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Futures Project- Folic Acid and NTDs Intervention for Hispanic Women of Childbearing Age

BACKGROUND OF FOLIC ACID AND NEURAL TUBE DEFECTS

Folic acid is a B vitamin needed to make healthy new cells. Folic acid is a synthetic form of folate, which is found naturally in foods such as green leafy vegetables, dried navy and other beans, lentils, nuts, orange juice, and some fortified cereals.[1] Women who are planning to become pregnant need to consume an adequate amount of folate or supplement with folic acid to help prevent birth defects such as neural tube defects (NTDs).

NTDs affect approximately 3,000 pregnancies each year in the United States (U.S.).[2] Formation of the neural tube, the embryonic precursor to the brain and spinal cord, occurs during the fourth week of human gestation.[2] NTDs happen when the tube does not close completely. This can cause spina bifida, anencephaly, and even encephalocele. Spina bifida is the most common NTD and it affects about 1,500 babies a year in the US. The bones of the vertebra do not close completely and a part of the spinal cord pokes through the spine. Spina bifida can be treated by surgery before or after birth. Paralysis of the legs as well as problems controlling their bladder and bowel are common complications of this NTD. Anencephaly is one of the most severe NTDs. 1,000 babies in the US are affected each year. This condition occurs when the upper part of the neural tube that forms the brain does not close all the way. Babies with anencephaly are missing parts of their brain, skull, and cap. Sadly, babies with anencephaly do not survive long after birth if only for a few hours. Girls are three times more likely than boys to have anencephaly. A very rare NTD, encephalocele, only affects about 275 babies each year in the U.S. Encephalocele is a condition where a sac that contains the membranes that cover the brain pokes through an opening in the skull. Part of the brain gets poked through either at the base of the skull where it meets the neck, between the forehead and nose, or in the middle of the upper part of the skull. Babies with encephalocele usually need surgery to place back parts of the brain in to the skull and then close the opening. The outlook for children with encephalocele usually includes intellectual disabilities (75% of affected), movement problems or paralysis, vision problems, and/or seizures.[2]

Megan Ann McCrory 5/7/15 9:45 AM
Comment: Too casual; use protrudes for example

Megan Ann McCrory 5/7/15 9:45 AM
Comment: Same comment

In 1992, the U.S. Public Health Service issued a recommendation that all women in the U.S. capable of becoming pregnant should consume 400 mcg of folic acid daily to reduce their risk of having an NTD-affected pregnancy.[1] In 1998, the U.S. Food and Drug Administration mandated enrichment of cereal grain products with folic acid. Prior to the mandate, approximately 4,000 pregnancies per year were affected by a NTD in the U.S.[3] A 36% decrease in the NTD rate was observed from the period prior to fortification (1995–1996) to the period following fortification (1992-2000).[3]

HISPANIC WOMEN

The Hispanic population is among the fastest growing in the U.S., representing 14.2% of the U.S population.[4] This population has higher fertility and birth rates than non-Hispanics. Additionally, they are more likely to have children at a younger age and continue having children into older age. Finally, although the rate of unintended pregnancies among poor women is high regardless of race or ethnicity, it is highest among poor Hispanic women.[4] While the rates of NTD-affected pregnancies have declined, rates are still higher among Hispanic women. Nationally, Hispanic women have a rate of 4.17 per 10,000 for having a child affected by spina bifida compared with the rate for non-Hispanic white women (3.22 per 10,000) and the rate for non-Hispanic black women (2.64 per 10,000).[3] Disparities also exist in the consumption of folic acid, with 13% of Hispanic women reporting daily folic acid consumption compared to 31% of non-Hispanic white women. Given the disparity in NTD rates for Hispanics, their high birth rates, and their unplanned pregnancy rates, targeted preconception and pregnancy-related information for this audience could significantly impact NTD rates.[3]

LITERATURE REVIEW

Megan Ann McCrory 5/7/15 9:52 AM
Comment: A more specific subtitle would be preferable, as what you have up above is also literature review.

Various studies have been conducted considering the effects of the use of educational materials on folic acid intake in pregnant women and women of childbearing age. One study conducted in grocery stores frequented by Latina residents of Detroit, Michigan utilized various educational materials such as a recipe card with a culturally appropriate recipe supplying 75 micrograms of folate per serving and bilingual folic acid education curriculum and handouts. The study employed a 12-item survey designed and administered to participants in grocery stores to assess knowledge, awareness of, and sources of folic acid. Limitations to this study included difficulty reaching the priority population of Latina women of childbearing age in supermarkets.[5]

Megan Ann McCrory 5/7/15 9:53 AM
Comment: What were the questionnaire results of the study?

Another study implemented the use of 'promotoras', which are cost-effective community health workers or lay health educators that are employed by various health programs to influence behaviors among different racial and ethnic groups. One promotora conducted a baseline survey, an educational intervention workshop, a 2-month follow-up telephone call, and a 4-month post-intervention survey to all participants of the study. Pre- and post-surveys asked questions about current vitamin consumption, awareness and knowledge about folic acid and NTDs. The 2-month follow-up telephone call allowed the promotora to discuss participants' current consumption of a multivitamin with folic acid. The educational workshop consisted of a 30- to 45-minute class ranging from 1-10 participants and was held at various places in the community. This study was successful in significantly increasing knowledge and awareness of folic acid as well as consumption of folic acid supplements via phone calls and educational classes. The use of one promotora was a limitation of the study as he/she was unable to recruit and retain ample participants throughout the length of the study due to inability to schedule workshops for everyone to attend. Implementing the methods of this study on a larger scale with the use of more than one promotora could better validate the results.[3]

A systematic review looking at 30 studies evaluating the effectiveness of folic acid supplementation and fortification found that studies including a folic acid campaign were effective at raising awareness and knowledge of the importance of folic acid in the reduction of NTDs. The folic acid campaign included information about folic acid and NTDs in pamphlets as well as advertising other available resources. 8 large cohort studies assessed the effectiveness of fortification in the reduction of NTD prevalence rates and found the prevalence of spina bifida and anencephaly to decrease varying between 16% and 60%.[6]

Many interventions have been done in hopes of increasing folic acid intake and knowledge in women of childbearing age. A systematic review was conducted to review 31 studies that focused on increasing awareness, knowledge and consumption of folic acid before and during pregnancy. The women in the studies ranged from 15 to 49 years old and overall, awareness increased from 60-72%, knowledge from 21-45% and consumption from 14 to 23%. Unfortunately, the average usage of folic acid after intervention was only 25%. The review suggested the need to develop strong social marketing strategies to achieve an increase of folic acid consumption.[7]

Megan Ann McCrory 5/7/15 9:56 AM
Comment: Huge difference! Any thoughts as to why such variability among studies that could inform your intervention?

Megan Ann McCrory 5/7/15 9:57 AM
Comment: Usage? Does this mean taking supplements? If dietary intake, it is not expressed as usage. Also 25%--does this mean 25% of recommended intake or 25% of the sample? Unclear.

Hispanic women have the highest prevalence of births with NTDs therefore several interventions have been done to target this specific population. A folic acid promotion effort was designed to increase folic acid awareness, knowledge, and use of vitamins folic-acid containing vitamins in order to prevent birth defects among Hispanic women who are open to becoming pregnant in the next year or future. The intervention was conducted through public service announcements (PSAs) and media, and women were surveyed after each 3-month media campaign. The study found that women preferred health information in Spanish, and the most popular source of information was television, print, and verbally through their healthcare providers. These results are beneficial for the development of our intervention. This study showed that Spanish-speaking print sources are a beneficial way to provide information to women and that women of childbearing age are interested and willing to learn about folic acid and take a folic acid supplement.[4]

One non-experimental descriptive correlational investigation using an investigator-designed survey to collect data aimed to describe the folic acid awareness, folic acid intake, and pregnancy intention of young women aged 18–24 years in North Carolina. The results showed nearly half of the young women could identify folic acid rich food sources and identify that supplementation may prevent birth defects, but only 5% of the young women indicated the recommended daily allowance of folic acid. This study was beneficial to our intervention project because it shows the challenge in educating 18-24 year old non-pregnant women. This study sets a solid foundation for this population group for future studies.[8]

Megan Ann McCrory 5/7/15 10:00 AM
Comment: Indicated they consumed? Or were aware of?

In another study, a questionnaire was sent to randomly selected obstetricians/gynecologists (OB/GYNs) and urologists residing in Japan, South Korea, Taiwan, North America, Europe, Australia and New Zealand by post or e-mail to globally investigate awareness among OB/GYNs and urologists regarding the role of folic acid intake preconception and their attitudes toward the lifestyle of young women of childbearing age. An average of 85% of doctors believed information on folic acid should be disseminated to young women. This specific study is important to future interventions

Megan Ann McCrory 5/7/15 10:00 AM
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because it demonstrates the need to communicate with physicians on educating their female patients on folic acid.[9]

Another study utilized focus groups to discuss and explore motivators and barriers to folic acid supplementation use before and during pregnancy. This study is beneficial to our intervention project because it gives real insight on folic acid consumption before/during pregnancy. This study highlights the low observance of folic acid supplement recommendations and illustrates some key reasons why this occurs. The results provide guidance on areas that might be emphasized or incorporated into education programs, including the importance of daily folic acid supplement use, the severity of NTDs and the evidence regarding risk reduction. The importance of instigating appropriate communication strategies in the interpartum period (in addition to the conventional focus on first pregnancies) is also highlighted.[10]

Various studies have highlighted the use of educational materials, workshops, focus groups, and survey administration to women of diverse ethnic and racial groups, while some specifically targeted Hispanic women, in order to increase knowledge and awareness of folic acid supplementation and dietary intake and the risks of NTDs.

FUTURE TRENDS

According to the Healthy People 2020, 23.8% of nonpregnant females ages 15 to 44 years reported a daily total intake of at least 400 micrograms of folic acid from fortified foods or supplements in 2003-2006. The goal is to increase intake from 23.8% to 26.2% by the year 2020.[11]

Educational campaigns targeted at specific racial groups have tried to increase folic acid among women of childbearing age but the consumption is still not enough. Studies have shown that 70% of NTDs could have been prevented if the women took folic acid around the time of conception or in very early pregnancy. As stated previously, Hispanic women have the highest fertility rates among all ethnic/racial groups and also have the highest prevalence of neural tube defects. To be the most effective, a nutrition intervention needs to target the staple food products in a Hispanic diet to increase folic acid consumption. It would be beneficial to fortify corn masa flour with folic acid because this is consumed daily by the Hispanic population. Corn masa flour is used to make tortillas, tamales, and other staples in the Hispanic diet.[12] Corn masa flour receives $8 billion in sales, with Hispanic Americans being the primary consumer.[13]

An analysis found that fortification of corn masa flour would increase the intake of total daily folic acid in Mexican American women of childbearing age by approximately 20%.[14] Corn masa flour is already fortified with folic acid in Latin American countries, but the U.S. has not followed suit. The FDA was approached nearly three years ago, asking that corn masa flour be fortified, but the FDA claims that it may be risky and requests that food laboratory studies be conducted to determine the safety of fortification, specifically the stability of folate in corn masa flour. The Centers for Disease Control estimated that the fortification of corn masa flour would protect 120 Hispanic newborns from NTDs each year.

By 2025, we believe the FDA will have approved the fortification of corn masa flour. Because of this, the most effective intervention will be targeting the consumption

Megan Ann McCrory 5/7/15 10:01 AM
Comment: 85% seems pretty high to me (since doctors are not well-trained in nutrition). So it seems the message is getting through already…or are you striving for 100% because the more the better. Unclear.

Megan Ann McCrory 5/7/15 10:03 AM
Comment: IF this is a summary paragraph you'd want to briefly summarize the results in a sentence or 2, such as the educational approaches have been generally effective but when they do fall short what the problem is (which you could be sure to take into account in your intervention).

Megan Ann McCrory 5/7/15 10:06 AM
Comment: Nowhere so far in the proposal have you said what the RDA is.

Megan Ann McCrory 5/7/15 10:09 AM
Comment: Needs a citation.

of folic acid fortified corn masa flour, along with other folic acid rich foods in Hispanic women of childbearing age.

INTERVENTION

Our mission is to decrease NTDs in Hispanic pregnancies through proper consumption of folic acid. The purpose of this intervention is to educate Hispanic women of childbearing age on the importance of folic acid intake as well as increase consumption of folic acid rich foods before pregnancy. Our intervention aims to increase knowledge and intake of folic acid in the diet as well as the benefit of preventing NTDs in Hispanic women of Mexican descent between the ages of 18-24 years old who are not currently pregnant through the use of Spanish educational materials in print, television, and social media platforms.

STUDY DESIGN

The ideal personnel for conducting this intervention would be fluent in both Spanish and English in order to translate material for the women participating. The candidate(s) would be a registered dietitian (RD) and have over five years of experience in prenatal nutrition. This will be a leadership position, which requires strong organizational, communication and social skills.

For our intervention, we will recruit 50 participants, 25 for the control group and 25 for the intervention group. We will strive for a 75% retention rate. We will place advertisements in WIC clinics, doctor offices, Centro Internactional De Maternidad (CIMA), family planning clinics and grocery stores in Gwinnett County. On the advertisements, we will include the incentives, the commitment time, and the inclusion criteria. The incentive for participating is a $50 gift card to a local grocery store and is available to all participants who complete the 3-month commitment. The inclusion criteria includes 18-24 year old women, Hispanic women born in Mexico, living in the U.S., and women who are currently not pregnant or not planning to be pregnant in the next three months.

We will hold classes at the Norcross CIMA and each class will be held at the beginning of every month. The first class will include the intervention and control groups. The participants will be given an anonymous pre-intervention survey. This survey will ask about folic acid knowledge. Some of the questions on the survey include:

"Have you ever heard of folic acid before?"
"Do you know what neural tube defects are?"
"Are you currently taking any supplements?"
"How much folic acid does a women of childbearing age need?"

We will also have each participant fill out a validated food frequency questionnaire (FFQ) to measure current folic acid intake. The first class will provide general information on folic acid and NTDs, the importance of adequate folic acid intake before pregnancy, and the adequate amounts of folic acid. The class will be in a relaxed setting with encouraged discussion amongst the participants. We will randomly

Megan Ann McCrory 5/7/15 10:13 AM

Comment: If both are in the same class how will you prevent cross-contamination of information? You haven't said what the difference in treatment is between the two groups. Ok I do see it scanning ahead below, but a general overview is important. At the beginning of this section you say you are going to do a randomized controlled trial in which both groups will received educational materials, only the intervention group will receive special training on selecting folic-acid rich foods at a grocery store and in preparing them through hands-on cooking demos. You also want to justify your approach with sources to back up that the hand-on approach will be more effective at increasing intake of folic acid rich foods. I don't see that standing out strongly in your lit review.

Megan Ann McCrory 5/7/15 10:28 AM

Comment: In your evaluation section it seems as though you have a particular FFQ in mind which targets folic acid consumption. You should state what it is and cite it here. Also state how it was validated and provide some stats on that.

divide participants into control and intervention groups and provide each person with written instructions on the next step of the study.

The second class will include the intervention group only and will be held at a local grocery store. The RD will take the participants on a local grocery store tour and emphasize folic acid rich foods. The RD will use the Shop Well phone app, which will help the participants know which foods are rich in folic acid. The participants can select folic acid from a list of nutrients, and the app will give a list of all foods rich in folic acid. Also, the participants can scan a food item and the app will give the amount of folic acid in that item. This app will be very beneficial when grocery shopping and choosing folic acid rich foods.

The third class will include the intervention group only and will be held at the Norcross CIMA. The class will consist of a hands-on food demonstration. The food demonstration will teach participants how to cook with folic acid rich foods and provide recipes for the participants to use at home.

On the fifteenth day of every month, both the control and the intervention groups will receive Spanish educational print materials in the mail with the information that was covered in the previous class. Materials will be mailed to all participants every month throughout the intervention period. Also, a commercial will be played on two popular Hispanic television channels, Telemundo and Univision, one time per day (between 7 PM- 8 PM). The commercials will address folic acid importance, NTDs information, the adequate amount of folic acid, and folic acid rich foods.

At the end of the intervention, both groups will come to the Norcross CIMA to take the post-survey and fill out the validated food frequency questionnaire. At the end of the intervention, all participants who completed the study will receive the $50 grocery store gift card and the control group will have the opportunity to receive the same classes that the intervention group received. The results will be analyzed to assess the effectiveness of the intervention.

Megan Ann McCrory 5/7/15 10:29 AM

Comment: Need to cite this. Also, this is great but you needed to address the use of apps such as this in your lit review, not just include it because it was required. This would include not only the effectiveness of such apps in increasing desired intake but also on the ability of your population to use the app. Is there Spanish version too (since you indicated in one study a preference for materials in Spanish).

Megan Ann McCrory 5/7/15 10:35 AM

Comment: Need to provide some data to justify this statement.

Megan Ann McCrory 5/7/15 10:21 AM

Comment: You could see a greater increase in folic acid rich foods in your intervention group compared to the control group simply because you are giving them more attention with the grocery store tours and cooking demos. Ideally, you would also do these activities in your control group but direct those more towards healthy foods in general. This way they have the same attention.

TIMELINE

- January 2024- January 2025:
  - Development of curriculum and organization of material to use for advertisement
- February 2025:
  - Distribute advertising at local WIC, doctor offices, CIMA, family planning clinics, grocery store, and MARTA buses/bus stops
- March 5, 2025:
  - First class where Pre and Post Survey distributed to 50 candidates.
  - Candidates are randomly split into two groups: Control group and Intervention Group
- March 5, 2025-June 4, 2025:
  - Commercial will be played on two popular Hispanic television channels, Telemundo and Univision, one time per day (between 7 PM- 8 PM)
- March 15, 2025:
  - Intervention and control group will receive Spanish educational print materials in the mail with the information that was covered in the previous class
- April 5, 2025:
  - Intervention group meets at CIMA in Norcross for second class. At this time the group will be given a grocery store tour at local grocery store, walk through the store and point out folic acid rich foods (intervention only) use of Shop Well app

- April 15, 2025:
    - Intervention and control group will receive Spanish educational print materials in the mail with the information that was covered in the previous class
- May 5, 2025:
    - Intervention group meets at CIMA in Norcross for third class. During this class the group will be given a food demo with folic acid rich foods and take a post-survey.
- May 15, 2025:
    - Intervention and control group will receive Spanish educational print materials in the mail with the information that was covered in the previous class
- June 5, 2025:
    - Intervention and control group will meet at CIMA in Norcross to take post-survey.
    - Participants who completed the 3-month study will receive a $50 grocery store gift card

EVALUATION

Data from the pre- and post-surveys completed by the control and intervention groups will be evaluated using SPSS and evaluating the mean and standard deviation for folic acid intake. We will also evaluate and compare frequencies for each categorical question. Results of $p < 0.05$ will be considered statistically significant. Folic acid intake will be measured using a validated food frequency (FFQ) tool. The validated FFQ targets folate-rich foods and asks how often they consumed each food item over the last month (per week, per month, per day) and the quantity of each food item consumed. Food models will be used at the time of the survey to help participants identify portion sizes. Nutrient intakes will be computed using an in-house FFQ calculator. This FFQ calculator is based on the participant's frequency of consumption, amount of the item consumed (calculated as 0.5 for smaller than and 1.5 for larger than average serving size) and amount of folate in the serving size indicated. Nutrient values for each food item will be derived from the United States Department of Agriculture (USDA) National Nutrient Database for Standard Reference.[15]

GENIE RESULTS

We utilized the Guide for Effective Nutrition Interventions and Education (GENIE) tool to evaluate our research proposal and received a score of 28 out of 35 possible points.[16] The area we were lacking in was sustainability. We did not discuss the continuation of our intervention and we did not consider our intervention to partner and collaborate with other programs. Looking back, we may be able to consider using CIMA's facility in Norcross as a partnership and could involve them in the development of the class curriculum and advertisement for the intervention.

References

1. Genetic Center. What You Should Know About Folic Acid. *Cent Dis Control*. http://www.cdc.gov/ncbddd/folicacid/documents/wsk.pdf.

2. Denny K, Jeanes A, Fathe K. Neural Tube Defects, Folate, and Immune Modulation. *Birt Defects Res A Clin Mol Teratol*. 2013;97(9):602-609.

3. deRosset L, Mullenix A. Promotora de Salud: Promoting Folic Acid Use Among Hispanic Women. *J Womens Health*. 2014;23(6):525-531.

4. Prue C, Flores A, Hamner H. Effects of folic acid awareness on knowledge and consumption for the prevention of birth defects among Hispanic women in several U.S communities. *J Womens Health*. 2010;19(4):689-698.

5. Srimathi K. Folic Acid and the Prevention of Neural Tube Defects: A Survey of Awareness Among Latina Women of Childbearing Age Residing in Southeast Michigan. *Health Promot Pract*. 2007;8(1):60.

6. Temel S. Evidence-Based Preconceptional Lifestyle Interventions. *Epidemiol Rev*. 2013;36(1):19-30.

7. Chivu CM, Tulchinsky T. A Systematic Review of Interventions to Increase Awareness, Knowledge, and Folic Acid Consumption Before and During Pregnancy. *Am J Health Promot*. 2008;22(4):237-245.

8. Hilton J. A comparison of folic acid awareness and intake amoung young women ages 18-24 years. *J Am Acad Nurse Pract*. 2007;19(10):516-522.

9. Kondo A, Kamihira O, Lin H. Folic Acid Prevents Neural Tube Defects: International Comparison of Awareness among Obstetricians/Gynecologists and Urologists. *J Obstet Gynaecol Res*. 2007;33(1):63-67.

10. Macleod M, Barbour R, Mires G. Uptake of folic acid supplements before and during pregnancy: focus group analysis of women's views and experiences. *J Hum Nutr Diet*. 2012;26(2):140-147.

11. Maternal, Infant, and Child Health. *HealthyPeople.gov*. https://www.healthypeople.gov/2020/topics-objectives/topic/maternal-infant-and-child-health/objectives#4842.

12. McCullough M. Folic acid fortification to prevent birth defects his FDA roadblock. 2015. http://articles.philly.com/2015-02-15/news/59145605_1_acid-fortification-neural-tube-defects-folic-acid.

13. Smith MA, Oakley G. Folic Acid Fortification: How a Tortilla Could Be the Perfect Plug for a Hole in the Dike. *Teratol Soc*. 2015. http://connection.teratology.org/p/bl/et/blogid=17&blogaid=374.

14. Fleischman A, Oinuma M. Fortification of corn masa flour with folic acid in the United States. *Am J Public Health*. 2011;101(8):1360-1364.

15. Pritchard J, Seechum T, Atkinson S. A Food Frequency Questionnaire for the Assessment of Calcium, Vitamin D and Vitamin K: A Pilot Validation Study. *Nutrients*. 2010;2(8):805-819.

16. Guide for Effective Nutrition Interventions and Education. *Acad Nutr Diet*. http://genie.webauthor.com/public/partner.cfm?partner_name=GENIE.