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Update on the impact of voluntary folic acid fortification of corn masa flour on red blood cell folate concentrations—National Health and Nutrition Examination Survey, 2011–March 2020

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Abstract

Background: Folic acid is a micronutrient that is effective at preventing neural tube defects (NTDs). In 2016, the FDA authorized the voluntary fortification of corn masa flour (CMF) with folic acid to reduce disparities in NTDs among infants of women who do not regularly consume other fortified cereal grains, in particular Hispanic women of reproductive age (WRA).

Methods: We analyzed data from the National Health and Nutrition Examination Survey (NHANES) from 2011 to March 2020 assessing the impact of voluntary fortification of CMF on the folate status of Hispanic WRA. We analyzed folic acid usual intake and red blood cell (RBC) folate concentrations among non-pregnant, non-lactating Hispanic WRA, comparing pre-fortification (2011–2016) to post-fortification (2017–March 2020) data. RBC folate concentrations were used to create model-based estimation of NTD rates.

Results: The proportion of Hispanic WRA with folic acid usual intakes <400 μg/d did not change (2011–2016: 86.1% [95% Confidence Interval, CI: 83.7–88.5]; 2017–March 2020: 87.8% [95% CI: 84.8–90.7]; $p = .38$) nor did the proportion of Hispanic WRA with RBC folate below optimal concentrations (<748 nmol/L, 2011–2016: 16.0% [95% CI: 13.7–18.2]; 2017–March 2020: 18.1% [95% CI: 12.1–24.0]; $p = 0.49$). Model-based estimates of NTD rates suggest further improvements in the folate status of Hispanic WRA might prevent an additional 157 (95% Uncertainty Interval: 0, 288) NTDs/year.

Conclusions: Voluntary fortification of CMF with folic acid has yet to have a significant impact on the folate status of WRA. Continued monitoring and further research into factors such as

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Data and analyses were replicated by Amy Fothergill.

SUPPORTING INFORMATION
Additional supporting information can be found online in the Supporting Information section at the end of this article.

fortified product availability, community knowledge, and awareness of folic acid benefits would inform and improve future public health interventions.

Keywords

corn masa flour; folic acid; food fortification; neural tube defects

1 | INTRODUCTION

Folic acid consumption periconceptionally reduces the risk of neural tube defects (NTDs) (MRC Vitamin Study Research Group, 1991). In 1992, the U.S. Public Health Service recommended that all women capable of becoming pregnant consume at least 400 μg/days folic acid for the prevention of NTDs. In 1996, the Food and Drug Administration (FDA) authorized the mandatory fortification of enriched cereal grain products (ECGP) with 140 μg folic acid/100 g product (Department of Health and Human Services Food and Drug Administration, 1996). Despite the effectiveness of folic acid fortification in NTD prevention, not everybody consumes ECGPs as their primary staple foods. NTD prevalence remains high among women with lower folic acid intake, in particular Hispanic women of reproductive age (12–49 years, WRA) who might consume corn masa flour (CMF) products instead of ECGPs (Williams et al., 2015). In 2016, the FDA authorized the voluntary fortification of CMF products with up to 140 μg folic acid/100 g product to reduce the risk of an NTD-affected pregnancy among Hispanic WRA (Flores et al., 2018).

Red blood cell (RBC) folate concentrations serve as a biomarker for NTD risk. The World Health Organization established an optimal RBC folate concentration threshold for NTD prevention of 906 nmol/L (calculated with the Molloy method of microbiologic assay, equivalent to 748 nmol/L with the CDC assay method) (Cordero et al., 2015; Pfeiffer et al., 2016). Using data from the National Health and Nutrition Examination Survey (NHANES) 2011–March 2020 (data collection ended in March 2020 due to the COVID-19 pandemic), we analyzed the estimated usual intake of folic acid and RBC folate statuses of Hispanic WRA following the introduction of voluntary fortification of CMF products, providing an update to previously reported results with additional years of data (Wang et al., 2021).

2 | METHODS

NHANES is a cross-sectional survey monitoring the health and nutritional status of the U.S. civilian population consisting of in-home and phone interviews and physical examinations conducted in mobile examination centers. Interviews provide self-reported demographic information including age, sex, race/ethnicity, education, and poverty-income ratio (PIR). For analysis, we categorized education into three groups (MRC Vitamin Study Research Group, 1991): less than high school (Department of Health and Human Services Food and Drug Administration, 1996), high school graduate or obtained GED, and (Williams et al., 2015) at least some education beyond high school. We categorized PIR into 4 levels (MRC Vitamin Study Research Group, 1991): <1.0 (Department of Health and Human Services Food and Drug Administration, 1996), 1.0–1.9 (Williams et al., 2015), 2.0–3.9, and (Flores et al., 2018) ≥4.0. A questionnaire for language spoken at home and time residing in the United States (if not U.S.-born) was provided to participants who self-identified as Hispanic as proxies for acculturation, which has been shown to mediate NTD risk among Mexican-American women (Hamner et al., 2013). For analysis, we categorized language spoken at home into three groups (MRC Vitamin Study Research Group, 1991): predominantly English (Department of Health and Human Services Food and Drug Administration, 1996), equal English and Spanish, and (Williams et al., 2015) predominantly Spanish. We categorized time residing in the United States into three groups (MRC Vitamin Study Research Group, 1991): U.S.-born (Department of Health and Human Services Food and Drug Administration, 1996), born outside the United States and residing in the United States ≥15 years, and (Williams et al., 2015) born outside the United States and residing in the United States <15 years. A subset of participants provides two 24-hr dietary recalls using USDA's AMPM method (Steinfeldt et al., 2013). Dietary supplement use over the past 30-days is also collected at home. These data were used to categorize participants into folic acid consumption groups and to carry out nutrient intake analyses. Four mutually exclusive folic acid intake source groups were defined as (MRC Vitamin Study Research Group, 1991) ECGP/CMF only (Department of Health and Human Services Food and Drug Administration, 1996), ECGP/CMF + ready-to-eat cereals (RTE) (Williams et al., 2015), ECGP/CMF + folic acid supplementation (SUPP), and (Flores et al., 2018) ECGP/CMF + RTE + SUPP. United States Department of Agriculture (USDA) food codes were used to identify RTE from the 24-hr dietary recalls; any reported folic acid consumption that could not be identified as RTE or SUPP was assumed to be consumed from potentially fortified sources (ECGP/CMF), individuals with no identified RTE or SUPP consumers were categorized as ECGP/CMF only. Estimated folic acid usual intakes from dietary sources were modeled using the National Cancer Institute one-part amount model utilizing the two 24-hr recalls; folic acid from supplements were added onto the modeled dietary usual intake to provide a total modeled folic acid usual intake. We analyzed total modeled folic acid intake both continuously and dichotomized at 400 μg/days. The NHANES examination response rates for WRA ranged from 48.7% (2017–March 2020) to 72.2% (2013–2014).

Data from the physical examination component included body mass index and biospecimens collection for laboratory analysis. RBC folate concentrations were measured using a microbiologic assay and analyzed both continuously and dichotomized at 748 nmol/L, an established optimal blood folate (OBF) concentration. NTD rates were modeled using RBC folate concentrations and previously developed and validated Bayesian models (Crider et al., 2018). We estimated the number of preventable NTDs by calculating the difference in modeled NTD rates in the post-fortification time period (2017–March 2020) and 5 NTDs/10,000 live births, an achievable NTD prevalence through increased folic acid intake, taking into account current estimates of fertility rates among Hispanic women, the U.S. Census estimates of number of Hispanic women aged 15–45 (Osterman et al., 2023; United States Census Bureau, 2021).

Analyses were limited to nonpregnant, non-lactating Hispanic WRA with available dietary recall and RBC folate data. Additional analyses were conducted in Mexican Americans only (the largest identifiable subgroup among the Hispanic population) and stratified by folic acid intake source, language spoken at home, and time in the United States. Comparisons were made between NHANES 2011–2016 (pre-fortification) to NHANES 2017–March 2020 (post-fortification) using chi-squared tests and Wald-adjusted *t*-tests. Usual intakes were estimated using SAS (version 9.4; SAS Institute), and all other analyses were conducted in R (version 4.1.3; R Core Team) alongside the *survey* package using survey weights to account for probabilistic selection and nonparticipation (Lumley, 2004).

3 | RESULTS

Compared to 2011–2016, there was a smaller proportion of Hispanic WRA with less than a high school education and an increase in WRA with a high school degree or GED ($p < .001$) in 2017–March 2020. There were also fewer WRA with a lower PIR (<1.0, 1.0–1.9) and a higher proportion of WRA with a PIR ≥4.0 ($p = .02$). In the post-fortification time period, a larger proportion of WRA were in the ECGP/CMF only folic acid intake source group and less in ECGP/CMF + RTE and ECGP/CMF + RTE + SUPP folic acid intake source groups in 2017–March 2020 ($p = .03$; Supplemental Table 1).

There were no differences in the modeled usual intakes among Hispanic WRA between 2011 and 2016 (223 μg/days [Interquartile Range, IQR: 140–275]) and 2017–March 2020 (197 μg/days [IQR: 132–275]; $p = .84$). Likewise, there was no difference in the proportion of Hispanic WRA with modeled intakes below 400 μg/days between 2011 and 2016 (86.1% [95% Confidence Interval, CI: 83.7–88.5]) and 2017–March 2020 (87.8% [95% CI: 84.8–90.7]; $p = .38$; Supplemental Table 2). There were no differences in either modeled usual intakes or proportion with modeled intakes <400 μg/days when analysis was restricted to Mexican Americans (Modeled usual intake: $p = .35$; Usual intake <400 μg/days: $p = .28$). When restricting the analysis to Hispanic WRA who consumed only ECGP/CMF, all but one person had modeled usual intakes <400 μg/days.

RBC folate concentrations were similar between 2011–2016 (1004 nmol/L [95% CI: 984–1024 nmol/L]) and 2017–March 2020 (998 nmol/L [95% CI: 972–1025 nmol/L]; $p = .74$). There was no change in the proportion with RBC folate concentrations below OBF (2011–2016: 16.8% [95% CI: 15.0–18.5]; 2017–March 2020: 19.4% [15.6–23.1]; $p = .20$; Table 1). When analyzing only Mexican Americans, no changes were observed in RBC folate concentrations ($p = .31$) or proportion with RBC folate concentrations below OBF ($p = .49$). RBC folate concentrations and proportion with RBC folate concentrations below OBF were likewise similar among Hispanic WRA whose folic acid source was ECGP/CMF only (RBC folate concentrations: $p = .71$; RBC below OBF: $p = .53$). There were significant increases in RBC folate concentrations among Hispanic WRA whose folic acid source was ECGP/CMF only who primarily spoke Spanish at home ($p = .01$) and those born outside the United States and residing in the United States <15 years ($p = .01$). However, these improvements did not significantly shift the proportion of Hispanic WRA to OBF concentrations (Primarily Spanish: $p = .07$; Born outside United States <15 years: $p = .80$). Restricting the sample to only Mexican Americans whose folic acid source was ECGP/CMF only showed no statistically significant change in RBC folate concentrations ($p = .67$) and the proportion with RBC folate concentrations below OBF ($p = .67$).

Using modeled data, U.S. Census data, and information on fertility rates among Hispanic WRA, an additional 157 NTDs (95% Uncertainty Interval [UI]: 0–288) could be prevented per year by increasing the folate status among non-U.S.-born Hispanic WRA residing in the U.S. <15 years, could prevent an additional 38 NTDs/y (95% UI: 4–78). An estimated 127 NTDs/years (95% UI: 78–235) could be prevented by increasing folate status among Hispanic WRA who consume only ECGP/CMF (Figure 1).

4 | DISCUSSION

Folic acid is an important micronutrient and a primary intervention for NTD prevention (Crider et al., 2022). Voluntary fortification of CMF with folic acid was implemented as an effort to reduce NTD rates among women who might not be consuming folic acid through ECGPs, in particular Hispanic women, who remain more likely to have a baby born with an NTD (Flores et al., 2018). This report provides an update to the estimated folic acid intakes and folate status of Hispanic WRA in the United States following the implementation of voluntary fortification of CMF.

Folic acid usual intake among Hispanic WRA did not significantly change in the 3.2 years following the implementation of voluntary fortification of CMF with folic acid. Restricting the analysis to Mexican Americans did not impact these results. There were improvements in RBC folate concentrations among lesser acculturated Hispanic WRA whose folic acid source were ECGP/CMF only, suggesting that the most vulnerable subpopulations may be benefiting from the voluntary fortification of CMF. However, these improvements in RBC folate concentrations did not significantly shift the proportion of women into OBF concentrations, limiting the impact of voluntary fortification on NTD prevention. Overall, these updated results are consistent with the previous report on the lack of impact of voluntary corn masa fortification on folate status among Hispanic WRA (Wang et al., 2021). These results may support the conclusions of previous studies suggesting that very few manufacturers have introduced CMF product fortified with folic acid since the introduction of voluntary fortification (Kancherla et al., 2019; Redpath et al., 2018). Model-based estimates of NTD rates from RBC folate concentrations suggest that improving the folate status among all Hispanic WRA could prevent an additional 157 NTDs/years. Specifically raising the folate status Hispanic WRA most reliant on potentially fortified grains (ECGP/CMF) as their primary source of folic acid could prevent 127 NTDs/years.

The results of this study are subject to several limitations. First, NHANES is cross-sectional in design and therefore cannot directly infer causality between changes in biomarker status and the implementation of voluntary fortification. Second, the study was limited in sample size following voluntary fortification, utilizing only the 3.2 years (NHANES 2017–March 2020) pre-pandemic NHANES cycle, which suffered from lower response rates than previous cycles (48.7%). Third, the USDA codes used to categorize foods from the dietary recall portion of NHANES do not explicitly define foods that contain CMF; while previous analyses used a subset of USDA codes as a proxy for CMF consumption, they may not accurately reflect CMF consumption patterns (e.g., lack of distinction between flour and corn tortillas for foods labeled “tacos”). Fourth, estimated reductions in NTD rates were based upon fertility rates and census data of Hispanic women 15–45 years rather than the entire 12–49 years defining WRA due to sampling and reporting differences in the preexisting literature. Fifth, the persons who participated in NHANES are weighted to reflect the general U.S. population; however, the target population at most risk of low folate status may experience barriers to participate in research. Finally, this analysis cannot assess if manufacturers have implemented folic acid fortification of CMF and it has been previously reported that few manufacturers have begun fortifying CMF products with folic acid (Kancherla et al., 2019).

Hispanic WRA remain at a higher risk for NTDs compared to other racial and ethnic groups (Flores et al., 2018; Williams et al., 2015). Voluntary fortification of CMF with folic acid has yielded little change in the estimated usual intake of folic acid and has not significantly impacted the folate status of Hispanic WRA. Improving the folate status of Hispanic WRA could further prevent up to 157 NTDs per year. Additional research examining the direct effect of folic acid fortification on NTD rates through surveillance and surveying community knowledge of folic acid among Hispanic WRA could inform future public health interventions.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are openly available in NHANES at https://wwwn.cdc.gov/nchs/nhanes/Default.aspx.

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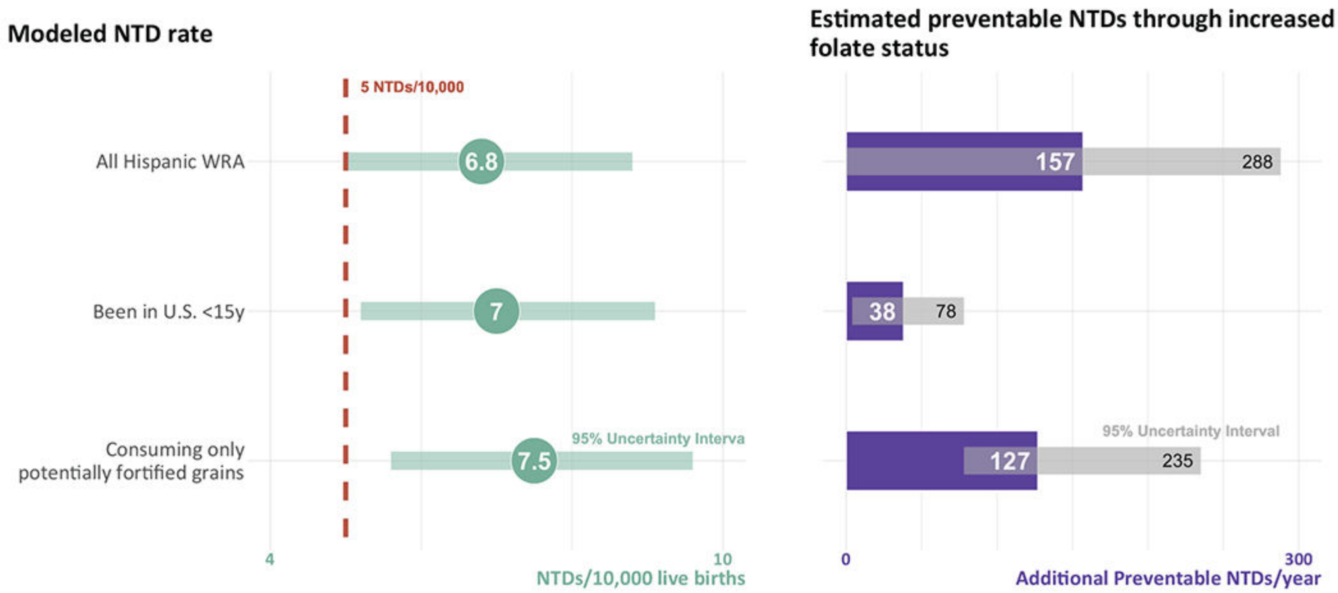

FIGURE 1.

Model-based estimation of neural tube defects (NTDs) among Hispanic women of reproductive age (12–49 years) using red blood cell folate distributions NHANES 2011–March 2020.

TABLE 1

Red blood cell (RBC) folate concentrations of U.S. Hispanic women of reproductive age (12–49 years), stratified by pre- and post-implementation of corn masa fortification.

	2011–2016				2017-Mar 2020					
	RBC concentrations		Concentrations <748 nmol/L[a]		RBC concentrations		Concentrations <748 nmol/L			
	n	Mean (95% CI)[b]	*n*	Weighted % (95% CI)	*n*	Mean (95% CI)	*n*	Weighted % (95% CI)	*p*-value[c]	*p*-value[d]
Total	1643	1004 (984, 1024)	278	16.8 (15.0, 18.5)	672	998 (972, 1025)	117	19.4 (15.6, 23.1)	.74	.20
Mexican Americans	1016	1017 (991, 1044)	163	16.0 (13.7, 18.2)	406	995 (960, 1031)	64	18.1 (12.1, 24.0)	.31	.49
Folic acid (FA) source										
ECGP/CMF only	914	936 (917, 955)	199	21.9 (19.7, 24.1)	414	942 (912, 974)	87	23.5 (18.8, 28.2)	.71	.53
ECGP/CMF + RTE	404	1034 (996, 1075)	47	10.9 (8.0, 13.7)	127	1006 (957, 1057)	17	14.6 (6.4, 22.8)	.36	.38
ECGP/CMF + SUPP	248	1146 (1096, 1198)	24	9.8 (6.3, 13.3)	111	1167 (1086, 1254)	12	11.4 (4.1, 19.1)	.66	.66
ECGP/CMF + RTE + SUPP	77	1238 (1115, 1376)	8	8.5 (1.9, 15.2)	20	1320 (1202, 1450)	1	-	.37	
Language spoken at home										
Primarily English	655	1016 (986, 1046)	104	16.0 (13.6, 18.4)	256	974 (918, 1033)	47	21.6 (13.1, 30.2)	.19	.20
Equal English and Spanish	337	974 (938, 1011)	65	19.2 (14.8, 23.7)	136	959 (888, 1036)	27	23.4 (15.3, 31.6)	.72	.36
Primarily Spanish	644	1006 (973, 1041)	109	16.6 (13.4, 19.8)	276	1046 (1008, 1086)	42	14.7 (11.1, 18.2)	.12	.41
Missing	7		0		4		1			
Time in United States										
U.S. born	901	1006 (982, 1031)	148	16.4 (14.1, 18.7)	362	961 (917, 1007)	64	21.5 (15.6, 27.4)	.08	.10
Born outside United States ≥ 15 years	293	1046 (995, 1099)	41	14.7 (10.0, 19.3)	194	1080 (1025, 1138)	29	15.0 (7.9, 22.1)	.37	.94
Born outside United States < 15 years	389	961 (921, 1003)	83	19.8 (14.8, 24.8)	114	987 (933, 1045)	24	20.4 (13.3, 27.5)	.44	.89
Missing	60		6		2		0			
ECGP/CMF only	914		199		414		87			
Mexican Americans	545	955 (926, 985)	110	20.7 (17.4, 24.1)	229	944 (899, 991)	45	22.4 (15.2, 29.7)	.67	.67
Language spoken at home										
Primarily English	365	936 (902, 971)	76	21.2 (17.3, 25.2)	154	906 (840, 976)	36	27.7 (16.6, 38.7)	.42	.27
Equal English and Spanish	181	939 (882, 999)	42	23.1 (16.6, 29.7)	90	889 (821, 961)	21	27.3 (19.8, 34.7)	.27	.40

	2011–2016				2017-Mar 2020					
	RBC concentrations		Concentrations <748 nmol/L[a]		RBC concentrations		Concentrations <748 nmol/L			
	n	**Mean (95% CI)[b]**	***n***	**Weighted % (95% CI)**	***n***	**Mean (95% CI)**	***n***	**Weighted % (95% CI)**	***p*-value[c]**	***p*-value[d]**
Primarily Spanish	361	933 (895, 973)	81	22.6 (17.6, 27.6)	167	1018 (972, 1065)	29	16.7 (12.6, 20.8)	.01	.07
Missing	7		0		3		1			
Time in United States										
U.S. born	499	949 (921, 978)	95	19.9 (16.2, 23.5)	227	902 (847, 962)	48	25.9 (18.3, 33.4)	.15	.15
Born outside United States ≥15 years	164	972 (916, 1032)	32	20.3 (13.6, 27.0)	112	1020 (949, 1097)	20	16.7 (8.3, 25.2)	.30	.50
Born outside United States < 15 years	216	876 (832, 922)	66	27.7 (19.8, 35.6)	74	961 (913, 1011)	19	26.3 (17.9, 34.6)	.01	.80
Missing	35		6		1		0			

Note: Data from the National Health and Nutrition Examination Survey (NHANES) 2011–March 2020.

Abbreviations: CI, confidence interval; CMF, corn masa flou; ECGP, enriched cereal grain product; RTE, ready-to-eat cereals; SUPP, supplements containing folic acid.

[a] Optimal RBC folate concentration for neural tube defects prevention.

[b] Geometric mean.

[c] *p*-values represent differences in RBC folate concentrations determined by Wald-adjusted *t*-test.

[d] *p*-values represent differences in % with RBC folate concentrations <748 nmol/L determined by Wald-adjusted *t*-test.