Title

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Journal

Current Developments in Nutrition, 8(11)

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Publication Date

2024-11-01

DOI

10.1016/j.cdnut.2024.104472

Peer reviewed

Current Developments in Nutrition 8 (2024) 104472

Current Developments in Nutrition

journal homepage: https://cdn.nutrition.org/

Brief Communication: Research Report

Early Formula Supplementation Differs by Maternal Body Mass Index but Does Not Explain Breastfeeding Outcomes in Mothers Who Intend to Exclusively Breastfeed

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A B S T R A C T

Background: Early formula supplementation (EFS, formula on birthdate or day after) is associated with maternal obesity and reduced breastfeeding, but the effect of prenatal breastfeeding intention on these relationships is understudied.
Objectives: We evaluated how EFS affected breastfeeding outcomes after controlling for obesity, sociodemographic and health factors.
Methods: Multivariable regression modeling, stratified by prenatal breastfeeding intention.
Conclusions: Our findings suggest that EFS may be less disruptive to breastfeeding in mothers with strong intention to meet breastfeeding recommendations, regardless of maternal BMI.

Keywords: breastfeeding, breastfeeding intention, exclusive breastfeeding, Baby Friendly Hospital, obesity, infant formula, PREVAIL cohort

Introduction

The Baby Friendly Hospital Initiative outlines 10 steps for hospitals to support, promote, and protect breastfeeding, including requirements for staff training and clinical best practices [1,2]. One of the key clinical steps is that no food or drink other than human milk be given to exclusively breastfed (EBF) newborns unless medically indicated, as in the case of jaundice, dehydration, or excessive weight loss [1,2]. Rationale for this measure is based on evidence that early formula supplementation (EFS) decreases the frequency of breast emptying, reduces milk supply, and exacerbates breastfeeding difficulties [2–6]. EFS has been linked to early breastfeeding cessation and lack of return to full breastfeeding [2,4].

Obesity is associated with a range of health conditions that may delay lactogenesis and impede lactation, such as hypertension, type II and gestational diabetes, and greater incidence of medicalized birth [7–10]. In addition, mothers with obesity are more likely to experience physical barriers to establishing breastfeeding, for example, difficulty with latching and positioning [7,9,11], yet are less likely to receive supportive lactation care [12,13]. Maternal obesity is an established risk factor for higher rates of elective and medically indicated EFS [4,14], as well as reduced duration of breastfeeding [7,10,11,15] and reduced likelihood of meeting maternal prenatal breastfeeding goals [16,17].

Strong prenatal breastfeeding intention has been shown to be a powerful predictor of breastfeeding duration and exclusivity [16,18–20]. We previously demonstrated a complex relationship

Abbreviations: ACME, average causal mediation effect; EBF, exclusive breastfeeding; EFS, early formula supplementation; PREVAIL, The Pediatric Respiratory and Enteric Viral Acquisition and Immunogenesis Longitudinal cohort; SDPS, sociodemographic propensity score.

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https://doi.org/10.1016/j.cdnut.2024.104472
Received 3 July 2024; Received in revised form 25 September 2024; Accepted 29 September 2024; Available online 9 October 2024

among strength of prenatal intention, obesity, and breastfeeding outcomes, with mothers with obesity achieving breastfeeding exclusivity and duration recommendations at very low rates despite strong prenatal intentions [16]. Despite the overlapping effects of EFS, obesity, and intention strength on breastfeeding outcomes, the combined effects of these factors are understudied. Few studies of the effects of EFS on breastfeeding outcomes have included maternal obesity, and none that we identified included both obesity and intention in the analysis. Using data from a longitudinal birth cohort, we compared breastfeeding duration and exclusivity by EFS accounting for maternal BMI, with and without stratification by prenatal breastfeeding intention.

Methods

The Pediatric Respiratory and Viral Immunogenesis Longitudinal Cohort (PREVAIL) is a 2-y birth cohort in Cincinnati, OH, conducted from 2017 to 2020. A full description of study methods has been previously published [21]. PREVAIL was approved by the institutional review boards at the CDC, Cincinnati Children's Hospital Medical Center and the birth hospitals where enrollment occurred. Briefly, expectant mothers were provisionally enrolled in the third trimester of pregnancy from 2 urban hospitals with written policies requiring that formula be given to EBF infants only when medically indicated. Final inclusion criteria were delivery of a healthy, singleton infant, residence within 20 miles of the hospitals, ownership of a cell phone capable of receiving text-administered surveys, and completion of a 2-wk postnatal home visit. Participants with a history of illicit drug use during pregnancy, maternal HIV infection, gestational age <35 wk, major congenital anomalies, or an infant birth weight of <2500 g were excluded. This analysis further excluded participants who reported that they did not initiate breastfeeding at the 2-wk study visit.

Participants completed a prenatal questionnaire that included family sociodemographics, breastfeeding intentions, maternal height, and prepregnancy weight. Race was defined as Black or White/other owing to the small numbers of participants (<5%) who described themselves as other than Black or White. Family income was categorized as <\$50,000/y or ≥\$50,000/y, aligned with the area median income [22]. Maternal education was defined as the completion of ≥2 y of postsecondary education or training or not. A mother was considered living with a partner if she reported cohabitation, independent of marital status. Prepregnancy BMI (in kg/m^2) was calculated and categorized as healthy (18.5 to <25), overweight (25 to <30), or obesity (≥30). Mothers with a BMI of <18.5 were excluded from analysis. Postdelivery obstetrics chart reviews identified delivery mode (cesarean section or vaginal delivery), gestational age, diabetes (any) during pregnancy, and hypertension during pregnancy.

Intention strength was categorized using the responses to the validated Infant Feeding Intentions Scale [20], administered in the third trimester of pregnancy. Mothers were classified as having a strong prenatal intention to meet breastfeeding recommendations if they indicated agreement to the question, "When my baby is six months old, I will be breastfeeding my baby without using any formula or other milk." All other participants were categorized as having a weak intention [20].

Date of first formula use and date of breastfeeding cessation were maternally reported on study questionnaires administered at weeks 2 and 6, months 4 and 6, and quarterly thereafter until breastfeeding cessation was reported [21]. EFS was defined as first formula use on the child's birthdate or the day after. Breastfeeding duration was calculated in days, censored at age 2 or the date of last known breastfeeding for those lost to follow-up. EBF at 6 mo was defined as maternal response of "all breast milk" to the question "Since your baby was 4 months old, which of the following best describes the type of milk your baby was fed?" at the 6-mo study visit, regardless of earlier formula use.

Statistical analysis

Spearman correlations were used to examine associations between EFS and sociodemographic categories, perinatal health factors, intention strength, and breastfeeding outcomes. To control for confounding with limited sample size, a sociodemographic propensity score (SDPS) was calculated by combining all sociodemographic variables significantly correlated with EFS into a logistic regression model predicting EFS [23]. The probability for each participant was standardized and the resulting score used to adjust all regression models.

Proportional comparisons were made using Fisher exact test, with pairwise comparisons adjusted using Holms corrections. Duration of breastfeeding and risk ratio of EBF at 6 months by BMI category were compared using linear regression and a logistic (probit) model, respectively. Regression models were first fit using the entire study population, then stratified by intention strength. All models were adjusted by the SDPS and perinatal health covariates significantly correlated with EFS but correlated with obesity at $r < 0.70$ to meet nonmulticollinearity assumptions [24].

Causal mediation analysis was performed to estimate the extent that EFS explained differences in breastfeeding duration or EBF at 6 mo by BMI category. Criteria for mediation included a significant relationship between BMI category and EFS and between BMI category and the breastfeeding outcome prior to adding EFS to the model [25]. Using a nonparametric bootstrap approach with 1000 simulations [26], full mediation was defined as a significant average causal mediation effect (ACME) of EFS and a nonsignificant direct effect of BMI category in the fully adjusted model, whereas partial mediation was defined as a significant ACME and a significant direct effect of BMI category.

Healthy BMI and no EFS were the reference categories unless otherwise specified. Analyses were performed using the R Environment for Statistical Computing (version 4.2.3).

Results

PREVAIL enrolled 245 mother–infant pairs; 33 (14%) were excluded for not initiating breastfeeding, whereas 5 (2%) were excluded for BMI < 18.5, leaving 207 (84%) meeting criteria for this analysis. Table 1 summarizes the sociodemographic, intention, and perinatal health characteristics of the study population, the Spearman correlation coefficients between EFS and each category, and the resulting coefficients used to create the SDPS. The sample was sociodemographically diverse and representative of the Cincinnati metropolitan area [22]. Overall, 36% ($n = 75$) of participants had a BMI in the healthy range,

TABLE 1
Correlations between study characteristics and early formula supplementation in mothers with a prenatal intention to exclusively breastfeed to 6 mo of age.

Study characteristics[1]	Sample (N = 207)	No EFS[2] (n = 128; 62%)	EFS (n = 79; 38%)	r[3]	P[4]	SDPS coefficient[5]
Sociodemographic						
Maternal age	29.6 (25.9, 33.2)	30.5 (27.1, 33.8)	28.2 (24.3, 32.4)	−0.19	0.006	−0.02
Black race	84 (41)	38 (30)	46 (58)	0.28	<0.001	0.21
Lives with partner	145 (70)	104 (81)	41 (52)	−0.31	<0.001	−0.72
Income <$50,000/y	94 (45)	43 (34)	51 (65)	0.30	<0.001	0.63
Public insurance	105 (51)	50 (39)	55 (70)	0.30	<0.001	0.14
<2 Y postsecondary education	87 (42)	40 (31)	47 (59)	0.28	<0.001	0.09
Primiparous	96 (46)	57 (45)	39 (49)	0.05	0.50	—
Prenatal intention strength						
Strong	127 (61)	92 (72)	35 (44)	−0.28	<0.001	
Weak	80 (39)	36 (28)	44 (56)	0.28	<0.001	
Maternal health						
Cesarean delivery	82 (40)	47 (37)	35 (44)	0.08	0.28	
Hypertension in pregnancy	49 (24)	22 (17)	27 (34)	0.19	0.005	
Diabetes in pregnancy	37 (18)	17 (13)	20 (25)	0.15	0.03	
Gestational age (wk)	39 (38, 39)	39 (38, 39)	39 (38, 39)	0.06	0.39	
BMI category (kg/m^2)						
Healthy (18.5–24.9)	75 (36)	57 (45)	18 (23)	−0.22	0.001	
Overweight (25–29.9)	47 (23)	33 (26)	14 (18)	−0.09	0.18	
Obesity (≥30)	85 (41)	38 (30)	47 (59)	0.29	<0.001	
Outcomes						
Duration of breastfeeding (d)	135 (33, 368)	249 (74, 398)	42 (15, 146)	−0.42	<0.001	
EBF at 6 mo	53 (26)	47 (37)	6 (8)	−0.32	<0.001	

Values are median (IQR) or n (%).
Abbreviations: EBF, exclusive breastfeeding; EFS, early formula supplementation; PREVAIL, Pediatric Respiratory and Enteric Viral Acquisition and Immunogenesis Longitudinal Cohort; SDPS, sociodemographic propensity score.
[1] Categorical reference values: White/other race; does not live with partner; income ≥$50,000/y; privately insured; 2 or more years of post-secondary education or training; multiparous; vaginal delivery; no hypertension in pregnancy, and no diabetes in pregnancy.
[2] EFS was defined as maternal-reported use of infant formula on the child's date of birth or second day of life.
[3] r values represent the Spearman correlation between the variable and EFS.
[4] P values represent the significance of the Spearman correlation between the variable and EFS.
[5] Coefficients resulting from logistic model of EFS by all significantly correlated sociodemographic variables used to create an individual sociodemographic propensity score to control for residual confounding.

23% (n = 47) had overweight, and 41% (n = 85) had obesity. Over 60% of the mothers (n = 127, 62%) had a strong prenatal intention to EBF to 6 mo; prenatal intention did not differ by BMI category (P = 0.40). Black race, lower income, public insurance, lower education level, hypertension, diabetes, and obesity correlated positively with EFS, whereas maternal age, healthy BMI, and living with a partner correlated negatively with EFS. The perinatal health variables hypertension and diabetes in pregnancy correlated with obesity at a low level (r = 0.23 and 0.20, respectively), meeting criteria for inclusion in regression models.

Overall, 38% (n = 79) of infants received EFS. Infants of mothers with a healthy BMI (24.0%, n = 18) or a strong intention (28%, n = 35) received EFS at significantly lower proportions than those with obesity (55%, n = 47; P < 0.001) or a weak intention (55%, n = 44; P < 0.001), respectively. In multivariable probit models (Table 2), risk ratios of EFS were higher for mothers with obesity than those with a healthy BMI overall and in those with a strong prenatal intention. Risk of EFS did not differ by overweight in any group, and there was no relationship between EFS and any BMI category in the weakly intentioned group. BMI category was a significant predictor of breastfeeding duration overall and when stratified by intention. Likelihood of EBF at 6 mo differed by elevated BMI in the overall and the strongly intentioned, but not the weakly intentioned, group.

As risk of EFS did not significantly differ by BMI category in the weakly intentioned group or by overweight in any group, mediation analysis was used to test the extent that EFS explained differences in breastfeeding duration and EBF at 6 mo by obesity in the overall and the strongly intentioned groups. In the overall study population, EFS partially mediated the relationship between obesity and breastfeeding duration (ACME: −9.3; 95% CI: −29.0, −1.0) and showed borderline significance for EBF at 6 mo (ACME: −0.02; 95% CI: −0.05, 0.0). However, when comparing those with strong breastfeeding intention, the addition of EFS in the mediation model did little to change the effect of obesity on breastfeeding duration or likelihood of EBF at 6 mo (Table 2) and EFS did not significantly mediate the relationship in either model.

Discussion

In this analysis, all infants initiated breastfeeding and were born in hospitals with the policy to provide supplemental formula only if medically indicated. Yet, we found that 38% of infants in our study received EFS, with dramatically higher rates associated with maternal obesity. Consistent with previously

TABLE 2
Mediation of BMI category by early formula supplementation as a predictor of breastfeeding duration and exclusive breastfeeding at 6 mo, stratified by prenatal breastfeeding intention.

	All included (N = 207)		Weak intention (n = 80)		Strong intention (n = 127)	
Early formula supplementation as predicted by BMI category						
	RR	95% CI	RR	95% CI	RR	95% CI
Overweight	1.01	0.63, 1.79	0.92	0.49, 1.72	1.87	0.63, 6.08
Obesity	1.69	1.08, 2.64	1.17	0.68, 2.03	4.33	1.79, 12.03
SDPS	1.57	1.29, 1.90	1.59	1.26, 2.02	1.52	1.05, 2.23
Diabetes	1.56	0.96, 2.53	1.31	0.73, 2.38	2.09	0.85, 5.22
Hypertension	1.46	0.94, 2.26	1.28	0.74, 2.22	1.80	0.86, 3.81
Breastfeeding duration models						
Total effect of BMI	β_{days}	95% CI	β_{days}	95% CI	β_{days}	95% CI
Overweight	−120.83	−183.2, −58.46	−93.47	−154.1, −32.8	−164.31	−276.1, −52.5
Obesity	−123.91	−180.62, −67.19	−97.10	−151.8, −42.4	−184.20	−288.0, −80.4
SDPS	−74.66	−98.64, −50.67	−52.25	−75.3, −29.2	−80.90	−124.2, −34.6
Diabetes	−20.26	−82.31, 41.79	−14.45	−74.4, 45.4	−30.28	−145.5, 84.9
Hypertension	−41.73	−98.22, 14.76	−56.12	−110.9, −1.3	−16.18	−118.1, 85.7
Mediation model	β_{days}	95% CI	β_{days}	95% CI	β_{days}	95% CI
Overweight	−119.48	−181.01, −57.95	−94.88	−154.3, −35.5	−161.00	−273.6, −48.4
Obesity	−111.69	−168.42, −54.97	−93.58	−147.2, −39.9	−169.26	−281.8, −56.7
EFS	−68.50	−121.09, −15.9	−61.39	−110.2, −12.6	−38.5	−148.0, 71.0
SDPS	−64.23	−89.20, −39.25	−41.91	−66.0, −17.9	−76.75	−124.7, −28.8
Diabetes	−10.42	−72.09, 51.25	−8.90	−67.7, 49.9	−23.16	−140.5, 94.2
Hypertension	−33.15	−89.26, 22.96	−50.82	−104.7, 3.0	−10.17	−113.9, 93.5
	%Mediated	ACME (95% CI)	%Mediated	ACME (95% CI)	%Mediated	ACME (95% CI)
Overweight	Did not meet criteria for mediation		Did not meet criteria for mediation		Did not meet criteria for mediation	
Obesity	7.7%	−9.3 (−29.0, −1.0)	Did not meet criteria for mediation		4.9%	−4.80 (−21.6, 11.7)
Exclusive breastfeeding models						
Total effect of BMI	RR	95% CI	RR	95% CI	RR	95% CI
Overweight	0.42	0.24, 0.74	0.44	0.2, 1.1	0.28	0.1, 0.7
Obesity	0.52	0.31, 0.86	0.75	0.3, 1.6	0.26	0.1, 0.6
SDPS	0.51	0.39, 0.66	0.51	0.3, 0.8	0.52	0.3, 0.8
Diabetes	0.69	0.36, 1.27	0.01	NA	1.02	0.4, 2.7
Hypertension	0.60	0.32, 1.07	0.45	0.01, 1.2	0.58	0.2, 1.3
Mediation model	RR	95% CI	RR	95% CI	RR	95% CI
Overweight	0.40	0.22, 0.71	0.42	0.2, 1.0	0.28	0.1, 0.7
Obesity	0.58	0.34, 0.97	0.76	0.4, 1.6	0.35	0.1, 0.9
EFS	0.52	0.29, 0.88	0.72	0.3, 1.6	0.41	0.2, 1.1
SDPS	0.55	0.42, 0.71	0.53	0.3, 0.8	0.56	0.4, 0.8
Diabetes	0.79	0.41, 1.47	0.01	NA	1.33	0.5, 3.7
Hypertension	0.65	0.34, 1.17	0.46	0.1, 1.3	0.68	0.3, 1.6
	%Mediated	ACME (95% CI)	%Mediated	ACME (95% CI)	%Mediated	ACME (95% CI)
Overweight	Did not meet criteria for mediation		Did not meet criteria for mediation		Did not meet criteria for mediation	
Obesity	13.2%	−0.02 (−0.05, 0.00)	Did not meet criteria for mediation		19.0%	−0.07 (−0.28, 0.01)

Categorical reference values: healthy BMI; no diabetes, no hypertension, and no EFS. Causal mediation analysis was performed to test whether the effect of elevated BMI on breastfeeding duration and exclusive breastfeeding at 6 mo of age was explained by EFS (formula provided on day of birth or day after). All models were adjusted by SDPS, maternal diabetes (any) during pregnancy, and maternal hypertension. Mediation criteria required a significant association between EFS and BMI category and a significant effect of EFS in the fully adjusted model.
Abbreviations: ACME, average causal mediation effect (effect explained by EFS); BF, breastfeeding; EFS, early formula supplementation; SDPS, sociodemographic propensity score.

published work [2–6], when comparing all who initiated breastfeeding, we found that EFS correlated negatively with breastfeeding duration and that very few mothers recovered EBF after EFS. We also found that EFS explained a small, but significant, portion of the effects of obesity on breastfeeding duration. However, when comparing mothers who planned to EBF to 6 mo, these effects disappeared; the effects of overweight and obesity on breastfeeding duration and EBF at 6 months were little changed with the addition of EFS to the models and EFS was not significant in the models when controlling for BMI category.

The rate of EFS (38%) in our population was much higher than a similar study conducted by Colling et al. (22%) [14]. The reason for this difference may lie in the study populations. The sample in the study by Colling et al. [14] was overwhelmingly White (94%) and the hospital surveyed served a suburban population with a median income above $100,000/y [27]. In contrast, our sample was enrolled from hospitals within the city of Cincinnati. Many of our study mothers identified as Black (41%) or lower income (45%), factors that correlated significantly with EFS in our analysis and lower rates of EBF in the literature [3,17,28,29]. When we examined only the White, higher-income mothers in our study, the EFS rate was 20%, closely paralleling the proportion reported in the study by Colling et al. [14].

Given the substantial differences between our findings and those reported in the study by Colling et al. [14], we cannot discount that health care biases associated with race, income, and obesity [12,13,30,31] may have played a role in our outcomes. In our study, mothers with obesity disproportionately identified as Black (61%; $P < 0.001$), low income (59%; $P = 0.004$), or both (49%; $P < 0.001$). Health factors associated with lactation difficulties in the literature, such as gestational age or cesarean section [19,32], were not significantly correlated with EFS, and diabetes and hypertension were not significant predictors of EFS or our breastfeeding outcomes when controlling for BMI category and SDPS in multivariable models. In contrast, obesity and all sociodemographic variables correlated significantly with EFS, and obesity and SDPS remained significant predictors of our outcomes, including among those who planned to EBF to 6 mo. With our modest sample size, it was not possible to disentangle race, income, and obesity in analysis or to test for interaction among these factors. A larger study population, including qualitative work on the experience in-hospital and documented reasons for EFS, is needed to better understand how these factors intersect and to identify key points for health care personnel training.

Consistent with previous reports [2–4,14], we found that risk of EFS was higher in mothers with obesity. EFS correlated negatively with both breastfeeding outcomes and partially mediated the effect of obesity in our overall study population. However, these relationships were no longer significant when comparing only mothers who intended to EBF to 6 mo. Previous work in this cohort and others has shown that prenatal breastfeeding intention and a healthy BMI are strong predictors of longer breastfeeding duration and achievement of meeting public health breastfeeding recommendations [16,18,20,33]. The stratification of our regression models further demonstrates these findings. There were no relationships between EFS, obesity, and breastfeeding in the weakly intentioned group; over half of the infants received EFS with no differences by BMI category, and only 8% ($n = 6$) of mothers were EBF at 6 mo, independent of EFS status. However, overweight and obesity were both strongly associated with reduced breastfeeding duration and lower likelihood of EBF at 6 mo with or without EFS in the strongly intentioned group; EFS did not significantly change or explain these relationships. It should be noted that in the strongly intentioned group, the proportion EBF at 6 mo differed by EFS receipt (46% compared with 14%; $P < 0.001$). However, the 7-fold increase in recovery of EBF after EFS in this group compared with those with a weak intention (14% compared with 2%; $P = 0.08$) and lack of effect of EFS on breastfeeding duration when controlling for BMI category suggests that EFS may be less disruptive to breastfeeding outcomes in those who prenatally plan to exclusively breastfeed for the recommended duration.

This work has its limitations. Although we achieved >80% power to detect moderate effect sizes in our regression analyses, post hoc power analysis revealed that, when stratified by EFS receipt and intention, our power to detect proportional differences by group was limited to effect sizes ≥10-fold at a standard level of significance. Although the timing of formula introduction suggests that it occurred during the maternity stay, formula introduction date was provided by maternal recall and may not represent in-hospital provision. Finally, PREVAIL did not collect data on access to paid maternity leave or date of return to work, so we could not include these established predictors of breastfeeding duration and exclusivity [34] in our models.

This work benefits from its longitudinal design, sociodemographic diversity of the cohort, a sample representative of a mid-sized Midwestern city [22], and validated assessment of prenatal intention [20]. In mothers with strong breastfeeding intention, obesity was associated with decreased duration of breastfeeding and low rates of EBF at 6 mo with or without EFS, suggesting that barriers aside from intention and effort exist for these mothers to meet their breastfeeding goals.

Author contributions

The authors' responsibilities were as follows—SCC: conceived and designed the project, completed the data analysis, was the primary author of all drafts, and had primary responsibility for final content; LN-R, ALM: contributed to the design of the study, the acquisition of data, and interpretation of analysis; MAS, ARB: contributed to study design and acquisition of data; and all authors: participated in the revision of drafts and read and approved the final manuscript.

Conflict of interest

The authors report no potential conflicts of interest.

Funding

The PREVAIL Cohort was funded by a cooperative agreement from the US Centers for Disease Control and Prevention (CDC; IP16-004), with additional support provided by the Molecular Epidemiology in Children's Environmental Health Training program (5 T32 ES 10957-18) and the National Center for Advancing Translational Sciences of the NIH (UL1TR001425). Data analysis and manuscript preparation was funded by the MOM2CHild study (R01HD109915). The CDC and NIH had no role in the design, analysis, or writing of this article. The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the CDC or NIH.

Data availability

Data described in the manuscript, code book, and analytic code will be made available upon request pending approval by the primary investigators of PREVAIL.

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