

## Inadequate folic acid intakes are prevalent among young women with neural tube defects

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Inadequate folic acid intake is linked to neural tube defects (NTD) (1,2), congenital anomalies (3) and other chronic diseases (4-6). Clinical trials indicate that periconceptional use of folic acid supplements (400-800  $\mu\text{g}/\text{day}$ ) can reduce the incidence of neural tube defects up to 70% (1,2). The Food and Drug Administration has required that all enriched foods be fortified with folic acid (140  $\mu\text{g}/100\text{ gm flour}$ ) (7). Because synthetic folic acid has twice the

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bioavailability of naturally occurring folate (8,9) and most pregnancies are unintended (10), the Institute of Medicine recommends that women take 400  $\mu\text{g}/\text{day}$  synthetic folic acid in addition to a varied diet (11). The Centers for Disease Control recommend that women who have had a prior pregnancy affected by neural tube defects should take 4,000  $\mu\text{g}/\text{day}$  folic acid when planning their pregnancies (12).

Women with spina bifida (the neural tube defect with the greatest chance for survival, 4.4 cases of spina bifida per 1000 live births in the United States) are at high risk for having children with neural tube defects (12,13). They are also at risk for poor folate nutriture because of chronic use of antibiotics (14), anticonvulsant medications (15), bladder augmentation surgery (16), and a potential defect in homocysteine metabolism (17), all of which increase folate requirements. Despite the increased risk for poor folate status, the adequacy of their folate intakes has not been reported. In this paper, we describe the adequacy (18) of usual dietary folate intake (naturally occurring food folate) and synthetic folic acid intake from fortified foods and supplements for a clinic-based sample of young women with spina bifida.

### SUBJECTS AND METHODS

The study population included all female patients born between 1965 and 1975 treated for spina bifida at the Kennedy Krieger Institute in Baltimore, Md, or the Alfred I. duPont Institute in Wilmington, Del. Individuals were excluded if they were pregnant or could not answer the questions for themselves in English. The study methodology was approved by the Institutional Review Boards at the Johns Hopkins Medical Institutions and the Alfred I. duPont Institute.

Participants' demographic information and medication use was collected via interview. Participants were queried about vitamin/mineral supplement use and their awareness of the recommendation for folic acid intake for women of childbearing age. To determine supplement use, respondents were asked, "During the past year have you taken any vitamins or minerals?" Answer categories were "no" (non-users), "yes, fairly regularly" (regular users) and "yes, but not regularly" (irregular users).

Naturally occurring food folate intakes were assessed using the 100-item food frequency portion of the Health Habits and History Questionnaire (19), which provides valid group mean nutrient estimates for naturally occurring food folate ( $\mu\text{g}/\text{day}$ ) (20). Synthetic folic acid intakes from supplements were estimated using the Dietsys Analysis Software and the DietSys 3.0 Foods database (version 3.0, 1988, Bethesda, Md.) (19).

Dietary data were collected before folic acid fortification of enriched flour and grain products was implemented in 1998 (9). However, to link our results to the current food supply, synthetic folic acid (folic acid from fortified grain products and supplements) intake was calculated assuming fortification of enriched grain products at 140  $\mu\text{g}$  folic acid/100 g flour. Synthetic folic acid content of grains was assigned to servings of breads, pasta and rice according to data provided by Hine (21). The DietSys software's calculation of folate intake includes synthetic folic acid from fortified ready-to-eat cereals (RTEC). Our estimation of naturally occurring food folate adjusts for this synthetic folic acid. Data from Schaller and Oson(7) was used to estimate synthetic folic acid for RTEC, which were fortified prior to 1998.

In this study, total folate intake combines naturally occurring food folate and synthetic folic acid from fortified foods and supplements. Total dietary folate equivalents (DFE) in  $\mu\text{g DFE}/\text{day}$  was

## RESEARCH AND PROFESSIONAL BRIEFS

estimated using the following equation (11):  $\text{ug of DFE} = \text{ug naturally occurring food folate} + [1.7 \times (\text{ug synthetic folic acid})]$ .

We used the probability approach to estimate the prevalence of inadequate DFE intake (11,18,22). The requirement distribution for DFE intake was derived from published information which assumes DFE intake requirements are normally distributed, the estimated average requirement is 320 ug DFE/day and recommended dietary allowance (RDA) is 400 ug DFE/day, and the coefficient of variation (CV) of the distribution is 10% (11, 18). We compared each individual's usual DFE intake with the DFE requirement distribution and calculated the area under the curve to the right of this level of intake as the probability of inadequacy (18,22). Summing the probabilities and dividing by the number of subjects provides an estimate of the prevalence of inadequate DFE intakes. Analysis of variance and  $\chi^2$  methods were used to compare intakes and adequacy across groups, with significance defined as  $P < .05$ . Analyses were performed using the Statistical Package for the Social Sciences for Windows (version 9.0, 1999, SPSS Inc., Chicago, Ill).

### RESULTS

The clinics provided 101 names of potential study participants, and 3 additional names were obtained through network sampling (23). Twenty-five women could not be contacted, and 17 were determined ineligible. Of 62 eligible women, 13 refused to participate, 1 woman was unable to schedule an appointment during the data collection period (April 1994 to February 1995), and 3 others had incomplete dietary data. Thus, a total of 45 women participated in the study.

The majority of the respondents were white, completed at least high school, and lived with their parents or another relative (Table 1). Mean age 23.8 years (range, 17 to 34 years). Few had ever married or had children. Approximately 75% of respondents took anticonvulsant and/or antibiotic medication.

Mean naturally occurring food folate intake [ $\pm$  standard error (se)] was  $178 \pm 21$   $\mu\text{g/day}$  (range, 12 to 690  $\mu\text{g/day}$ ) (Table 2). The main dietary sources of naturally occurring food folate were breads, cereals, rice, pasta, and orange juice. Respondents' projected synthetic folic acid intake from fortified foods (mean(se) after implementation of fortification was  $146 \pm 13$   $\mu\text{g/day}$  (30 to 426  $\mu\text{g/day}$ ). Only

one respondent achieved 400  $\mu\text{g/day}$  synthetic folic acid solely through fortified foods. Ten respondents met the 400  $\mu\text{g/day}$  synthetic folic acid recommendations; of these, 9 were supplement users. Average daily grain product intake (mean $\pm$ se) was  $2.3 \pm 0.2$  servings/day (0.5 to 7 servings/day). The number of respondents who consumed at least 1 daily serving of each of 3 types of enriched grain products examined was as follows: breads, 13 (29%); cereals, 12 (27%); and pasta or rice, 12 (27%). Thirty-one percent ( $n=14$ ) reported regular multivitamin use during the past year, and 26% ( $n=12$ ) reported irregular vitamin use. Respondents' projected synthetic folic acid intake was  $263 \pm 34$   $\mu\text{g/day}$  (range, 30 to 1020  $\mu\text{g/day}$ ). The mean ( $\pm$ se) total DFE was  $590 \pm 56$ . The estimated prevalence of inadequacy for dietary folic acid was 34%.

Table 2 compares folate intake and inadequacy of DFE intake by supplement use. Total folate intakes were similar between non-users and irregular users of supplements and they were grouped together for this comparison. Predictably, supplement users had higher total DFE intakes and were 7 times more likely to have adequate DFE intakes than non-users. However, total naturally occurring food folate intakes and synthetic folic acid intakes were not different from non-users. These results emphasize the role supplements play in consumption of folic acid for this population.

Only 41% were aware of recommendations for women to increase folic acid intake during childbearing years; awareness was not associated with supplement use, dietary or synthetic folic acid intakes, or inadequacy ( $P > .05$ ).

### DISCUSSION

In this sample of women with spina bifida, the estimated prevalence of inadequate DFE intakes was 34.2%. Further, only 31% regularly consumed supplements containing folic acid, and only 41% were aware of recommendations regarding folic acid.

The median dietary naturally occurring food folate intake of this sample (134  $\mu\text{g/day}$ ) was lower than the median intake of a national sample of US women, 19 to 30 years (223  $\mu\text{g/day}$ ) (24), but becomes comparable when synthetic folic acid from RTEC is added to our calculations. Thirty-one percent of women in this sample regularly consumed supplements containing folate as compared with 33% of US women (25). The level of

**Table 1**  
Characteristics of 45 women with spina bifida

Characteristics	Respondents	
	n	%
Age (y)		
17-20	9	20.5
21-23	16	35.5
24-26	8	17.8
$\geq 27$	12	26.7
Education completed		
<High school	4	8
High school diploma	20	44
>High school	21	48
Currently attending school	16	35
Race/ethnicity		
Non-white	6	13
Household composition		
Live alone	8	18
Spouse or significant other	5	11
Parents/guardian	21	47
Other relative	9	20
Roommate (non-relative)	2	4
Marital status		
Never married	35	79
Married	8	15
Separated/divorced/widowed	2	6
Parity (1 or more children)	4	9
Employment history		
Currently working full-time or part-time	22	48
Not working currently	9	29
Never worked	14	23
Social Security insurance recipient	30	66
Anticonvulsant/antibiotic medication use	34	75

**Table 2**

Total folate, synthetic folic acid intake and estimated prevalence of inadequate intake by supplement use among young women with neural tube defects

	Total N=45	Supplement users N=14	Nonusers N=31	P value <sup>b</sup>
	← mean ± SE <sup>a</sup> →			
Total folate intake ug/d	441±42	653±70	346±42	<.001
Total ug DFE <sup>c</sup> /d	591±56	893±98	454±53	<.001
Naturally occurring food folate ug/d	178±21	150±33	191±27	Ns
Synthetic folic acid from fortified foods ug/d	146±13	128±18	155±17	Ns
Synthetic folic acid from supplements ug/d	117±32	375±59	—	Na
Total synthetic folic acid ug/d	263±34	503±66	155±17	<.001
Prevalence (%) of inadequate DFE intake	34±7	7±7	46±9	.007

<sup>a</sup>SE=standard error.<sup>b</sup>Analysis of variance tests used to determine statistical differences between supplement users and non-users.<sup>c</sup>DFE=dietary folate equivalent.

awareness of recommendations regarding folic acid was also similar to the general US female population (26).

Although it has been reported that women can meet their folic acid needs through intake of fortified grains (27), the respondents in our study could not meet their needs in this way without increasing fortification levels of enriched foods. In this sample, supplement use was the best method of assuring adequate folic acid.

The results of this study should be considered in light of limitations related to food composition databases and data collection instruments used. The food composition database does not provide accurate estimates of naturally occurring food folate content in the United States and may underestimate the naturally occurring food folate intake and overestimate the probability of inadequate of folate intake in this population (11). However, this database contains the best known information about folate composition available and provides the first information on folate inadequacy for this population. There is lack of consensus on the suitability of food frequency questionnaires for estimating usual nutrient intakes of populations such as done in this study (28-32). Assessment of dietary intake was just one part of this study and limitations in resources required the use of a food frequency questionnaire.

Importantly, this population has higher folate needs than the general US population. Special attention needs to be paid to their folate intake because they are genetically predisposed to a disorder of

homocysteine metabolism (16), which requires more folate than the average person; they are taking medications that may further increase folate requirements (14,15); and they are of childbearing age and have a higher risk for having children with neural tube defects than the general population (12).



## APPLICATIONS

Health care providers need to increase awareness and urge adequate folate intakes among their patients, especially women with spina bifida (33). Although the optimal level of folic acid intake for this group is unknown, it is probably more than 400 µg/day (34). Therefore, a sensible approach would be to counsel all young women with spina bifida about sources of naturally occurring food folate and synthetic folic acid and to suggest folic acid supplements containing at least 400 µg/d.

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changes were considered primary study endpoints.

## METHODS

Healthy (ie, no significant health conditions) but overweight women (aged 18 to 55 years; body mass index [BMI] 25 to 32 kg/m<sup>2</sup>) who wanted to maintain a 20- to 40-lb weight loss but claimed difficulty in adhering to changed eating habits after several attempts were recruited via newspaper advertisement. Subjects were randomized to treatment with either the diet of low-energy/low-fat foods or to the diet of portion-controlled (premeasured) meal replacement shake powder that would replace 1 or more meals per day.

Both plans provided 1,200 kcal/day, with approximately 55% and 15% of total energy from carbohydrate and protein, respectively, and less than 30% from total fat. Intervention was minimal. Exercise was not monitored.

Lean body mass (LBM), body fat percentage, and fat mass assessments were made at baseline, 3 months, and 1 year. An instrument using pressure contact electrode bioelectric impedance current (model TBF-105, Tanita, Arlington Heights, Ill) measured the resistance to a small electrical current. Fat and LBM have different water and electrolyte contents and impede the current differently (7).

All assessments were made following an overnight fast, without shoes, and with subjects wearing light clothing by the same investigator. The same instruments were used as the balance-beam scale and the body composition analyzer. The study was IRB approved.

All participants were initially provided with several days worth of groceries (eg, fruits and vegetables). Women following the standard, 1,200 kcal traditional food diet received literature containing instructions for weight loss and healthful eating, including sample diets and exchange lists for variety (8-11). No counseling was provided. The meal replacement group was instructed to replace 3 meals per day with a milk-based meal replacement shake (vitamin fortified, H=220 kcal, 1.5 g total fat, 5 g fiber, 15 to 19 g protein), supplemented with fresh fruits and vegetables similar, with the exception of the meal replacement meals.

Subjects were required to come to the clinic in the morning, fasted, on key data collection days at baseline, Week 12, and Week 52. All subjects also came to the facility briefly once a month (any time of

# Liquid meal replacement vs traditional food: A potential model for women who cannot maintain eating habit change

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**A** 1,200 kcal/day balanced diet is considered the preferred weight loss treatment for overweight women who manage their weight primarily on their own (1,2).

Very-low-energy diets, pharmaceuticals, and surgery are generally reserved for the morbidly obese and obese patients with weight-associated medical

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problems (1-3). Although a 1,200 kcal/day diet program should produce weight loss in overweight women, weight regain is probable, as permanent changes in eating and lifestyle habits are difficult to accomplish (4-6).

This study compares the effects on body weight and body composition of 2 diet plans similar in macronutrients followed over a 1-year period. The study attempted to duplicate free-living by using minimal intervention and enrolling healthy women wanting to lose weight without help from a health professional (ie, no obesity-related health problems). The 2 diets differed. One plan incorporated liquid meal replacements into the program. The other plan followed a more traditional diet plan of low-fat and low-energy foods (no meal replacements). Body weight and body composition

**Table**

Body weight, fat mass, % fat, and lean body mass: mean, change from baseline, and treatment differences for women using liquid meal replacement or traditional food diets

	n	Baseline	Week 12	Week 52
← mean±standard deviation →				
<b>Weight (kg)</b>				
Meal replacement	28	75.2±6.9	69.2±6.4	68.9±7.7
Traditional food	33	77.5±7.5	73.7±7.6	76.2±9.4
← mean±standard error →				
<b>Weight change (kg)</b>				
Meal replacement	28	...	-6.3±0.6	-6.4±0.9
Traditional food	33	...	-3.8±0.5	-1.2±0.7
Treatment difference			<i>P</i> <i>CI</i> .008** (-4.0, -0.6)	<i>P</i> <i>CI</i> .000*** (-8.8, -2.8)
← mean±standard deviation →				
<b>Fat mass (kg)</b>				
Meal replacement	28	32.8±5.9	26.8±5.0	27.5±6.7
Traditional food	33	34.5±6.2	30.3±6.2	33.9±7.9
← mean±standard error →				
<b>Fat mass change (kg)</b>				
Meal replacement	28	...	-6.0±0.8	-5.3±0.9
Traditional food	33	...	-3.9±0.6	-0.9±0.9
Treatment difference			<i>P</i> <i>CI</i> .050* (-4.1, 0.1)	<i>P</i> <i>CI</i> .002** (-6.6, -1.5)
← mean±standard deviation →				
<b>Fat %</b>				
Meal replacement	28	44.0±5.0	38.9±4.8	39.7±5.9
Traditional food	33	44.8±5.2	41.7±5.6	44.5±6.8
← mean±standard error →				
<b>Fat % change</b>				
Meal replacement	28	...	-5.1±0.7	-4.3±0.9
Traditional food	33	...	-3.1±0.7	-0.3±0.8
Treatment difference			<i>P</i> <i>CI</i> .060 (-4.0, 1.0)	<i>P</i> <i>CI</i> .002** (-6.3, -1.5)
← mean±standard deviation →				
<b>Lean body mass (kg)</b>				
Meal replacement	28	41.4±4.0	41.8±3.9	40.9±3.8
Traditional food	33	42.2±4.5	42.4±4.7	41.6±5.0
← mean±standard error →				
<b>Lean body mass change (kg)</b>				
Meal replacement	28	...	-0.4±0.3	0.5±0.3
Traditional food	33	...	-0.3±0.4	0.6±0.5
Treatment difference			<i>P</i> <i>CI</i> .588 (-0.8, 1.5)	<i>P</i> <i>CI</i> 0.782 (-1.0, 1.3)

\**P*<.050.

\*\**P*<.010.

\*\*\**P*<.001.

day), to report any medications taken or side effects and to obtain meal replacement powder packets (if indicated). All subjects participating received \$400 (in quarterly increments) over the course of the study. The meal replacement group received free powder packets, but had to purchase skim milk for preparation.

For both groups, significance levels of mean changes from baseline were assessed by paired *t* test. The differences between treatment groups at baseline, Week 12, and Week 52 were assessed by independent *t* tests. The means are pre-

sented with the confidence intervals and standard deviations. All tests are 2-tailed.

**RESULTS**

Seventy-five (N=75) women enrolled and 64 completed all 52 weeks. Dropouts were evenly distributed (6 meal replacement, 5 traditional food). Three subjects were eliminated from the analysis as their BMI was < 25. No significant side effects were reported. Both treatment groups were similar at baseline for age (meal replacement: 36.1 ± 7.2 years; traditional food: 37.5 ± 6.2 years) and BMI (meal

replacement: 28.6 ± 1.7; traditional food: 29.2 ± 1.7).

At 3 months, subjects from both groups had significant reductions from baseline weight and body fat without loss of lean body mass (0.3 to 0.4 kg gain for both groups; see Table). There were no significant differences in fat reductions.

After 1 year, the meal replacement group maintained their initial (Week 12) weight/fat loss, whereas the traditional food group regained most of their initial weight and fat losses. Treatment differences were significant for weight (*P* <.001), fat mass (*P* <.002), and percent fat (*P* <.002), but not LBM.

**DISCUSSION**

Portion sizes, ignorance of food composition, frequency of eating, and overconsumption of foods high in fat and energy are factors that contribute to the failure of weight control after dieting (12-14). Permanently changing eating habits may not be achievable for some, and should perhaps be factored into developing long-term solutions for weight control. Other factors, such as environment and stress, contribute to weight control failure (15-19). Therefore, meal replacements may be a useful tool for women unable to alter their eating habits enough to maintain a lower weight. Meal replacements also require a change in eating, but the change is relatively straightforward, involving only 1 daily meal. This routine provides a constant that reduces daily energy intake, preventing weight regain even if he or she returns to previous eating habits at other meals. Similar results have been reported for periods up to 5 years (20-22).

Meal replacement plans have been criticized for not contributing to improved eating habits because they replace entire meals, transiently removing the food choice and portion size problems at the meal they replace (4,16,17,23). The person therefore never learns or adopts the eating habits necessary to keep unwanted weight from returning. In our study, meal replacements were not stopped, but reduced in frequency of use to control weight. Although both treatment groups followed diets similar in energy and nutrient content (and initially had similar weight and fat losses), the traditional food group regained by the end of the study. Providing pamphlets and exchange lists initially worked but did not sustain the subject for the entire year of the study. Diet improvements and compliance with better eating habits appeared