Original Article

Inappropriate bottle use: an early risk for overweight? Literature review and pilot data for a bottle-weaning trial

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Abstract

Identifying early risk factors for childhood obesity is critical, as weight in infancy and early childhood tracks to later periods. Continued bottle use – primarily from excess milk intake – is emerging as a potential risk factor for early childhood overweight. Over three fourths of US infants drink from bottles beyond the recommended weaning age of 12 months, and two thirds of UK infants use a bottle at 18 months. This paper is divided into three parts. Part I reviews the literature on beverage intake, weight and bottle use in young children. Part II describes pilot data on milk bottle use and weight in 12–60-month-olds, collected prior to a randomized controlled (RCT) trial of a bottle-weaning intervention. Median daily milk bottle consumption at 12 months was 5.0 (interquartile range = 3–6). Among 12–36-month-olds, current users were significantly more likely to be >95th% weight-for-height (19% vs. 0%, $P < 0.02$), and more were >85% weight-for-height (27% vs. 11%, $P < 0.11$), vs. non-users. In contrast, current bottle use was not associated with either overweight or obesity in 37–60-month-olds. Part III describes the RCT, begun in fall 2008. It is enrolling 464 parent/12-month-old dyads from a nutrition assistance programme for low-income families. Children's bottle use, anthropometrics, dietary intake and nutrient density (via 24 h recall) are assessed quarterly through 24 months of age. For the intervention, site nutritionists employ a project-developed, visually attractive flip chart. An observational study nested within the RCT will describe dietary changes during this period of feeding transitions.

Keywords: anthropometry, child feeding, childhood obesity, diet and physical activity interventions studies, infant and child nutrition, weaning.

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Introduction

Identifying early risk factors for childhood obesity is critical, as weight in infancy and early childhood tracks to later periods. Overweight infants are more likely to be overweight in pre-school (Scaglioni *et al.* 2000; Mei *et al.* 2003) and adulthood (Rolland-Cachera *et al.* 1987). Overweight pre-schoolers are twice as likely to be overweight as adults (Garn & Lavelle 1985). Large cohort studies find that infancy

weight status tracks to overweight at 7 (Stettler *et al.* 2002a; Salsberry & Reagan 2005) and 17 years of age (Ekelund *et al.* 2006; Stettler *et al.* 2002b). A summary of the extant literature finds strong evidence for an association between rapid infancy weight gain and later obesity (Stettler 2007).

'Inappropriate bottle use' in infants and young children is a potential, but little researched early risk factor for obesity. Dental caries (Van Houte *et al.* 1982; Quartey & Williamson 1999; Ramos-Gomez

et al. 1999; Goodman *et al.* 2004) – known as ‘baby bottle tooth decay’ – is the main rationale given for timely weaning (Koranyi *et al.* 1991). As used herein, ‘inappropriate bottle use’ refers to children over 12 months of age, drinking ≥ 2 bottle-type containers/day. While professional guidelines recommend bottle weaning at or around 12 months of age (US Department of Agriculture, Food and Nutrition Service 2001; American Academy of Pediatric Dentistry 2003; Bright Futures 2008), more than 25% of US 12-month-olds (Brotanek *et al.* 2005) and 9% of 3-year-olds continue to use bottles (Kaste & Gifte 1995). Low-income and Hispanic pre-schoolers have particularly high rates of bottle use (Kaste & Gifte 1995; Kimbro *et al.* 2007) and of overweight (Whitaker & Orzal 2006). Excess milk intake via bottles is also a known risk factor for iron deficiency (Mills 1989; Graham *et al.* 1997; Lampe & Velez 1997; Moertel *et al.* 1997; Brotanek *et al.* 2005), as the excess calcium from cow’s milk interferes with iron absorption (Oliveira & Osorio 2005; Ziegler 2007).

Excess milk intake via bottle may promote overweight through several possible mechanisms. Macro-nutrient intake in early life affects later adiposity. High protein in infancy and early childhood increases the risk of childhood overweight (Scaglioni *et al.* 2000) and body fatness (Rolland-Cachera *et al.* 1995). A large, double-blinded randomized trial is now testing this ‘early protein hypothesis’ (Koletzko *et al.* 2005; Koletzko 2006). In adults, there are conflicting data regarding liquids’ impact upon satiety compared with solids (Almiron-Roig *et al.* 2003), with some research suggesting that excess intake of energy-dense beverages (e.g. whole milk, sweet beverages) increases total energy intake (DiMeglio & Mattes 2000; Mourao *et al.* 2007) because solid intake is not

displaced. Early patterns may imprint a preference for energy-dense foods and diminished ability to self-regulate intake (Birch & Fisher 1998; Hill 2002). Children with higher adiposity levels have more difficulty regulating energy intake (Johnson 2000).

This paper is divided into three parts:

Part I: literature review – reviews the empirical literature on beverage intake, weight and bottle use in infants and young children.

Part II: pilot study – describes pilot data on milk bottle use and weight in pre-school children. Data were collected at two Women, Infants, and Children (WIC) Program sites. WIC is a US federal programme that offers food coupons and nutrition counselling to low-income pregnant, post-partum and breastfeeding women, infants and children through 5 years of age who are at nutritional risk.

Part III: description of Feeding Young Children Study (FYCS) – the ‘FYCS’, a bottle-weaning intervention study enrolling low-income multi-ethnic 12-month-olds, begun in 2008 (US Department of Agriculture 2008a). FYCS incorporates: (1) a randomized controlled trial (RCT) of a bottle-weaning intervention that will assess bottle use, anthropometrics, dietary intake and nutrient density outcomes; and (2) an observational study, nested within the RCT, that will describe dietary intake and nutrient density data for this period of feeding transitions.

I. Literature on beverage intake, weight and bottle use

We reviewed the literature to identify studies of pre-school children related to: (1) beverage intake and weight; (2) bottle use and overweight; and (3) bottle

Key messages

- Prolonged and excessive bottle use is a potential, but little researched risk factor for overweight in infancy and early childhood.
- Our pilot data from 150 low-income multi-ethnic toddlers support prior work finding that bottles are associated with excess milk intake and a higher risk of obesity in younger children.
- A randomized controlled trial of a bottle-weaning intervention and observational study of how continued bottle use into the second year of life affects children’s dietary patterns, feeding behaviours and weight, nested within this trial, are described.

use and milk consumption. A Pubmed search of English language articles, from 1996 to 2008, employed the following search strategies: 'milk + overweight + children', 'bottle use + weight + milk', 'bottle use + milk + consumption', 'beverage + preschool + weight' and 'beverage + weight + young children'. We excluded studies that did not provide empirical data on the variables cited in '(1)', '(2)' or '(3)' for children in the age range of 1–6 years of age. Papers reporting exclusively on either school-age children – including the growing literature on sugar-sweetened beverages (SSBs) – or infant feeding were also excluded.

As per the US Centers for Disease Control, we refer to overweight as 85th–<95th age-adjusted body mass index (BMI) percentiles, and obesity as ≥ 95 th age-adjusted BMI (Centers for Disease Control and Prevention 2008). For younger children in whom BMI is not typically calculated, the analogous parameter is weight-for-length.

What data exist on beverage intake and weight in young children?

There are limited data on diets of low-income multi-ethnic pre-schoolers (Newby 2007); none incorporate bottle use as a variable. The Feeding Infants and Toddlers Study (FITS) is the most comprehensive description of dietary patterns of young children in the United States (Devaney *et al.* 2004). While a FITS report cautions against excess beverage intake (Skinner *et al.* 2004), the study did not assess children's use of bottles, or weight. Current studies in the literature on *beverage intake and weight* in pre-schoolers, described below, vary by study design, sample size and demographics, level of excess milk or juice intake, and baseline weight. None ascertain bottle use.

Population-based studies

A number of papers have analysed beverage intake and weight in the US National Household and Nutrition Examination Survey (NHANES) study, a population-based cross-sectional study. In analyses of 2–5-year-olds in NHANES, children ($n = 1345$) with

higher beverage intake had higher total energy intake, but no increased risk of $>85\%$ BMI (O'Connor *et al.* 2006). No excess milk (mean = 12 oz day⁻¹) or juice (mean = 5 oz day⁻¹) intake and lack of longitudinal data or control for baseline weight status preclude statements about earlier intake patterns upon subsequent weight status. An analysis of NHANES 2–3-year-olds' consumption of 100% fruit juice and overweight found no association (Nicklas *et al.* 2008). Again, however, these cross-sectional data are limited by the lack of baseline and follow-up data on weight status.

An analysis of SSBs at 5 and 7 years showed no association with increased fatness at 9 years of age in a British longitudinal cohort study, but SSB energy intake was far lower than in the United States. Analyses with regard to milk were considered suspect because of potential spuriousness (Johnson *et al.* 2007). Among $n = 856$ Crete (Greece) kindergarteners, 30% of whom were overweight or obese, SSB consumption doubled the odds of being overweight or obese [odds ratio (OR) = 2.35, $P = 0.023$], and was inversely associated with a healthy diet, including adequate milk and yoghurt intake in a cross-sectional study (Linardakis *et al.* 2008).

With regard to milk intake, NHANES 2–5-year-olds classified as 'high-fat milk users' (vs. three other mutually exclusive beverage pattern groups) consumed 786 g of whole milk/day (27.5 oz) and obtained 35% of total energy intake from beverages. In contrast, the other groups' total energy intake from beverages was significantly lower, at 18, 19 and 29% for the 'water', 'mix/light drinker' and 'fruit juice' clusters, respectively ($P < 0.05$). High-fat milk users were more likely to be $>85\%$ BMI, 27%, vs. 26, 15 and 20% for the 'water', 'mix/light drinker' and 'fruit juice' clusters, respectively ($P < 0.01$). The high-fat milk user group had the poorest quality diet, which the authors suggest may be due in part to milk displacing other micronutrient-dense foods and reducing dietary variety (LaRowe *et al.* 2007). In an Italian sample ($n = 957$) of 3–11-year-olds, milk consumption was not associated with BMI, controlling for total diet, including SSBs, but data were not presented separately for younger children (Barba *et al.* 2005).

Systematic review and meta-analysis

A systematic review and meta-analyses, both of which focus on SSBs in schoolchildren, found conflicting results. A 2008 meta-analysis of 1996–2006 papers reported no association between SSBs and BMI (Forshee *et al.* 2008), though, just the Newby paper, cited above, included pre-school children. In contrast, an earlier systematic review of 1966–2005 papers (Malik *et al.* 2006) found an association between SSBs and risk of overweight, with just the Newby and Walsh studies, cited above, focusing upon children <6 years of age. We note that the latter based its conclusions on ‘the weight of epidemiologic and experimental evidence’ rather than quantification of an effect size, which the Forshee paper estimated to be ‘near zero’.

WIC studies

Among 1–4-years-olds in the WIC Program who were ≥ 85 th% in age and sex-adjusted BMI (kg m^{-2}) at baseline, juice/sweet drink intake predicted excess adiposity gain (additional BMI Z score gain of 0.009 standard deviation (SD)/month, $P < 0.01$; $n = 971$) (Faith *et al.* 2006) and doubled the odds of being >95th% BMI 12 months later [adjusted ORs range = 1.8–2.0 and corresponding 95% confidence interval (CI) range = 1.1–3.8, by volume of daily sweet drinks consumed; $n = 10\,904$] (Welsh *et al.* 2005). In contrast, another WIC study found that weight change was not significantly related to intake of fruit juice [beta = 0.01 lbs/year (95% CI = –0.01 to 0.20, $P = 0.28$)], milk [beta = 0.00 lbs/year (95% CI = –0.02 to 0.02, $P = 0.86$)] or fruit drinks [beta = –0.03 lbs/year (95% CI = –0.07 to 0.01, $P = 0.28$)] (Newby *et al.* 2004). However, this study only collected dietary intake data at baseline (vs. both baseline and follow-up), did not analyse data by initial weight, and compared with children in our pilot data study site (K. Bonuck, unpublished observation), had more children who were ‘White’ (84% vs. 4%) and >85th% BMI (20% vs. 33%).

Other studies

Earlier studies are confined to small samples of children whose juice and/or milk intake did not exceed

recommended levels and whose rate of overweight was lower than low-income and/or WIC preschoolers. Not surprisingly, in three of these four studies, ‘higher’ drink intake was not related to growth at 2 and 3 years of age ($n = 105$, no race/ethnic data, 15% ≥ 90 % BMI) (Skinner *et al.* 1999), 3–5 years of age ($n = 215$, juice data only) (Alexy *et al.* 1999) and 6 years of age ($n = 72$ White children, ‘few’ ≥ 85 % BMI) (Skinner & Carruth 2001). In a fourth, greater obesity was seen in 2 and 5-year-olds ($n = 168$) in relation to juice (but not milk) intake, but no univariate racial/ethnic or overweight/obese data is presented (Dennison *et al.* 1997). Similarly, in a study of $n = 49$ 3-year-olds followed for 3 years, beverage intake was not associated with BMI changes. However, this (all White) sample was stratified by maternal pre-pregnancy BMI status at baseline, rather than child BMI, did not consume excess milk (mean = 9.2 oz day^{–1}), and consumed just slightly excess amounts of juice (6.8 oz day^{–1}) (Kral *et al.* 2008).

In summary, these studies suggest that in young children who consume excess caloric beverages are heavier at the outset, and followed over time, there may be an association between beverage intake and weight. In contrast to the growing literature on SSBs and schoolchildren, there are few studies of low-income multi-ethnic pre-schoolers. Given young children’s high beverage intake, and evidence for obesity tracking to later ages, further research on how beverage intake – in the context of total diet intake – relates to weight gain is warranted.

What data exist on bottle use, weight and milk intake in young children?

A study of 1026 18-month-olds’ diets, from a large UK longitudinal cohort study (Roger *et al.* 2002), found that low maternal education was associated with prolonged bottle use (Northstone *et al.* 2002), but did not analyse weight status. Of the four papers on *bottle use and overweight*, three found that bottle use was linked to overweight. In a US national survey of 1976 low-income, primarily (79%) Black or Hispanic 3-year-olds, 35% of whom were ≥ 85 th% BMI, ‘taking a bottle to bed’ doubled the odds of overweight or

obesity (OR = 2.10, $P < 0.001$) (Kimbrow *et al.* 2007). Analyses of other US national survey data for 3027 children aged 3–5 years found that weaning age was positively related to BMI ($P < 0.01$). Each additional month of bottle use predicted a 3% increase in the odds of being in a higher BMI category as measured by <85th%, 85th–95th% or >95th% (OR = 1.03, 95% CI = 1.01–1.05) (Bonuck *et al.* 2004). In our prior study of 95 WIC toddlers aged 18–56 months, bottle users were significantly more likely to be >90% BMI compared with those weaned (46% vs. 35%, $P < 0.05$) (Bonuck & Kahn 2002). The one study not finding an association between bottle use and overweight was based upon only 14 bottle users (8%) out of 165 primarily White, high socio-economic status 3½-year-olds (Safer *et al.* 2001). Thus, generalizability to low-income, multi-ethnic 12–24-month-olds with higher rates of bottle use is limited.

In all four studies on *bottle use and milk consumption*, bottle users consumed significantly greater volumes of milk compared with non-users. These include the UK cohort study of 1026 18-month-olds in which bottle users' 24-h milk consumption was 488.3 mL (SD = 294), compared with just 381.5 mL (SD = 252) for cup-users and 454.8 mL (SD = 231) for combined bottle/cup users (Northstone *et al.* 2002). In a study of 34 18-month-olds, bottle users consumed a mean of 26.3 oz day⁻¹, vs. 16.1 oz for cup users (Lampe & Velez 1997). In report of daytime bottle use among 150 12–38-month-olds, 67% of bottle-fed children compared with 32% of weaned children consumed ≥16 oz of milk/day (Sutcliffe *et al.* 2006). The latter report did not find that bottle users ate or drank less than non-bottle users, but it was based upon just eight brief diet items. In the fourth study, the sample of 165 3½-year-olds, cited in the above paragraph, bottle users' 24-h intake of milk was 575.1 mL (SD = 336.0) compared with just 324.0 (SD = 228.1) for those who had weaned (Safer *et al.* 2001).

In summary, the above seven total studies of bottle use, weight and beverage intake in young children suggest that bottle use was linked to both overweight and excess milk consumption. However, none collected prospective, detailed data on the effect of excess beverage intake via bottles upon weight and dietary intake/nutrient density.

Part II. Pilot data on milk bottle use and weight in pre-school children

Introduction

The literature review in part I supports the rationale for an RCT of a bottle-weaning intervention and related observational study of dietary changes and weight status. In part II, we describe a pilot study of bottle use and weight from one of the two FYCS sites, conducted to derive recruitment rate and sample size estimates for FYCS. To reduce the burden upon the busy WIC site nutritionists collecting these data, and because 85% of bottles in a similar population contained milk (Kahn *et al.* 2007), we only collected data on milk (vs. juice or other beverages) bottles. To reduce respondent and participant burden, we did not assess milk type. As 90% of New York State WIC pre-schoolers drink whole milk (O'Connor *et al.* 2006), it is assumed that most milk was whole milk.

Methods

Setting

The study site is in a lower income neighbourhood of New York City, with many persons of Dominican, Puerto Rican and Caribbean descent. Agency data reflect the site's clientele as: Hispanic = 50%; Black (non-Hispanic) = 31%; Asian/Pacific islander = 6%; White (non-Hispanic) = 6%; and other = 7%. Among the site's $n = 4367$ children aged 2–5 years receiving benefits, 33% were >85% BMI, while 18% were >95% BMI.

Study design

Site nutritionists collected data from a convenience sample of all parents/caregivers ('parents') of children aged 12–60 months presenting for certification or recertification during a 3-week period in March 2006. Four nutritionists administered a brief survey [previously pilot tested by the investigators (Kahn *et al.* 2007)] asking whether the child currently drinks milk from a bottle. Parents answering 'yes' were asked the usual daily number of milk bottles (or fraction thereof) consumed: upon waking, in the morning, with

lunch, in the afternoon, with dinner, at bedtime and/or during the night. If the child was ≥ 13 months old at interview, parents were asked to recall the child's milk bottle use on their first birthday.

Height and weight data for children is routinely collected at WIC certification/recertification. Recumbent length is assessed for children < 2 years, either recumbent length or standing height for 2–3-year-olds, and standing height for children > 3 years. Current US growth charts correct for the disjunction between weight-for-length and weight-for-height percentiles in older growth charts (Ogden *et al.* 2002). In our pilot data, percentiles for children < 2 years of age are based upon weight-for-length; for children ≥ 2 years, percentiles are based upon weight-for-height. For simplicity, we refer to both as weight-for-height.

Our analyses employ weight-for-height rather than BMI, consistent with the World Health Organization's preferred approach for identifying paediatric obesity. In addition, there is high sensitivity, specificity and agreement between weight-for-length and BMI among children aged 2–6 years (Abrantes *et al.* 2003). Finally, there are weight-for-length/height reference curves covering our sample age range of 12–60 months, but no corresponding BMI reference curves for children under 2 years of age.

Bottle use tends to decrease, rather than increase, over time. This is particularly true for milk bottles, compared with other beverages such as juice or SSBs. Thus, while these data are cross-sectional rather than longitudinal, data are presented with the assumption that a child's prior milk bottle use was equal to or greater than their current use.

Statistics

We calculated age-specific and sex-specific weight for length percentiles based upon the US government growth charts (Centers for Disease Control and Prevention 2008) for children. Anthropometric data and milk bottle utilization patterns were analysed in STATA (StataCorp. 2007, *Stata Statistical Software: Release 10*. College Station, TX: StataCorp. LP), with the latter presented as interquartile ranges (IQR). Box plots were generated to display a five-number summary of bottle utilization patterns. Any observa-

tion lying more than 1.5 IQR lower than the first quartile or 1.5 IQR higher than the third quartile is considered an outlier, and represented as a dot.

Fisher's exact test was used to test for significant associations between current bottle use and weight-for-height. In these analyses, we dichotomized the sample at 12–36 months vs. 37–60 months, in part because this permits stratification of the sample by more vs. less stable periods of growth. That is, shifting two or more weight-for-height percentiles is more common in 12–36-month-olds compared with 37–60-month-olds [17.8% vs. 7.8% (Mei *et al.* 2004)].

Data were collected for 159 children. Upon review of the data, nine records were excluded from analysis (five because of missing sex data, three were duplicate records and one had an outlying weight-for-height value), yielding an analytic sample of 150 children.

Results

Sample description

Among this sample whose age ranged from 12–60 months, 60% (90/150) currently drank ≥ 1 milk bottle/day (see Table 1). This was true, despite a mean age of 29.2 months (SD = 13.7), which is nearly 17 months beyond the advised weaning age. The sample's weight-for-height percentiles are greater than expected, with 26% and 17% of the sample above the 85th and 95th percentiles, respectively.

Table 1. Descriptive statistics, total sample

	%	<i>n</i>
Age		
mean (SD) months	29.2 [mean]	(13.7) [SD]
Sex		
Female	55	83/150
Male	45	67/150
Current bottle use, total		
Yes	60	90/150
No	40	60/150
Weight-for-height, total		
$\geq 85\%$ weight-for-length	26	39/150
$\geq 95\%$ weight-for-length	17	25/150

SD, standard deviation.

Milk bottle consumption: entire sample ($n = 150$)

The *number* of current daily milk bottle consumers, by age, is shown in Fig. 1. All ($n = 11$) of the 12-month-olds used a bottle, as did 80% of 13–24-month-olds, 54% of 25–36-month-olds and 39% of 37–48-month-olds. Parents of the $n = 127$ children >13 months were asked to recall their child's milk bottle use on their first birthday. As this proportion (54%, 68/127, not shown) is much lower than the 100% reported for current 12-month-olds, these data were deemed to be subject to recall bias, and thus not used in analyses.

The *amount* of daily milk bottles currently consumed, by age, is shown in Fig. 2. Twelve-month-olds consumed a median of five bottles/day (IQR = 3–6). Milk bottle use remains high throughout the second year of life, with 13–18-month-olds consuming a median of four bottles/day (IQR = 3–5) and 19–24-month-olds consuming a median of 2.5 bottles/day (IQR = 0–3). Use reaches a nadir at 25–30 months, and then rises slightly before decreasing at 37 months.

Milk bottle consumption: current milk bottle users only ($n = 90$)

Fig. 3 (in contrast to Fig. 2) presents milk bottle use by age, for current users only. Median use parallels that of the entire sample, at five, four and three milk bottles/day among 12, 13–18 and 19–24-month-olds, respectively. Use remains high from 25 through 42 month, with IQRs of two to three bottles/day. After 3½ years of age, children not yet weaned actually increased their milk bottle consumption, though these data are based on only six children.

Milk bottle consumption by overweight status

Table 2 shows that among 12–36-month-olds, current milk bottle users were significantly more likely to be ≥ 95 th% weight-for-height compared with children who had weaned (19% vs. 0%, $P = 0.02$). While more 12–36-month-old milk bottle users were ≥ 85 th% weight-for-height (27% vs. 11%, $P = 0.11$), this association was not statistically significant. In contrast,

Fig. 1. Number of milk bottle users by age, entire sample ($n = 150$).

Fig. 2. Amount of current daily milk bottles* by age, all observations ($n=150$). *Box plots present interquartile ranges; medians contained within the interquartile range.

Fig. 3. Amount of current daily milk bottles* by age: current users only ($n=90$). *Box plots present interquartile ranges; medians contained within the interquartile range.

current bottle use was not associated with either overweight or obesity in the 37–60-months-olds.

Discussion

While professional guidelines recommend that children wean from a bottle at about 12 months of age, the children in our sample consumed a median of 5.0 milk bottles/day at this age. This represents, at minimum, 80% of 12-month-olds' recommended

daily caloric intake, assuming whole milk. Just 20% had weaned by their second birthday, and still less than half (46%) had weaned by their third birthday. Intake from milk bottles among 2 and 3-year-olds represents, at minimum, 40% of their recommended daily caloric intake (American Heart Association 2007). Thus, these data support prior work finding that bottles are associated with excess milk intake.

Bottle use was significantly associated with ≥ 95 th% weight-for-height, but not ≥ 85 th% weight-

Table 2. Overweight status by age and current bottle use

	Current bottle users	Non-current bottle users	Fisher's exact test
	% (n)		P
≥85th% weight-for-height			
12–36 months (n = 102)	27 (20/75)	11 (3/27)	0.11
37–60 months (n = 48)	27 (4/15)	36 (12/33)	0.74
≥95th% weight-for-height			
12–36 months (n = 102)	19 (14/75)	0 (0/27)	0.02
37–60 months (n = 48)	20 (3/15)	24 (8/33)	1.00

for-height in younger (i.e. 12–36-months-old) children. This significant association between beverage intake's effect upon weight in the heaviest children parallels previous work. In these younger children who experience dynamic growth shifts, excess energy intake at this age renders them vulnerable to shifting into an overweight or obesity status, which may track with age. Reducing early weight gain may delay the age of adiposity rebound (a rise in BMI $\approx$ 8 years of age, after a nadir at 4–5 years of age) and thus reduce the risk of overweight in later life, given an association between earlier adiposity rebound and adult obesity (Reilly *et al.* 2005; Taylor *et al.* 2005).

Possible reasons for the lack of association between bottle use and weight in children ≥ 37 months include: (1) no association, in fact, exists; (2) decreased (though still excess) milk intake compared with the younger group; and/or (3) less stable estimates, given the smaller sample.

As a pilot, this study had several limitations. First, the small sample of heterogeneously aged children limits drawing conclusions from it. Second, cross-sectional analyses cannot capture individual-level changes in bottle use and anthropometrics, over time. Third, we did not collect data on potential confounders (e.g. dietary intake), milk type or other beverages from bottles.

Nonetheless, these data suggest a synergistic relationship between prolonged bottle use and milk consumption associated with an increased risk of overweight. Higher levels of overweight among bottle users are consistent with our prior work and expand upon it by providing estimates of the number of milk bottles.

Part III. Description of FYCS

This section describes the FYCS project, begun in October 2008, and expected to conclude in 2010 (US Department of Agriculture 2008a). An overview of the project and its specific aims is first presented, followed by a description of the study's design and intervention strategy.

Project overview and aims

FYCS collects prospective data on bottle use, anthropometrics and diet. The focus of FYCS is upon the synergistic effect of bottles and their contents. In young children, these bottles and cups are primarily filled with whole milk (O'Connor *et al.* 2006). FYCS is an RCT of a bottle-weaning intervention aimed at reducing the risk of overweight in low-income multi-ethnic toddlers in WIC. An observational study, nested within the RCT, will provide dietary intake and nutrient density data for this age of feeding transitions.

FYCS enrolls 12-month-olds who, according to our pilot work presented in *part II*, consume a median of five milk bottles/day. FYCS contemporaneously assesses their beverage intake, bottle use and weight at 12, 15, 18, 21 and 24 months of age.

WIC, a programme for low-income families, serves approximately 25% of pre-school children in the United States (US Department of Agriculture 2008b). Low-income pre-schoolers are at particularly high risk of overweight (Nelson *et al.* 2006; Centers for Disease Control and Prevention 2008). Given that overweight tracks from an early age, WIC is an ideal

setting to test interventions aimed at preventing paediatric overweight.

The study's specific aims and related hypotheses are:

Aim #1: To reduce inappropriate bottle-feeding practices (RCT)

Hypothesis:

1. The intervention group will reduce inappropriate feeding practices more than controls, as measured by: absolute weaning; number of bottles; ounces consumed from bottles; and content, pattern and timing of bottles.

Aim #2: To decrease the risk of overweight in children (RCT)

Hypotheses:

1. The intervention group will see a decrease in the percentage of children >85th percentile weight-for-length and >95th percentile weight-for-length over the 12-month follow-up compared with controls.

2. The intervention group will have lower age-adjusted and sex-adjusted weight-for-length *Z* scores, and a decreased weight gain velocity over the 12-month follow-up compared with controls.

Aim #3: To describe dietary intake and nutrient density (observational study)

1. We will describe beverage and food intakes and nutrient density at baseline and over time in relation to bottle use patterns and anthropometrics for the sample and by treatment group.

Recruitment

Project staff will enroll a total of 464 parent-child dyads from two WIC study sites. One was the site of our pilot study, while the second has a similar clientele and is programmatically linked with it. WIC participants presenting for their child's 12-month-old certification or recertification are recruited from the waiting areas. The primary eligibility criterion is that the child be drinking ≥ 2 (non-water) bottles or sippy cups/day. Eligible participants who signed informed consent are enrolled into FYCS and completed the

baseline interview. The study has been approved by the institution's human subjects committee. Participants received gift check incentives for all completed interviews.

Baseline assessments

Demographics and eating behaviours

The baseline interview collects data on family demographics, the child's anthropometrics and his/her eating behaviours and preferences. These latter items, many adapted from other work (Wright *et al.* 2007), include: whether the child self-feeds, perception of meal times as 'relaxed' or 'stressful', the child's behaviour at meals (e.g. 'cries/screams during meals') and the child's preferences/ease of feeding (e.g. '... prefers drinks to food', '... is easy to feed').

Dietary intake and nutrient density

Next, a 24-h recall of the child's solid and beverage intake is collected chronologically through a 'multiple-pass method'. FYCS uses Nutrition Data Systems for Research (NDSR; Nutrition Coordinating Center, University of Minnesota, MN), a Windows-based software, linked to a nutrient density calculation tool for analysis at the ingredient, food, meal or total daily intake level. Participants are telephoned 2–10 days after baseline for a second 24-h recall of intake on a week-end day.

Drinking container

We annotated NDSR's standard script to assess the type of container from which the beverage was consumed. Note, neither NDSR nor any other software assess drinking container type. Using a visual display of various types of beverage containers (e.g. bottles, sippy cups with and without valves, open-lid cups) in a range of sizes, participants indicate how far each was filled. Participants are sent home with a picture of this display to refer to at the second 24-h recall.

Randomization

Project staff randomize participants to the intervention or control group *after* conducting the above

assessments, to minimize bias. A green-coloured randomization sheet is then affixed to the outside of the chart, clearly indicating that this client is in the intervention group. Participants then see the WIC nutritionist, who assesses financial and nutritional eligibility and reviews the child's diet and activity patterns. Thus, our intervention fits within the scope of routine WIC visits.

Originally, WIC nutritionists were to randomize the participants so as to mask treatment group from the FYCS staff. In actual practice, this research task became too burdensome for busy clinical nutritionists. To minimize potential bias: (1) FYCS staff randomize participants *after* all baseline assessments; and (2) study IDs and the study database omit treatment group status, so when FYCS staff attempt the second 24-h recall (within 2–10 days of the baseline, see below), their records do not indicate treatment group.

The potential for WIC nutritionists to inadvertently deliver the intervention to controls is minimized by: (1) *Visual Cue* – FYCS staff bring the flip chart to WIC nutritionists before they see intervention participants (after they themselves have conducted baseline assessments) and collected it from them afterwards; (2) *Infrequency* – less than 4% (per agency data) of all children seen at the two sites will be flagged to receive the intervention, reducing the likelihood of it becoming habitual; and (3) *Reinforcement* – our near daily presence at the sites, a monthly newsletter and biweekly visits by our WIC nutritionist consultant reinforce the importance of care as usual for controls. Contamination from parents in the intervention group is highly unlikely because clients receive their checks from the WIC nutritionist and leave the site immediately following the WIC nutritionist counselling.

Intervention

WIC nutritionists engage intervention group parents in individual, brief (15–20 min) interviews using a project-developed flip chart. The flip chart's nutritionist view has discussion-guiding questions, while the client view has a related visual. Information points and other helpful conversational items are provided in *italics*. The flip chart was developed in collaboration

with the site nutritionists over several months. WIC parents in the target age group were then asked for their comments on this revised version in a series of focus groups. Next, the flip charts were pilot tested with individual clients similar to the FYCS target population at the site. Our WIC nutritionist consultant observed these interactions, which were used as the basis for further revisions into a final version that WIC nutritionists find useful and that clients find informative.

Controls

After the baseline, controls return to the waiting area to see the next available nutritionist, as the intervention group does. Unlike the intervention group, their charts are not flagged for the WIC nutritionists. Apart from the intervention itself, the controls follow the same interview schedule and receive the same study incentives as the intervention group.

Follow-ups and time line

Between 12 and 24 months of age, parent–child dyads make quarterly visits (i.e. at 15, 18, 21 and 24 months) to WIC to pick up benefit checks and receive nutritional counselling. Our follow-up interviews, which coincide with this schedule, repeat the baseline assessments cited above (except for birth data and background demographics).

We assume that 90% of 12-month-olds at the study sites consume ≥ 2 bottles/day. This estimate is based upon the sites' enrolment and retention data. Thus, we aim to enrol 464 parent–child dyads in order to retain 320 (160/group) at 24 months of age. As of spring 2009, we are meeting our recruitment goals.

Our primary outcome is bottle use. To estimate sample size and power for this outcome, we conducted a pilot intervention study (Kahn *et al.* 2007). Compared with baseline, average daily bottle use declined more in the intervention group (4.5–0.9) compared with controls (4.8–2.2) after 8 weeks. We assume that the number of bottles follows a Poisson distribution. Based on these data and controlling for the baseline rate, we will have 95% power to detect a

significant difference in the rate of bottle use between groups at $\alpha = 0.05$ after 12 months with 160 participants in each group.

Our secondary outcome is weight-for-length. Our part II pilot data found that more 12–36-month-old current bottle users were $\geq 85\text{th}\%$ weight-for-length vs. non-bottle users (27% vs. 11%). At 12-month follow-up, we estimate $\approx 50\%$ decrease in $\geq 85\text{th}\%$ weight-for-length in the intervention group. We assumed that at 12-month follow-up: (1) 29% of controls will have weight-for-length $\geq 85\text{th}\%$ compared with 15% of intervention group; and (2) each child will have at least two repeated measurements with exchangeable within-subject correlation. We will have 98, 94 or 89% power, for a correlation of 0.2, 0.5 or 0.8, respectively, to detect such a difference in frequencies, at $\alpha = 0.05$ after 12 months with 160 participants in each group.

Analyses are expected to be completed in 2011.

Discussion

Obesity tracks with age, beginning from infancy and early childhood. This paper reports on prolonged and excessive bottle use as a potential risk factor for overweight in infants and young children. The literature review in *part I* found, in general, conflicting data on beverage intake and overweight in young children. However, among those who were consuming excess caloric beverages, were heavier at the outset and were followed over time, there is some evidence for an association between beverage intake and overweight. When use of a bottle for drinks is considered, the literature finds that bottle use is linked to both overweight and excess milk consumption.

Part II presented pilot data on bottle use and weight. Twelve-month-olds in this low-income multi-ethnic sample consumed a median of five milk bottles/day, representing, at minimum, 80% of their daily caloric intake. At 2 and 3 years of age, current milk bottle users consumed, at minimum, 40% of their daily recommended caloric intake via bottles. Among the sample's 12–36-month-olds, current bottle users were significantly more likely to be $>95\text{th}\%$ weight-for-height. Limitations of these pilot data include: cross-sectional rather than longitudinal, heteroge-

neous age range and absence of data on diet or other confounders. Nonetheless, these data suggest that bottle use may be linked to overweight and excess milk consumption, and this is consistent with the literature.

Part III describes the design and initiation of the FYCS, for which the pilot data were collected. Begun in October 2008, FYCS is testing the effect of an intervention upon risk of overweight in low-income multi-ethnic toddlers. In addition, 24-h dietary recalls of the toddlers will describe dietary pattern changes during the weaning process and the transition to a primarily solid diet.

Timely weaning is critical to the acquisition of developmentally appropriate feeding skills, by exposing children to a wide range of tastes and textures. In addition, early exposure to healthy foods, ideally during the weaning period, increases children's later acceptance of such foods (Harris 2008). FYCS is the first study to collect detailed longitudinal data, including changes in anthropometrics and child feeding behaviours, during this critical period of development.

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Conflicts of Interest

None of the authors have any conflicts of interest.

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