

EVIDENCE-STATEMENT:

HEALTHY PREGNANCY (Screening, Testing, Counseling, Immunization, and Preventive Medication)

Folic Acid Supplementation (Counseling and Preventive Medication)

Clinical Preventive Service Recommendations

U.S. Preventive Services Task Force Recommendation

In 1996, the U.S. Preventive Services Task Force (USPSTF) recommended that all women of childbearing age who are capable of becoming pregnant (even those currently using contraception) consume 0.4 micrograms of folic acid per day to reduce the risk of a pregnancy affected by either spina bifida, anencephaly, or another neural tube defect.

This recommendation is archived and considered out of date.

CDC Recommendation

The CDC concurs with the U.S. Public Health Service (see description below).

**Evidence-Based Recommendation
American Academy of Family Physicians (AAFP)**

The American Academy of Family Physicians (AAFP) recommends that clinicians prescribe 0.4-0.8 mg/day of folic acid supplementation from at least 1 month prior to conception through the first trimester of the pregnancy to women who have not had a previous pregnancy affected by a neural tube defect.¹

**Evidence Rating: SR
(Strongly Recommends)**

Good quality evidence exists which demonstrates the substantial net benefit of folic acid supplementation over harm; the intervention is perceived to be cost-effective and acceptable to nearly all patients.¹

American Academy of Family Physicians (AAFP)

The American Academy of Family Physicians (AAFP) recommends that clinicians prescribe 0.4 mg folic acid supplementation to women not planning a pregnancy but of childbearing potential who have not had a previous pregnancy affected by a neural tube defect.¹

**Evidence Rating: R
(Recommended)**

Although evidence exists which demonstrates the net benefit of folic acid supplementation, either the benefit is only moderate in magnitude or the evidence supporting a substantial benefit is only fair. The intervention is perceived to be cost-effective and acceptable to most patients.¹

American Academy of Family Physicians (AAFP)

The American Academy of Family Physicians (AAFP) recommends that clinicians prescribe 4 mg/day of folic acid supplementation from 1 to 3 months prior to conception through the first trimester of pregnancy to women who are planning a pregnancy and have had a previous pregnancy affected by a neural tube defect.¹

**Evidence Rating: SR
(Strongly Recommended)**

Good quality evidence exists which demonstrates the substantial net benefit of folic acid supplementation over harm; the intervention is perceived to be cost-effective and acceptable to nearly all patients.¹

**Other Recommended
Guidance
U.S. Public Health
Service**

The U.S. Public Health Service recommends that²⁻³:

- All women of childbearing age in the United States who are capable of becoming pregnant should consume 0.4 mg of folic acid per day for the purpose of reducing their risk of having a pregnancy affected with spina bifida or other neural tube defects.
- Women who have had a prior NTD-affected pregnancy are at high risk of having a subsequent affected pregnancy and should consult their physicians when planning to become pregnant again.

Evidence Rating:

Not Specified

Information Sources

The recommendations and supporting information contained in this document came from several sources, including the:

- American Academy of Family Physicians (AAFP)
- American College of Obstetricians and Gynecologists (ACOG)
- Centers for Disease Control and Prevention (CDC)
- National March of Dimes Birth Defects Foundation
- Peer-reviewed research
- U.S. Public Health Service (USPHS)

The background and supporting information contained in this document is a compilation of research findings. All information presented in this document should be attributed to its referenced source and should not be considered a reflection of other organizations cited in the text.

Condition/Disease Specific Information

**Epidemiology of
Condition/Disease**

Spina bifida and anencephaly are severe, potentially fatal birth defects. Both are neural tube defects (NTD) resulting in failure of the neural tube to fuse correctly. Approximately 3,000 pregnancies are affected by NTDs, and approximately 2,200 infants are born with neural tube defects each year.⁴ Many NTD-affected pregnancies do not result in a live birth because they are electively or spontaneously aborted (commonly referred to as a miscarriage) or result in fetal death or stillbirth.⁴

Anencephaly is always fatal and affected infants die shortly after birth. The majority of infants born with spina bifida grow into adulthood, but have severe medical complications such as paralysis and varying degrees of bowel and bladder incontinence.²

Folic acid, a B vitamin, prevents NTDs. Evidence (from populations not consuming foods fortified with folic acid) shows that consuming the recommended daily amount of synthetic folic acid (0.4 mg) through folic acid supplements can reduce a woman's chance of having a NTD-affected pregnancy by 40% to 80%.⁵

	<p>Synthetic folic acid can be consumed via folic acid supplements, folic acid-containing multivitamins, cereals that have been fortified with folic acid, and fortified grains. The natural form of this vitamin, folate, can be found in foods such as green leafy vegetables, orange juice, and beans. Synthetic folic acid vitamin supplementation is recommended because it is easier for the body to absorb than folate found in food and because up to 50% of naturally occurring folate is lost during cooking.⁶</p>
<p>Condition/Disease Risk Factors</p>	<p>Despite the known benefit of folic acid, only 33% of women of childbearing age report taking vitamins that contain folic acid and certain subpopulations have even lower rates of vitamin supplementation.⁷</p> <p>NTD rates are highest among the Hispanic population. Efforts to ensure supplementation among this population are important for eliminating health disparities.⁸</p>
<p>Value of Prevention</p>	
<p>Economic Burden of Condition/Disease</p>	<p>The economic burden of NTDs is substantial. The total lifetime cost for a child born with spina bifida is estimated to be \$636,000 (in year 2002 dollars).⁹ Applying the prevalence rate for spina bifida from the National Birth Defect Prevention Network data¹⁰ to the 4 million live births each year, that amounts to \$814 million in lifetime costs for each one-year cohort of births (all children born in one year).⁹ Costs associated with NTDs are shared by parents, employers, and communities.</p>
<p>Workplace Burden of Condition/Disease</p>	<p>Apart from the excess medical costs for affected children, employers face productivity loss costs associated with employees' absences to care for children with spina bifida. The present value of the cost of such caregiver time was estimated to be \$252,000 per child (in year 1993 dollars).¹¹</p>
<p>Economic Benefit of Preventive Intervention</p>	<p>The economic benefit of folic acid supplementation is based on the cost savings that result from averted direct and indirect costs of each NTD that is prevented with supplementation.</p>
<p>Estimated Cost of Preventive Intervention</p>	<p>In 2004, the private-sector cost of counseling to promote folic acid supplementation averaged \$23 per session; approximately 95% of all paid claims fell within the range of \$0 to \$81 per session.¹²</p> <p>The cost of supplementation is highly variable, depending on the type of vitamin supplement that is taken and for how long. The cost of over-the-counter vitamins is relatively cheap and is an out-of-pocket cost for beneficiaries. Prescription strength folic acid (recommended for women who have had a previous pregnancy affected by a NTD) costs approximately \$100 per year.¹³</p>
<p>Estimated Cost of Treatment</p>	<p>Not Provided</p>

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Cost-Effectiveness and/or Cost-Benefit Analysis of Preventive Intervention

At present there is no evidence on the incremental cost-effectiveness of folic acid supplementation. A study undertaken before the implementation of the folic acid fortification program, examined a public and provider education program as a possible strategy to increase folic acid consumption through consumption of vitamin supplements and estimated that, compared to no program, the cost-effectiveness of supplementation was approximately \$5,000 per quality-adjusted life year (QALY).¹¹

Preventive Intervention Information

Preventive Intervention: Purpose of Counseling and Preventive Medication

Encouraging a woman to increase her folic acid intake prior to pregnancy via support, counseling, and/or prescription vitamins can lead to improved nutrition, thereby improving her chance of a healthy pregnancy and reducing her risk of an NTD-affected pregnancy.

Benefits and Risks of Intervention

A double-blind, placebo-controlled, randomized trial showed that folic acid supplementation before and during pregnancy decreased the risk of a first occurrence of a neural tube defect.¹⁴⁻¹⁵ The efficacy of such folic acid supplementation has since been confirmed by many other studies.

The South Carolina NTD prevention program has reported great success in preventing the recurrence of isolated NTDs by providing counseling and vitamins to women who have had a previous NTD-affected pregnancy.¹⁶

Initiation, Cessation, and Interval of Counseling and Preventive Medication

Folic acid supplementation is believed to have minimal risks. Folic acid is considered nontoxic even at very high doses and is rapidly excreted in the urine.

Folic acid supplementation information should be provided during routine healthcare visits and throughout the first trimester of pregnancy. Folic acid supplements should be prescribed/recommended, as medically indicated.

Intervention Process, Counseling, and Preventive Medication

Clinicians should 1) advise all women of child-bearing age who are capable of becoming pregnant about the importance of folic acid supplementation and 2) provide them with guidance on folic acid supplementation and, if needed, a prescription for folic acid supplements.

Treatment Information

Not Applicable

Strength of Evidence for the Clinical Preventive Service

The level of evidence supporting the recommendations contained in this section is described below.

Evidence-Based Research:

The American Academy of Family Physicians (AAFP)
 Strength of Evidence: SR (Strongly Recommended), R (Recommended)
 SR (Strongly Recommended)

- AAFP recommends that clinicians prescribe 0.4-0.8 mg/day of folic acid supplementation from at least 1 month prior to conception through the first trimester of the pregnancy to women planning to become pregnant who have not had a previous pregnancy affected by a neural tube defect. Good quality evidence exists which demonstrates the substantial net benefit of folic acid supplementation over harm; the intervention is perceived to be cost-effective and acceptable to nearly all patients.¹

R (Recommended)

- AAFP recommends that clinicians prescribe 0.4 mg folic acid supplementation to women not planning a pregnancy but of childbearing potential who have not previously had a baby with a neural tube defect. Although evidence exists which demonstrates the net benefit of folic acid supplementation, either the benefit is only moderate in magnitude or the evidence supporting a substantial benefit is only fair. The intervention is perceived to be cost-effective and acceptable to most patients.¹
- AAFP recommends that clinicians prescribe 4 mg/day of folic acid supplementation from 1-3 months prior to conception through the first trimester of pregnancy to women who are planning a pregnancy and had a previous pregnancy affected by a neural tube defect.¹ Good quality evidence exists which demonstrates the substantial net benefit of folic acid supplementation over harm; the intervention is perceived to be cost-effective and acceptable to nearly all patients.¹

Recommended Guidance:

U.S. Public Health Service (USPHS)

Strength of Evidence: Not Specified

- The U.S. Public Health Services recommends that all women of childbearing age in the United States who are capable of becoming pregnant should consume 0.4 mg of folic acid per day for the purpose of reducing their risk of having a pregnancy affected with spina bifida or other neural tube defects. Women who have had a prior NTD-affected pregnancy are at high risk of having a subsequent affected pregnancy, and should consult their physicians when planning to become pregnant again.²⁻³

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Campbell KP, Grosse S, Chattopadhyay S. Folic acid supplementation evidence-statement: counseling and preventive medication. In: Campbell KP, Lanza A, Dixon R, Chattopadhyay S, Molinari N, Finch RA, editors. *A Purchaser's Guide to Clinical Preventive Services: Moving Science into Coverage*. Washington, DC: National Business Group on Health; 2006.

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Folic Acid Supplementation (NTD) (Preventive Medication)

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