



Council for Responsible Nutrition

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September 28, 2016

VIA ELECTRONIC SUBMISSION

RE: IOM Review of WIC Food Packages, Pin Number IOM-FNB-14-02

At the request of the U.S. Department of Agriculture (USDA), the Institute of Medicine (IOM) has convened an expert Review Committee to review the food packages available to recipients through the Special Supplemental Nutrition Program for Women, Infants and Children (WIC).

The Council for Responsible Nutrition (CRN) appreciates the opportunity to submit comments to the expert Review Committee. CRN, founded in 1973 and based in Washington, D.C., is the leading trade association representing dietary supplement and functional food manufacturers and ingredient suppliers. CRN's more than 150 member companies produce a large portion of the dietary supplements marketed in the United States and globally, including popular national brands as well as the store brands marketed by major supermarkets, drug stores, discount chains, and natural food stores.

In its interim report, the Review Committee has confirmed that two major objectives of the WIC program are (1) to reduce the prevalence of inadequate nutrient intakes among program recipients and (2) to encourage and support dietary practices that are consistent with the *Dietary Guidelines for Americans*.

Yet current USDA food packages for WIC and the interim report of the Review Committee fail to include an important product that is entirely consistent with the 2015 *Dietary Guidelines for Americans* and that would contribute substantially to compensating for recognized nutrient shortfalls among women participating in the WIC program and indeed among all women of childbearing age. That product is a simple multivitamin/mineral providing 400 mcg folic acid

plus numerous other recognized shortfall micronutrients. We believe it is also of critical importance that the multivitamin/mineral authorized for the WIC population should include 150 mcg iodine.

Need for 400 mcg folic acid in addition to current dietary folate intake

The Report of the 2015 Dietary Guidelines for Americans Advisory Committee (DGAC) recognizes the strength of the scientific evidence that supplemental folic acid reduces the incidence of neural tube birth defects as well as other defects and recommends consumption of 400 to 800 mcg folic acid for all women of reproductive age:

"All studies were consistent in demonstrating that folic acid supplementation periconceptionally was associated with a decreased risk of having a child with a birth defect (e.g. neural tube defects, congenital heart defects, and cleft lip/palate)...Women of reproductive age should consume folic acid in the form of a supplement or through fortified foods in the range recommended by the U.S. Preventive Services Task Force (400 to 800 micrograms) in addition to consuming a diet rich in vegetables, fruits, and grains; lower in red and processed meats; and low in sweets."

The 2015 *Dietary Guidelines for Americans* include the affirmative recommendation made by the DGAC:

"[T]o prevent birth defects, all women capable of becoming pregnant are advised to consume 400 mcg of synthetic folic acid daily, from fortified foods and/or supplements. This recommendation is for an intake of synthetic folic acid in addition to the amounts of food folate contained in a healthy eating pattern."

These recommendations built on earlier recommendations made in the IOM report on Dietary Reference Intakes (DRI) for the B vitamins. The DRI committee used the term "folate" to include both folic acid and dietary folate. The following quote from page 259 of the DRI report inserts "folic acid" in brackets where the term "folate" is intended to refer specifically to synthetic folic acid:

"The recommendation made here for women capable of becoming pregnant is for intake that exceeds the Recommended Dietary Allowance (RDA) for folate. In particular, it is

recommended that women capable of becoming pregnant consume 400 mcg of folate [folic acid] daily from supplements, fortified foods, or both in addition to consuming food folate from a varied diet. At this time the evidence for a protective effect from folate [folic acid] supplements is much stronger than that for food folate."

The Centers for Disease Control and Prevention (CDC) played a leadership role in educating health professionals and the public about the key role of supplemental folic acid in preventing neural tube birth defects, and CDC still recommends that "all women between 15 and 45 years of age should consume folic acid daily because half of U.S. pregnancies are unplanned and because these birth defects occur very early in pregnancy (3-4 weeks after conception), before most women know they are pregnant. CDC estimates that most of these birth defects could be prevented if this recommendation were followed before and during early pregnancy." [CDC 2016]

The WIC food packages should help low-income pregnant women follow the advice of the CDC, the DRI reports, and the 2015 *Dietary Guidelines for Americans* by supporting the purchase and use of a simple multivitamin providing appropriate supplemental amounts of folic acid, iodine, and other essential shortfall nutrients. Other Federally-supported nutrition and health programs should support such use for all women of childbearing age.

What percent of neural tube birth defects could be prevented? What percent have been prevented?

CDC estimates that 50% to 70% of neural tube defects could be prevented by supplemental intake of folic acid before conception and early in pregnancy. Synthetic folic acid is the form of the nutrient used in the fortification of food and in the formulation of dietary supplements such as multivitamins. The Food and Drug Administration required fortification of many enriched grain products with folic acid as of January 1998, and CDC has studied the impact of that fortification. As recognized in the Interim Report of this IOM Review Committee on WIC Food Packages, "the incidence of neural tube defects in the United States dropped by approximately 36 percent from 1996 to 2006 and has subsequently remained stable." According to CDC, about 3000 pregnancies per year are now affected by neural tube birth defects in the U.S.

A reduction of 36 percent is important, but it does not reach the potential for a 70 percent reduction predicted by CDC. Addition of a simple multivitamin/mineral containing folic acid could help deliver the full potential benefit to the population of WIC recipients.

Effectiveness and cost of a multivitamin

Almost all clinical trials of folic acid for the prevention of neural tube defects have utilized a multivitamin, not folic acid alone. All epidemiological data on this issue are based on the reported use of a multivitamin containing folic acid, not the use of folic acid alone. Thus, the bulk of the evidence is based on the effectiveness of multivitamins containing folic acid.

Including a multivitamin with folic acid and other essential micronutrients as part of the WIC food packages for pregnant or lactating women would provide meaningful protection against neural tube defects in the infant and would also help correct other recognized nutrient shortfalls.

As is the case for most consumer goods, the cost of multivitamin/mineral products varies widely. However, it is possible to purchase a multivitamin/mineral supplement for a nickel a day. The IOM Review Committee could recommend and USDA should require that the product contain the recommended amount of 400 mcg of folic acid. The current RDA for pregnant women is 600 mcg Dietary Folate Equivalents (DFE) or 360 mcg of folic acid.

A nickel a day adds up to \$1.50 per month or \$9.00 every 6 months. The most efficient way of providing this benefit would be to issue a separate annual or semi-annual food instrument or voucher. Multivitamin/mineral products are typically marketed in containers providing several months' supply, and the cost per tablet decreases as the package size increases.

For that nickel a day, the multivitamin/mineral should provide not only folic acid but also recommended amounts of numerous other recognized shortfall micronutrients, including four other B vitamins; vitamins A, C, D and E; plus minerals iron, copper and zinc.

Multivitamin/mineral should include 150 mcg supplemental iodine

Another nutrient of particular importance for pregnant and lactating women is iodine, which is required for the metabolic production of thyroid hormones. During pregnancy,

maternal production of thyroid hormones increases dramatically, and the RDA increases accordingly, from 150 mcg per day for the general adult population to 220 mcg per day for pregnant women to 290 mcg per day for lactating women.

Healthy growth and neurological development of the fetus and of the breastfed infant are dependent on sufficient maternal intake of iodine, and inadequate intakes can result in neurologic and psychological deficits in children. Even mild deficiency during pregnancy is associated with cognitive impairment in the offspring. Although the general U.S. population has been considered to be iodine sufficient since the 1920's, urinary iodine values have declined substantially since the 1970's, likely due to reductions in the use of iodine-containing additives in breads and dairy products, the increasing use of non-iodized salt in processed and convenience foods, and new recommendations for reduced salt intake in the general population. NHANES data indicate that about 35% of pregnant women in the U.S. have iodine levels considered to be moderately deficient. [Leung, 2011; Caldwell, 2011]

The American Thyroid Association, the Endocrine Society, and the American Academy of Pediatrics have supported public health efforts to eliminate iodine deficiency during pregnancy and have recommended that women in North America receive a dietary supplement containing 150 mcg iodine daily during pregnancy and lactation.

The American Thyroid Association specifically "recommends that women receive 150 mcg iodine supplements daily during pregnancy and lactation and that all prenatal vitamin/mineral preparations contain 150 mcg of iodine." [Am Thyroid Assn, 2006]

The Endocrine Society states: "We recommend that once-daily prenatal vitamins contain 150-200 mcg iodine and that this be in the form of potassium iodide or iodate....Ideally, supplementation should be started before conception." Also: "We recommend that breastfeeding women maintain a daily intake of 250 mcg of iodine to ensure that breast milk provides 100 mcg iodine per day to the infant." [Endocrine Soc, 2012]

The policy statement by the American Academy of Pediatrics concludes: "Women should take a prenatal/lactation supplement with adequate iodide [defined as 150 mcg iodide provided as at least 197 mcg of potassium iodide]." [Am Acad Ped, 2014]

Conclusion

CRN appreciates the opportunity to comment on the important issue of revising the WIC food packages to provide increased support for the nutritional health of low-income pregnant and breastfeeding women and their infants and young children. Addition of a simple multivitamin/mineral supplement to the WIC food packages for eligible women would provide critical nutritional support and would be consistent with the recommendations of the 2015 *Dietary Guidelines for Americans*. Such a multivitamin/mineral should include 400 mcg folic acid, 150 mcg iodine, and appropriate amounts of other recognized shortfall micronutrients for this population.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "D. MacKay", with a checkmark-like flourish at the end.

Douglas MacKay, N.D.

Sr. Vice President, Scientific & Regulatory Affairs

Council for Responsible Nutrition

References

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