

• HISTORICAL NOTES •

The Primacy of Prevention: Folic Acid Fortification

Birth defects are among the main causes of infant death in both the United States and Puerto Rico (1). Birth defects also cause childhood morbidity, long-term disability, and may result in miscarriages and fetal deaths. Any intervention to reduce the incidence of these defects will therefore have widespread effects on the health and wellbeing of many. When the intervention is innocuous, inexpensive, politically acceptable, and easily implemented, failure to carry it out to its fullest potential is inexcusable. This is the case with the fortification of foods with folic acid, considered both “one of the 20th century’s clearest public health successes” (2) and a yet-to-be-completed task on the nation’s preventive agenda.

Since 1992, the Public Health Service, the Centers for Disease Control and Prevention (CDC), and other organizations involved in maternal and child health have recommended that women who could become pregnant take 400 micrograms of folic acid (a B vitamin) every day (3). This measure followed more than three decades of gradually-evolving research evidence, the most important and decisive emerging from a 1991 study by the British Medical Research Council Vitamin Study Group which was reported in the *Lancet* (4). This showed that folic acid taken before and during early pregnancy could reduce by up to 71 percent the number of birth defects of the brain and spine known as neural tube defects (NTD), two of the most common of these being spina bifida and anencephaly. These results were followed by a formal recommendation from the CDC: women who had previously had an infant or fetus with spina bifida, anencephaly, or encephalocele were urged to take 4 milligrams of folic acid supplementation a day (3).

Because most diets do not have enough folic acid to meet the desired level, the Public Health Service looked into three options to meet its recommendations and ensure adequate consumption of folic acid: improving dietary habits; fortifying foods with folic acid; and relying on dietary supplements containing folic acid (4). Each strategy had its proponents, and the battle lines were firmly drawn between 1992 and 1996. During this period, the Food and Drug Administration (FDA) reviewed additional unpublished studies and considered the alternatives suggested by the Public Health Service. Efforts to improve dietary habits would be long-term and likely to produce uneven results; supplements would have discriminated against the poorest women, who were at greater risk for neural tube effects (4). Although there was some concern that food fortification was too broad an intervention to target a specific demographic group, this strategy emerged as the most viable and efficacious.

In 1993 the FDA opted for food fortification, a historic action that represented the first food fortification act since the 1940s, a time during which flours and breads were enriched or fortified with vitamins and minerals. David Kessler, who understandably had misgivings about adopting a blunderbuss approach affecting the population as a whole, called the matter “one of the more difficult issues” he faced as FDA Commissioner (5).

In 1996 the FDA mandated that certain grain products and flours be fortified with folic acid. This mandate, which went into effect in January 1998, included the fortification of breads, macaroni products, rice, cornmeal, corn grits, and farina. This passive public health measure, requiring limited or no individual decision-making, had an important effect: a study carried out during the period October 1998 – December 1999 found that the reported prevalence of spina bifida had declined 31 percent and that of anencephaly 16 percent since the mandate had gone into effect (6).

But the drop in neural tube defects has not been sustained or consistent over time, nor has it affected all demographic groups equally. As a result, some of the intermediate gains have leveled off or reversed themselves, and some groups have lagged in benefiting from fortification. A report based on data from the National Health and Nutrition Examination Survey (NHANES) examined trends in serum folate and red blood cell (RBC) folate levels between 1999-2000 and 2003-2004. Comparisons between the two surveys found that serum folate concentrations among nonpregnant women in the childbearing ages decreased 16 percent during the period studied; RBC folate levels declined 8 percent (7).

In addition, the study found that median folate concentrations declined significantly among all three populations considered (non-Hispanic whites, non-Hispanic blacks, and Mexican Americans). The largest decrease occurred among non-Hispanic whites, but the lowest mean concentration of serum folate was found among non-Hispanic blacks. Equally important, between 1995 and 2002 there was no significant change in the prevalence of NTDs among infants born to non-Hispanic black women (7).

A more recent study also examined NHANES data, comparing pre- and post-fortification levels of RBC folate status by race/ethnicity and income level (8). This found that, although there were absolute gains registered among those with the lowest levels, the relative ratio of low folate status increased after fortification for the lowest compared with the highest income groups (from 1.27 to 2.08) and among whites compared with blacks (from 1.64 to 3.75). The authors therefore conclude that,

although all income and racial/ethnic groups in the US benefited in absolute terms from the FDA mandated policy, this overall improvement exacerbated disparities and “those individuals remaining with low RBC folate status following fortification were more concentrated in groups with lower income and non-Hispanic Black race” (8).

These findings suggest that fortification of some foods at the current level, while necessary, may not be sufficient to protect women and their children against the risk of neural tube disorders. There is therefore renewed interest in targeting those women who are not adequately protected, and widening the number of fortified products so that a broader range of foods are covered and the protective effects of folic acid benefit more people.

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