Folic Acid for the Prevention of Neural Tube Defects: U.S. Preventive Services Task Force Recommendation Statement

U.S. Preventive Services Task Force*

Description: In 1996, the U.S. Preventive Services Task Force (USPSTF) recommended that all women planning or capable of pregnancy take a multivitamin supplement containing folic acid for the prevention of neural tube defects. This recommendation is an update of the 1996 USPSTF recommendation.

Methods: The USPSTF reviewed the evidence on folic acid supplementation in women of childbearing age published since the 1996 USPSTF recommendation. The USPSTF did not review the evidence on folic acid food fortification, counseling to increase dietary intake, or screening for neural tube defects.

Recommendation: The USPSTF recommends that all women planning or capable of pregnancy take a daily supplement containing 0.4 to 0.8 mg (400 to 800 μg) of folic acid. (Grade A recommendation).

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For author affiliation, see end of text.

* For a list of the members of the USPSTF, see the **Appendix** (available at www.annals.org).

The U.S. Preventive Services Task Force (USPSTF) makes recommendations about preventive care services for patients without recognized signs or symptoms of the target condition.

It bases its recommendations on a systematic review of the evidence of the benefits and harms and an assessment of the net benefit of the service.

The USPSTF recognizes that clinical or policy decisions involve more considerations than this body of evidence alone. Clinicians and policymakers should understand the evidence but individualize decision making to the specific patient or situation.

Summary of Recommendation and Evidence

The USPSTF recommends that all women planning or capable of pregnancy take a daily supplement containing 0.4 to 0.8 mg (400 to 800 μg) of folic acid. This is a grade A recommendation.

See the **Figure** for a summary of the recommendation and suggestions for clinical practice.

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See **Table 1** for a description of the USPSTF grades and **Table 2** for a description of the USPSTF classification of levels of certainty about net benefit.

Rationale

Importance

Approximately 1 in every 1000 pregnancies is affected by a neural tube defect.

Recognition of Risk Status

Although a personal or family history of a pregnancy affected by a neural tube defect is associated with an increased risk for having an affected pregnancy, most cases occur in the absence of any positive history.

Benefits of Preventive Medication

The USPSTF found convincing evidence that supplements containing 0.4 to 0.8 mg (400 to 800 μg) of folic acid in the periconceptional period reduce the risk for neural tube defects.

Harms of Preventive Medication

Adequate evidence suggests that folic acid from supplementation at usual doses is not associated with serious harms.

USPSTF Assessment

The USPSTF concludes that, for women who are planning or capable of pregnancy, there is high certainty that the net benefit is substantial.

Clinical Considerations

Patient Population Under Consideration

This recommendation applies to women who are planning or capable of pregnancy, but it does not apply to women who have had a previous pregnancy affected by neural tube defects or women taking certain antiseizure medicines. Most organizations recommend that these women take higher doses of folic acid.

Assessment of Risk

The use of certain antiseizure medicines and a personal or family history of neural tube defects are well-established risk factors. Other reported risk factors include mutations in folate-related enzymes, maternal diabetes, and obesity.

Timing

Most studies indicate the need to start folic acid supplementation at least 1 month before conception and to continue daily supplements through the first 2 to 3 months of pregnancy. Studies also indicate that 50% of pregnancies in the United States are unplanned, and clinicians should therefore advise all women who are capable of pregnancy to take folic acid supplements.

Dosage

Good evidence from randomized trials in settings without fortification of food suggests that a multivitamin with 0.8 mg (800 μg) of folic acid reduces the risk for neural tube defects. Observational studies done before fortification report a reduction of neural tube defects in women taking a supplement with 0.4 mg (400 μg) of folic acid (the generally available dose). Evidence indicates that most women in the United States are not ingesting fortified foods at a level thought to provide optimal benefit. In a setting in which food is fortified with folic acid, the effective amount of additional folic acid supplementation is unclear.

Discussion

Burden of Disease

Neural tube defects result from a malformation of the embryo's central nervous system that may result in a serious birth defect like anencephaly or spina bifida. Neural tube defects are among the most common birth defects in the United States (1). Approximately 1 in every 1000 pregnancies is affected. The Centers for Disease Control and Prevention estimates that the birth rates in 2005 for 2 of the most common neural tube defects, spina bifida and anencephaly, were 17.96 and 11.11 per 100 000 live births, respectively (2).

Two well-established risk factors for neural tube defects are a history of a fetus or child with a neural tube defect or having a first-, second-, or third-degree relative with such a defect (3, 4). The prevalence of defects varies by ethnicity and race: Hispanic and non-Hispanic white persons have higher rates of neural tube defects than black and Asian persons (5). Maternal medical conditions, such as diabetes and obesity, have also been associated with an increased risk. Women with epilepsy who take certain antiepileptic medications, such as valproic acid or carbamazepine, are also at increased risk.

Scope of Review

In 1992, the U.S. Public Health Service recommended the daily consumption of 0.4 mg (400 μg) of folic acid in women of childbearing age (15 to 44 years) (6). In 1996, the USPSTF made a similar recommendation on the basis of several studies, including 1 large randomized, controlled trial (RCT) that demonstrated a statistically significant reduction in incidence of neural tube defects in women who took a multivitamin with 0.8 mg (800 μg) of folic acid in the periconceptional period (7, 8). The USPSTF recommended that all women planning pregnancy take a daily multivitamin containing folic acid at a dose of 0.4 to 0.8 mg beginning at least 1 month before conception and continuing through the first trimester, to reduce the risk for neural tube defects (grade A recommendation). In addition, it recommended a daily multivitamin containing 0.4 mg of folic acid for all women capable of pregnancy, to reduce the risk for neural tube defects in unplanned pregnancies (grade B recommendation). The purpose of the current USPSTF review was to update the evidence on folic acid supplementation in women of childbearing age published since the 1996 USPSTF commendation. The USPSTF did not review the evidence on folic acid for women who had a history of pregnancy affected by neural tube defects nor the evidence on folic acid food fortification, counseling to increase dietary intake, or screening for neural tube defects.

Effectiveness of Preventive Medication

In addition to the RCT that was available in 1996, the USPSTF found further observational evidence published since that time that supports the hypothesis that supplementation with 0.4 to 0.8 mg (400 to 800 μg) of folic acid in the periconceptional period reduces the risk for neural tube defects in offspring.

In 2004, Czeizel and Dudás (7) did a cohort study including women who were considering pregnancy and gave them multivitamins containing 0.8 mg (800 μg) of folic acid 1 month before planned conception. The authors reported a protective effect of folic acid against neural tube defects: 1 neural tube defect occurred in 3056 women who took folic acid supplements and 9 occurred in 3056 women who did not. The difference between the supplemented and unsupplemented groups was statistically significant after adjustment for birth order, chronic maternal disorders, and history of fetal death or congenital abnormality.

A meta-analysis of studies about pre- and periconceptional multivitamin use and congenital malformations also reported a protective effect of multivitamins containing folic acid against neural tube defects, with an odds ratio (OR) of 0.67 (95% CI, 0.58 to 0.77) in case–control studies and an OR of 0.52 (CI, 0.39 to 0.69) in RCTs and

cohort studies. In 1995, Shaw and coworkers (9) did a case–control study and reported an OR of 0.65 (CI, 0.45 to 0.94) for use of supplements containing folic acid 3 months before conception and an OR of 0.60 (CI, 0.46 to 0.79) for use 3 months after. A smaller study that adjusted for dietary folic acid intake reported an OR of 0.55 (CI, 0.25 to 1.22) for regular users and an OR of 0.92 (CI, 0.55 to 1.55) for some use of supplements containing folic acid, but neither of these findings was statistically significant (4).

Data from the 2001–2002 NHANES (National Health and Nutrition Examination Survey), limited to nonpregnant female participants from age 15 to 49 years, indicate that 8% of women consumed 400 μg/d or more of folic acid from fortified foods, and 26% of women took 400 μg/d or more of folic acid through supplements within the previous month (10). Therefore, 34.3% of women of reproductive age consumed 400 μg/d or more through a combination of fortified foods and supplements. Recently, the 2007 March of Dimes Gallup survey used a random digit–dialed telephone interview of women of childbearing age to assess folic acid intake. Of this sample, 40% reported taking folic acid daily, compared with 32% in 2003, 40% in 2004, and 33% in 2005. When stratified by age, 47% of women from age 25 to 34 years reported taking a daily supplement with folic acid compared with 30% of women age 18 to 24 years (11). A recent study using NHANES data reported decreases in folic acid intake by women of childbearing age. The authors hypothesized that this was due to a reduction in fortification levels and the popularity of low-carbohydrate diets that are deficient in foods fortified with folic acid (12).

Potential Harms of Preventive Medication

The USPSTF found adequate evidence that folic acid from supplementation at usual doses is not associated with serious harms. Previous concerns, discussed in the 1996 USPSTF recommendation, about potential harms related to folic acid supplementation (particularly in light of mandatory food fortification [13]) focused on several hypothesized areas: the masking of symptoms of vitamin B_{12} deficiency and consequent neurologic complications, drug interactions, allergic reactions, carcinogenic effects, and effects on the rate of twinning (14). In its current review, the USPSTF found no evidence on drug interactions, allergic reactions, or carcinogenic effects.

The USPSTF also found no clear, consistent evidence that preconceptional folic acid use results in an increased rate of twinning. Many studies with methodological problems posit an association between folic acid and twinning; however, most of these studies did not appropriately adjust for fertility interventions, an important confounder. In a 2005 retrospective cohort study, Vollset and colleagues (15) suggest that the association of folic acid supplementation with twinning is the result of confounding by infertility treatment and by differential reporting of folic acid use. This study examined the association between risk for twinning in 176 042 women and exposure to a multivitamin or folic acid supplementation before or during pregnancy. After adjustment for age and parity, the authors reported an OR of 1.59 (CI, 1.41 to 1.78) for twin delivery after preconceptional folic acid supplementation. After accounting for the underreporting of folic acid use and in vitro fertilization, the OR for twin delivery after preconceptional supplementation decreased to 1.02 (CI, 0.85 to 1.24) and was no longer statistically significantly greater than the risk for women who did not take folic acid.

Another concern about folic acid supplementation includes masking of vitamin B_{12} deficiency. The USPSTF found no evidence to support this potential harm. Given the low prevalence of vitamin B_{12} depletion in young women, folic acid supplementation in women of childbearing age would not likely result in a substantial number of cases of neurologic sequelae due to masking of vitamin B_{12} deficiency. In a study using data from NHANES and the Hispanic Health and Nutrition Examination Survey, the Centers for Disease Control and Prevention National Center for Health Statistics reported that fewer than 1% of the total population from age 4 to 50 years had serum vitamin B_{12} levels less than 100 pg/mL in 1998, the level below which deficiency is likely (16). Furthermore, an ecological study comparing patients before and after folic acid fortification found no evidence of an increase in low vitamin B_{12} levels without anemia (17). Finally, folic acid supplementation is often given in the form of a multivitamin or prenatal vitamin that includes supplementation with B_{12}, reducing the likelihood of its masking a deficiency in this population.

Estimate of Magnitude of Net Benefit

New evidence from observational studies provides additional support to earlier evidence from controlled trials that folic acid supplementation provides benefit in the reduction of risk for pregnancies affected by neural tube defects. The USPSTF found 4 fair- or good-quality studies published since the 1996 USPSTF commendation that reported benefits. Odds ratios for reductions in neural tube defects associated with periconceptional folic acid supplementation ranged from 0.11 to 0.65. A meta-analysis reported an OR of 0.67 in case–control studies and 0.52 in RCTs and cohort studies for neural tube defects associated with use of multivitamins containing folic acid. Adequate evidence indicates that folic acid supplementation leads to few harms. The USPSTF balanced the benefits and harms of folic acid supplementation in women of childbearing age and determined that the net benefit was substantial.

How Does Evidence Fit With Biological Understanding?

The function of folate is to act as a coenzyme in the metabolism of amino acids and nucleic acids (14). Its mechanism of action in the prevention of neural tube defects has not been established. However, a main function of folate is participation in one-carbon transfers, which are important in methylation reactions and in purine and py-

Figure. **Folic acid for the prevention of neural tube defects: clinical summary of U.S. Preventive Services Task Force Recommendation.**

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FOLIC ACID FOR THE PREVENTION OF NEURAL TUBE DEFECTS
CLINICAL SUMMARY OF U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATION

Population	**Women planning a pregnancy or capable of becoming pregnant**
Recommendation	**Take a daily vitamin supplement containing 0.4 to 0.8 mg (400 to 800 μg) of folic acid.**
	Grade: A

Risk Assessment	Risk factors include: • A personal or family history of a pregnancy affected by a neural tube defect • The use of certain antiseizure medications • Mutations in folate-related enzymes • Maternal diabetes • Maternal obesity Note: This recommendation does not apply to women who have had a previous pregnancy affected by neural tube defects or women taking certain antiseizure medicines. These women may be advised to take higher doses of folic acid.
Timing of Medication	Start supplementation at least 1 month before conception. Continue through first 2 to 3 months of pregnancy.
Recommendations of Others	ACOG, AAFP, and most other organizations recommend 4 mg/d for women with a history of a pregnancy affected by a neural tube defect.

For a summary of the evidence systematically reviewed in making these recommendations, the full recommendation statement, and supporting documents, please go to www.preventiveservices.ahrq.gov.

AAFP = American Academy of Family Physicians; ACOG = American College of Obstetricians and Gynecologists.

Table 1. **What the USPSTF Grades Mean and Suggestions for Practice**

Grade	Definition	Suggestions for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer/provide this service.
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer/provide this service.
C	The USPSTF recommends against routinely providing the service. There may be considerations that support providing the service in an individual patient. There is moderate or high certainty that the net benefit is small.	Offer/provide this service only if other considerations support offering or providing the service in an individual patient.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.	Read the clinical considerations section of the USPSTF Recommendation Statement. If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.

USPSTF = U.S. Preventive Services Task Force.

Table 2. **U.S. Preventive Services Task Force Levels of Certainty Regarding Net Benefit**

Level of Certainty*	Description
High	The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.
Moderate	The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by such factors as: the number, size, or quality of individual studies inconsistency of findings across individual studies limited generalizability of findings to routine primary care practice lack of coherence in the chain of evidence. As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.
Low	The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of: the limited number or size of studies important flaws in study design or methods inconsistency of findings across individual studies gaps in the chain of evidence findings that are not generalizable to routine primary care practice a lack of information on important health outcomes. More information may allow an estimation of effects on health outcomes.

* The U.S. Preventive Services Task Force (USPSTF) defines *certainty* as "likelihood that the USPSTF assessment of the net benefit of a preventive service is correct." The net benefit is defined as benefit minus harm of the preventive service as implemented in a general primary care population. The USPSTF assigns a certainty level based on the nature of the overall evidence available to assess the net benefit of a preventive service.

rimidine synthesis. Folate is necessary for the regulation of DNA synthesis and function and, therefore, probably affects important events in embryogenesis that may lead to neural tube defects.

RECOMMENDATIONS OF OTHERS

In 2003, an updated guideline from the American College of Obstetrics and Gynecology recommended periconceptual folic acid supplementation (0.4 mg) in a multivitamin for most women capable of pregnancy (18). For a woman planning to become pregnant and without a history of neural tube defects, the American Academy of Family Physicians (AAFP) strongly recommends prescribing folic acid supplementation of 0.4 to 0.8 mg/d. The AAFP also recommends prescribing 0.4 mg of folate supplementation to a woman of childbearing age if she is not planning a pregnancy (19). The American College of Obstetrics and Gynecology, AAFP, and most other organizations recommend 4 mg/d for women with a history of neural tube defects. "The American Academy of Pediatrics endorses the U.S. Public Health Service recommendation that all women capable of becoming pregnant consume 400 μg of folic acid daily to prevent neural tube defects," particularly for adolescent, "sexually active women who do not plan to use effective contraception or abstain from sexual intercourse" (20, 21). Because of teratogenesis and impaired folate metabolism associated with certain antiepileptic drugs, the American Academy of Neurology recommends folic acid supplementation of no less than 0.4 mg/d for women of childbearing age with epilepsy (22, 23).

From the U.S. Preventive Services Task Force, Agency for Healthcare Research and Quality, Rockville, Maryland.

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Potential Financial Conflicts of Interest: None disclosed.

Requests for Single Reprints: Reprints are available from the USPSTF Web site (www.preventiveservices.ahrq.gov).

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Appendix: U.S. Preventive Services Task Force

Members of the U.S. Preventive Services Task Force† are Ned Calonge, MD, MPH, *Chair*, USPSTF (Colorado Department of Public Health and Environment, Denver, Colorado); Diana B. Petitti, MD, MPH, *Vice-chair*, USPSTF (Arizona State University, Phoenix, Arizona); Thomas G. DeWitt, MD (Children's Hospital Medical Center, Cincinnati, Ohio); Allen J. Dietrich, MD (Dartmouth Medical School, Hanover, New Hampshire); Kimberly D. Gregory, MD, MPH (Cedars-Sinai Medical Center, Los Angeles, California); David Grossman, MD, MPH (Group Health Cooperative, Seattle, Washington); George Isham, MD, MS (HealthPartners Inc., Minneapolis, Minnesota); Michael L. LeFevre, MD, MSPH (University of Missouri School of Medicine, Columbia, Missouri); Rosanne M. Leipzig, MD, PhD (Mount Sinai School of Medicine, New York, New York); Lucy N. Marion, PhD, RN (School of Nursing, Medical College of Georgia, Augusta, Georgia); Bernadette Melnyk, PhD, RN (Arizona State University College of Nursing & Healthcare Innovation, Phoenix, Arizona); Virginia A. Moyer, MD, MPH (Baylor College of Medicine, Houston, Texas); Judith K. Ockene, PhD (University of Massachusetts Medical School, Worcester, Massachusetts); George F. Sawaya, MD (University of California, San Francisco, San Francisco, California); J. Sanford Schwartz, MD (University of Pennsylvania School of Medicine and The Wharton School, Philadelphia, Pennsylvania); Timothy Wilt, MD, MPH (Minneapolis Veterans Affairs Medical Center, Minneapolis, Minnesota).

†This list includes members of the Task Force at the time this recommendation was finalized. For a list of current Task Force members, go to www.ahrq.gov/clinic/uspstfab.htm.