Effectiveness of a Pediatric Primary Care Intervention to Increase Maternal Folate Use: Results from a Cluster Randomized Controlled Trial

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Objective To assess the impact of provision of folate vitamins and a preconception health intervention on folate use among mothers bringing infants to pediatric primary care.

Study design We conducted a cluster randomized trial in mothers presenting with their infants (<12 months) at 4 urban pediatric practices in the Baltimore, Maryland, metropolitan area. There were 45 clinicians randomized into an intervention group (15-item preconception health screening and counseling and 90-day multivitamin supply) and control group (preconception health and community resource handouts and 90-day multivitamin supply). Participating mothers were enrolled in the study group assigned to their child's clinician. Baseline and 6-month follow-up interviews were performed. The outcome was daily use of folate, multivitamin, and a prenatal vitamin containing folate. Primary independent variables were time of assessment and mother's study group (intervention or control groups). Covariates investigated were mother's and child's age, race/ethnicity, education, marital status, income, insurance status, previous live births, and intention to have a pregnancy in the next 6 months.

Results We enrolled 415 mothers at baseline who were majority African American and low income. Of the 415 enrolled participants, 352 (85%) completed follow-up interviews. Among all participants, daily vitamin intake increased from baseline to 6-month follow-up (33.8% vs 42.6%; $P = .016$). After adjustment for covariates and clustered design, there was an augmented effect in the intervention vs control group (aOR, 2.04; 95% CI, 1.04-3.98).

Conclusions Offering vitamins and recommending folate intake to mothers within pediatric practice can increase use. Pediatric practice is an important contact point and context for improving maternal folate use. *(J Pediatr 2018;192:247-52).*

Trial Registration ClinicalTrials.gov NCT02049554.

Neural tube defects affect approximately 3000 pregnancies per year in the US, the 2 most common being spina bifida and anencephaly.[1] Daily folate supplementation reduces the risk of developing neural tube defects by approximately 70%.[2] Current recommendations by the US Preventive Services Task Force, the Centers for Disease Control and Prevention (CDC), and the American Academy of Pediatrics suggest a daily folate intake of 400 μg before and during early pregnancy for all women of childbearing age,[1,3,4] either by food intake or supplementation.

Despite interventions to increase folate intake, including the folate fortification of enriched breads, flours, corn meals, pasta, rice, cereal, and other grain products and recommendations for daily folate supplementation, women continue to report low folate intake.[5] According to Pregnancy Risk Assessment Monitoring System data, 32.4% of women who delivered a live birth in 2011 reported taking a vitamin containing folate daily in the month before pregnancy.[6] Women with a low income were at greater risk for no folate intake than women with higher incomes.[7] According to National Health and Nutrition Examination Survey, 25% of women of reproductive age had low (<195 ng/mL) red blood cell folate concentrations.[6]

Preconception care is 1 strategy that has shown potential for improving folate intake.[8-10] The American Academy of Pediatrics, American Congress of Obstetricians and Gynecologists, and the National Academy of Medicine, formerly the Institute of Medicine, have advocated for women to receive preconception care (counseling on optimizing health before pregnancy) at all healthcare encounters during the reproductive years.[10-12] Despite these recommendations, only 34% of women surveyed by Pregnancy Risk Assessment Monitoring System in 2011 received preconception care counseling and 27% reported receiving folate-specific preconception care.[7,8]

CDC Centers for Disease Control and Prevention

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Funded by Abell and The Aaron and Lillie Straus Foundations, and The Zanvyl and Isabelle Krieger Fund, DC-Baltimore Research Center on Child Health Disparities (P20 MD000198) from the National Institute on Minority Health and Health Disparities. The authors declare no conflicts of interest. The views expressed in this article are those of the authors, and no official endorsement by the Agency for Healthcare Research and Quality or the Department of Health and Human Services is intended or should be inferred.

Portions of this study were presented at the Pediatric Academic Societies Meeting, April 30-May 3, 2016, Baltimore, Maryland, and at the Academic Pediatric Association Region IV Conference, February 20-21, 2016, Charlottesville, Virginia.

https://doi.org10.1016/j.jpeds.2017.09.020

Pediatric clinicians have unique access to both preconceptional adolescents and interconceptional women and are, therefore, a logical contact point for preconception care.[13] There are 10 recommended well-child visits within the first 2 years of life and studies show that virtually all children less than 4 years of age attend well-child visits, often accompanied by their mother.[13] Although some studies have explored the impact of preconception care interventions on outcomes, including folate use,[14-20] few have been delivered in a pediatric primary care setting.[21]

The objective of this study was to assess the effectiveness of a preconception care intervention, delivered to women with children 12 months of age or younger attending pediatric primary care, on daily use of folate. We hypothesize that the provision of vitamins and additional pediatric preconception counseling will increase folate use.

Methods

This is a secondary data analysis based on data obtained from a cluster randomized trial (ClinicalTrials.gov: NCT02049554) testing a broader preconception health intervention in pediatric primary care. The trial was conducted across 4 pediatric practice sites serving large proportions of low-income families: a hospital-based clinic, a community clinic, a federally qualified health center, and a private practice in the Baltimore, Maryland, metropolitan area. Within each practice site, clinicians were randomly assigned using a random number generator to either the intervention or control group. Eligible mothers, presenting with their child less than 12 months of age for pediatric well-care and agreeing to participate, were enrolled in the study arm assigned to their child's clinician. Although contamination within practices could not be completely ruled out, we elected to minimize the potential of contamination by randomizing clinicians to intervention or control rather than randomizing participants. The study was approved by the Institutional Review Board at Johns Hopkins Medicine.

We recruited women presenting with their children for pediatric care. Research assistants reviewed clinic schedules to identify visits of patients 12 months of age or younger and approached potential participants in the clinic to explain the study and assess interest in participation and eligibility. If eligible, informed consent was obtained and a baseline interview completed during the visit. Folate use data was collected at the initial visit (baseline) and by phone 6 months later (follow-up) by a trained research assistant. Participants were compensated $25 for completion of baseline and 6-month assessments. Methods to ensure maximal rates of follow-up included multiple phone call attempts at each interview point, varying the time of day calls were made, making attempts up to 2 months after the due date of follow-up and examining clinic schedules to make contact with hard to reach participants.

Convenience sampling was performed of mothers presenting with their youngest child less than 12 months of age for pediatric well-care at 1 of the 4 participating practices. Targeting women within 12 months postpartum ensured that the intervention took place as close to the most recent pregnancy as possible, increasing chances to impact a subsequent pregnancy and because well-child visits are most frequent during the first year of life. Eligibility criteria included biologic mothers capable of completing assessments in English or Spanish recruited from October 2013 to March 2015. Women known to be pregnant at the time of the visit were excluded. Our sample size was based on the trial's primary outcomes of interest, receipt of preconception care and use of a hormonal or long-acting reversible contraception method for contraception. To detect a 20% increase in each outcome between control and the intervention groups using a 2-sided alpha of 0.05 and power of 80%, we projected a needed sample size of 200 per group to take into account the clustering of participants within providers. The total sample size projected was 400 women.

Intervention and Control Conditions

All participants in both groups received the CDC preconception women's health handout entitled "Show Your Love, Steps to a Healthier Me," a community resource listing, and a 90-day supply of multivitamins with 400 μg of folate.

In addition, mothers in the intervention group completed a 15-item preconception health screener that assessed exposure to primary health and behavioral preconception risk factors (including folate intake) as identified by the CDC, and tailored counseling. The preconception care screener addressed the following topics: folate intake; reproductive life plan and contraceptive use; access and utilization of primary care and family planning services; chronic illnesses and medication use; smoking, alcohol, and other substance use; depression; and partner violence. To ensure the preconception care screener targeted relevant constructs and was acceptable to the population, its development included a literature review on preconception women's health and review by a community advisory board.

Mothers shared the completed preconception care screener with their pediatric clinician, who was encouraged by the intervention protocol to provide focused counseling and make referrals to additional services as needed. Specifically, for mothers who indicated they had low or no folate intake, recommended counseling focused on the importance of folate intake for the health of their next child.

Measures

Given that all women received multivitamins containing folate at baseline, we conducted 2 primary analyses: to estimate the effect of providing multivitamins to all participants and the additional effect of the preconception care screener intervention on daily folate use.

The baseline and follow-up interview questions were based on previously published measures from the Pregnancy Risk Assessment Monitoring System questionnaires validated in a variety of different populations and used nationally.[22] The interviews, each approximately 30 minutes long, underwent rigorous one-on-one pretesting, including in-depth interviews probing how respondents understood and interpreted the questions.