was 33.28 grams higher ($F(2,199) = 16.22$, $p < .001$), and the protein intake was 3.75 grams higher ($F(2,199) = 12.14$, $p < .001$) among infants who received cereal in the formula bottle, compared to infants with no added cereal. The percentage of calories from carbohydrates was significantly higher among infants who received cereal in the formula bottle; in contrast, the percentage of calories from fat was significantly lower for infants who received cereal in the bottle (Table 4).

At 9-months, similar patterns were seen. After controlling for gender, adding cereal into the bottle was associated with an intake of 158 additional calories per day ($F(2,199) = 4.08$, *p*

=0.04). An intake of total carbohydrates was 27.61 grams higher per day for infants given cereal in the bottle than infants who did not receive cereal in their formula (p <.004). Similarly, the percentage of calories from carbohydrates was significantly higher, while the percentage of calories from fat was significantly lower among 9-month-old infants fed cereal with formula in the bottle. The total formula intake was not significantly different between the groups at either 6 or 9 months (Table 4).

Discussion

This study including mother-infant dyads from low-income and minority backgrounds indicates that early introduction to complementary foods is a common practice as approximately 29% of mothers gave complementary foods before 4 months. Similarly, in large national survey studies, the prevalence of introduction to complementary foods prior to 4 months of age was between 30% and 40% (Barrera et al., 2018; Clayton et al., 2013; Grummer-Strawn et al., 2008; Orozco et al., 2020; Siega-Riz et al., 2010).

By discontinuing breastfeeding before the recommended length, early introduction of complementary feeding could potentially increase the risk of rapid weight gain and overweight. For instance, in a study including 881 British children, the early introduction of complementary foods was associated with higher energy intake at 4 months and higher body mass index (BMI) in early childhood among formula-fed, but not breastfed infants (Ong et al., 2006). In another study, the early introduction of complementary food was associated with a higher BMI among children who were breastfed for less than 4 months (Differding et al., 2020).

In our sample, Latinx mothers were less likely to feed complementary foods to infants prior to 4 months of age when compared to non-Hispanic white mothers, which is similar to the trend seen in other recent studies (Chiang, 2020; English et al., 2019; Orozco et al., 2020;

Dharod et al., 2022). For instance, a study conducted by the CDC involving data from the 2016 to 2018 National Survey of Children's Health found that the prevalence of early introduction of complementary feeding was significantly higher among the African American group (40.5%) compared to the Latinx group (29.9%). However, the reasons for early introduction of complementary foods are not fully understood. There has been an association of early introduction to complementary foods with a mother's perception that their infant has a big appetite or is not satisfied with just breastmilk or formula (Clayton et al., 2013). Another possible reason may be that mothers are influenced by evidence that thickening infant foods with cereal decreases emesis and crying time while increasing the caloric density and sleep time among infants with gastroesophageal reflux disease (GERD) and growth faltering (Vanderhoof et al., 2003). GERD is a relatively common condition experienced by approximately 25% of infants (Singendonk et al., 2019), raising the possibility that some mothers may introduce cereal in the bottle to treat or prevent GERD. However, thickening infant formula has only modest effects among infants with GERD and healthy growth (Horvath et al., 2008), and no effects related to sleep among healthy infants without GERD (Messayke et al., 2020).

Over a third of the study's population reported experiencing very low food security, possibly contributing to parents feeding practices. After controlling for other socio-demographic characteristics such as employment status and racial and ethnic identity, we found that mothers who experienced moderate to very low levels of food security were more likely to introduce complementary foods early. This association is consistent with previous qualitative and quantitative studies showing that caregivers in food-insecure households are at risk of running out of formula at the end of the month, increasing the risk of substituting other foods for feeding infants (Burkhardt et al., 2012; Frank, 2015; Orr et al., 2019; Partyka et al., 2010). In addition, Orr et al. indicated that mothers from a food insecure household had higher odds of believing that feeding their infant immediately would be the best way to stop their infant from crying. Mothers of infants and young children in food-insecure households have an elevated risk of depressive symptoms (Cook & Frank, 2008). They may interpret infant fussiness as hunger, driving them to add cereal to the formula to mitigate possible infant hunger. A recent study among mothers from low-income families found that maternal depressive symptoms were associated with perceptions of their child having a negative temperament and practices such as adding cereal to the bottle or putting the infant to bed with a bottle (Savage & Birch, 2017). Future research on food insecurity and parental feeding practices, and views toward child fussiness as a sign of hunger should be considered.

Our study found a significant association between the early introduction of complementary foods and adding cereal into the bottle later in infancy at 6 and 9 months. This positive association may be attributed to the pattern of starting with adding cereal in the formula bottle and continuing it throughout infancy. At both 6 and 9 months, adding cereal into the bottle was associated with increased calorie intake by about 100 calories. A multi-country longitudinal study examining total calorie intake from early infancy to 5 years among 5500 children documented that a higher calorie intake during infancy was a strong predictor of overweight at age 5 (Beyerlein et al., 2017). Along with total calorie intake, an imbalanced diet of high carbohydrates during infancy may result in proneness to metabolic dysregulation and weight gain (Karaolis-Danckert et al., 2007; Rolland-Cachera et al., 2016). Feeding choices and macronutrient composition are also shown to play a role in predicting gut microbiota composition, which may play a critical role in predicting the risk for inflammation and body composition later in life (Differding et al., 2020). Especially studies have consistently shown that high protein intake during late infancy, between 6 and 12 months, is associated with high growth and high BMI in childhood (Günther et al., 2007; Hörnell et al., 2013; Voortman et al., 2016).

Future research is needed to examine the association between adding infant cereal to the bottle and weight status during infancy and childhood. We limited our study to infants receiving formula at 4 months to focus on the practice of adding cereal to formula. A three-group comparison among infants at four months who were exclusively breastfed, exclusively formula-fed, or fed with complementary foods would yield necessary evidence on how feeding patterns relate to calorie consumption and growth trajectories during infancy. In a recent systematic review, it was concluded that four feeding practices can put formula-fed infants at risk for excess weight gain: 1) size of bottle used ($<$ 6 oz versus $\geq$ 6 oz bottle); 2) putting an infant to bed with formula; 3) ensuring bottle emptying by infants; and 4) adding cereal into the bottle (Appleton et al., 2018). Our study and current literature highlight the inter-related nature of feeding practices indicating that investigating a combination of feeding practices is essential in understanding the relationship between nutrition and growth trajectory among infants.

Research and Practical Implications

As highlighted in this study, adding cereal into the bottle at 6 and 9 months seems to be a common pattern among low-income infants, mainly in minority groups. Exclusive breastfeeding rates are especially low due to social, economic, and environmental barriers. Observations of additional calories contributed by infant cereal were present among our sample of women from low-income households. Therefore, it is critical to implement nutrition education programs focused on promoting optimal infant feeding practices and the best formula feeding practices in reducing the risk of overweight/obesity among infants in low-income households.

Our study should be interpreted considering several methodological limitations. First, we relied on one 24-hour recall to estimate feeding practices and the nutrient profile at 6 and 9 months. Only one 24-hour recall was done at each month to accommodate to busy mothers and provide flexibility. Second, although our study represents a diverse group of mothers and infants from minority backgrounds, they were from one clinic site and may not be representative of other groups limiting generalizability. Third, we asked about food insecurity prior to or early in the pandemic and families of young children in low-income communities experienced an increase in food insecurity during the pandemic (Kowalski et al., 2021), suggesting that our estimates may have been low.

In conclusion, this study illustrates that early introduction to complementary foods, primarily cereal in the bottle, is common among low-income and minority groups. This practice that continues throughout infancy, is associated with increased caloric intake, and may be a pathway to maladaptive feeding practices and increased risk of excess weight gain and overweight throughout the lifespan.

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APPENDIX A: TABLES AND FIGURES

Table A1. Sociodemographic Characteristics and Feeding Practices among Low-income Mother-infant Dyads (n = 201)

Characteristics	Mean (SD)
Mother's age (in years)	29.8 (6.1)
Household size	4.5 (1.7)
Household income ($, monthly)[a]	1708.8 (1506.8)
	n (%)
Ethnicity	
African American	86 (42.8)
Hispanic	71 (35.3)
Non-Hispanic White	20 (10.0)
Others[b]	24 (11.9)
Marital Status	
Single/Divorced	123 (61.2)
Married/Living with partner	78 (38.8)
Education	
Less than High School	42 (20.9)
High School/GED	116 (57.7)
College degree	43 (21.4)
Employment Status	
Employed (full/part time)	76 (38.1)
Unemployed	125 (61.9)
Food Security Status	
High	126 (62.7)
Marginal/Low/Very Low	75 (37.3)
Primiparous Parity	80 (40.0)
Participation in WIC	168 (83.6)
Participation in SNAP	100 (49.8)
Infant Sex: Male	96 (47.8)
Introduced complementary foods < 4 months of age	59 (29.4)
Breastfeeding at 4 months of age	86 (42.8)
Adding cereal into the formula bottle at 6 months[c]	60 (29.9)
Added cereal into the bottle at 9 months[c]	29 (14.4)

[a] Income sample size=171 (remaining 30 reported either “don’t know” or “refused to provide information”); [b]Other groups include Asian, Pacific Islander, Mixed and Native American; [c]Adding cereal to the bottle information was based on the 24-hour recall.

Table A2. Sociodemographic Predictors of Early Introduction to Complementary Foods (< 4 months of age) among Infants in Low-income Households (n = 201)[a]

Characteristics	β (SE)	*OR*	CI	*p*
Ethnicity				
Non-Hispanic White	*Ref.*			
African American	0 .31(0.54)	1.37	0.47 - 3.98	0.55
Hispanic	-2.08 (0.70)	0.12	0.03 – 0.49	**0.00**
Other	-1.04 (0.73)	0.35	0.08 – 1.49	0.15
Employment status				
Employed (Full/Part-time)	*Ref.*			
Not employed	*-1.20 (0.39)*	0.30	0.13 – 0.65	**0.00**
Education status				
High school or more	*Ref.*			
Less than high school	*0.11 (0.60)*	1.12	0.34 – 3.70	0.84
Marital Status				
Married/living with	*Ref.*			
partner	-0.32 (0.45)	0.72	0.29 – 1.74	0.46
Single/Divorced				
Food security status				
High	*Ref.*			
Marginal/Low/Very low	0.91 (0.42)	2.49	1.09 -5.68	**0.03**
Parity				
Multiparous	*Ref.*			
Nulliparous	-0.13 (0.38)	0.87	0.41 – 1.85	0.72
Maternal age (Continuous)	-0.02 (0.03)	0.99	0.93 – 1.06	0.94

[a]Binary logistic regression test; OR: Odds Ratio; CI: Confidence Interval; Outcome variable: Introduced complementary foods (1) or not (0) prior to 4 months.

Table A3. Recommended Estimated Energy and Dietary Reference Intake Requirements of Infants Compared to Energy and Macronutrient Intake from FeeN Study Participants

Age	Calories[a] (Kcal/day)	Carbohydrate[b] (g/day)	Fat[b] (g/day)	Protein[b] (g/day)
0-6 months	438-645	60	31	9.1
7-12 months	608-844	95	30	11
FeeN 6 month average[c]	770 (+/- 284)	97 (+/- 43)	36 (+/- 12)	17 (+/- 8)
FeeN 9 month average[d]	939 (+/- 359)	125 (+/- 53)	39 (+/- 13)	25 (+/- 21)

[a]Information on infant calorie intake from (*Chapter1_NutritionalNeeds.Pdf*, n.d.)

[b]Information on infant carbohydrate, fat, and protein intake from (*WIC Infant Nutrition and Feeding Guide*, n.d.)

[c]6 month mean intake (+/- standard deviation) is based on sample size of 201

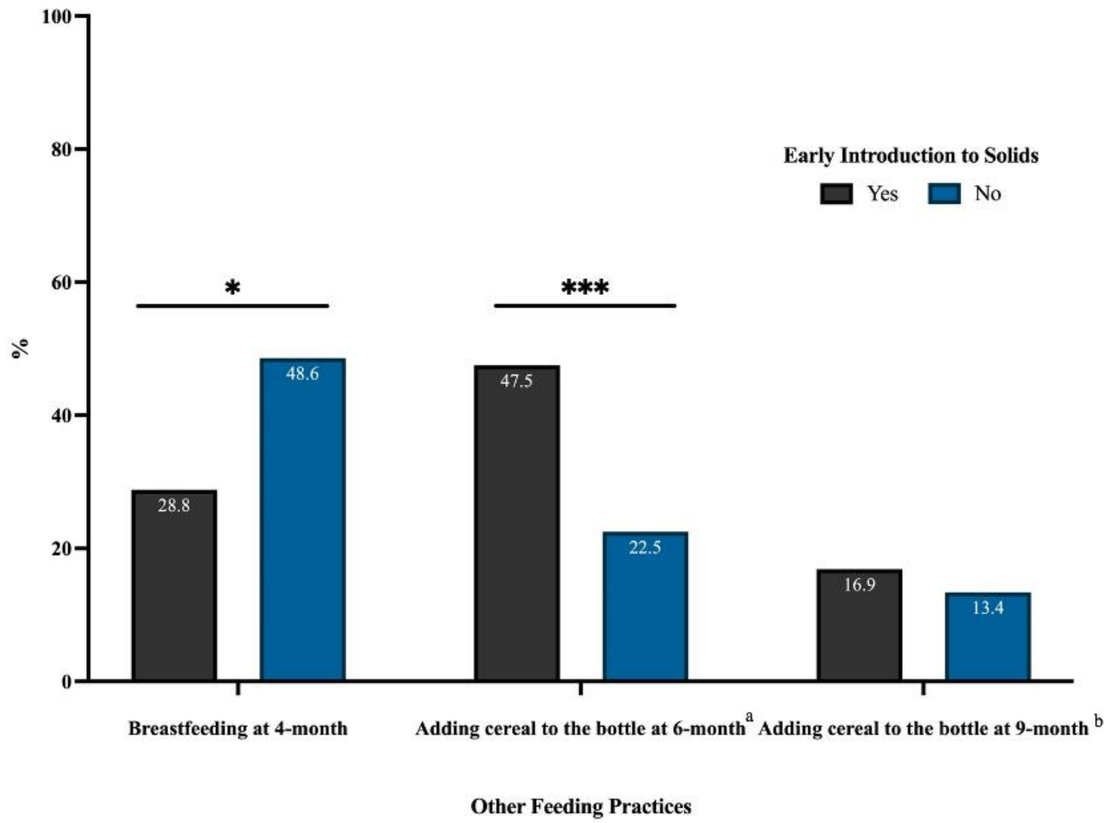
[d]9 month mean intake (+/- standard deviation) is based on sample size of 183

Table A4. Differences in Total Calorie and Macronutrients Intake among Infants at 6 and 9 Months Based on Receiving of Cereal in the Formula Bottle Versus Not[a]

	6 -month (n=201)			9 -month (n=185)		
	Mean differences[b]	F	*p*	Mean differences[b]	F	*p*
Total Calories (kcal)	165.16	15.51	***<.001***	158.90	4.08	***0.044***
Total Carbohydrates (gms)	33.28	16.22	***<.001***	27.61	8.48	***0.004***
Total Protein (gms)	3.75	12.14	***<.001***	3.94	2.86	0.092
Total Fat (gms)	1.47	0.65	0.421	0.68	0.07	0.791
% Carbohydrates	5.27	36.57	***<.001***	3.54	7.52	***0.006***
% Protein	-0.08	0.31	0.574	0.80	2.72	0.100
% Fat	-5.42	35.56	***<.001***	-4.78	15.79	***<.001***
Formula intake (in servings)[c]	0.00	0.00	0.983	0.72	1.87	0.172

[a]Nutrient values are based on the 24-hour feeding recall done at 6 or 9 months, the sample size for 6 month = 201; for 9 month = 185, dropped off 16 recalls because of incomplete/missing/poor quality recalls. [b]Mean difference between infants fed cereal with formula one or more times versus no such practice of adding cereal into the formula bottle; [c]Formula intake represents servings, with one serving representing 5 fluid ounces.

Figure A1. Differences in breastfeeding and adding cereal to the bottle practice between those who were fed solids prior to 4 months versus not



[a]Breastfeeding at 6-month n=201. [b]Adding cereal to the bottle at 9-month n=185.

*p=0.01

***p<0.01