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Women's Knowledge and Attitudes about the Role of Folic Acid in Preventing Neural Tube Defects

By

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By

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Emory University
2013

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An abstract of
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Abstract

Women's Knowledge and Attitudes about the Role of Folic Acid in Preventing Neural Tube Defects

By Katherine Lean

Background: Research has confirmed that neural tube defects can be prevented in pregnant women who take supplemental folic acid prior to conception until the end of the first trimester. Many women are unaware of the role of folic acid in the health of their unborn child. There is limited qualitative research regarding women's understanding of folic acid and how this shapes behaviors.

Objective: The purpose of this qualitative analysis was to understand the beliefs and attitudes of women of childbearing age who are capable of becoming pregnant towards folic acid and its importance in the prevention of neural tube defects.

Methods: A thematic analysis was conducted on secondary data from 16 focus group discussions with of women of childbearing age capable of becoming pregnant.

Results: This study showed that women study participants of reproductive age were unaware of the role that folic acid played in preventing neural tube defects. The information that women desired was simple, comprising concise facts about folic acid supplementation. After women learned about the importance of folic acid, their responses were typically of surprise, empowerment or skepticism. When asked of their current habits of vitamin consumption, intake was often inconsistent and required cues to action. Other barriers to folic acid intake were the cost of the supplements, side-effects and a lack of knowledge.

Conclusion: Twenty years after the proof that folic acid would prevent neural tube defects, most women of reproductive age still do not take folic acid vitamin supplements, a reminder of how difficult it is to change behavior and a reminder that fortification of foods needs to occur in conjunction with supplementation. An increase in the quantity and quality of information to women by healthcare professionals about folic acid and its role in the prevention of neural tube defects may aid in prevention. Additionally, an increase in health communication materials that address the importance of folic acid supplementation is needed. A mobile phone application which serves as a cue to action and a portal for folic acid information could be an effective tool for increasing consumption of supplements.

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Chapter 1: Introduction

Background of the Problem

Neural tube defects (NTDs) are birth defects that affect the brain and spinal cord of a developing fetus [1]. In a normal fetus, the neural tube, which forms the baby's brain and spinal cord, begins as a sheet of tissue in which the ends fold together to form a tube by the 28th day of pregnancy. In children who are born with neural tube defects, the neural tube does not fold together completely, leaving a gap in which nerves, tissues, fluid and the spinal cord can pass through leading to severe neurological and/or developmental defects[1]. If the neural tube fails to close near the brain of the developing fetus, anencephaly occurs. Anencephaly is a severe birth defect in which babies are born without sections of the brain and skull, leading to stillborn births or death within the first few hours of life[1]. If the segment of the neural tube leading to the formation of the spinal cord does not close, spina bifida occurs. Spina bifida is a birth defect of the vertebrae and spinal cord with varying severities which can lead to developmental disabilities, paralysis and decreased bowel and bladder function. Anencephaly and spina bifida are serious health concerns however, recent research has shown that taking folic acid can significantly reduce neural tube defects in pregnant women if taken correctly.

Over the past century, researchers have discovered the importance of B vitamins in human development. One B vitamin in particular, vitamin B9 which is commonly referred to as folic acid, has proven to be especially beneficial for pregnant women. The earliest report of a connection between the use of a B vitamin to cure a disease of folate deficiency in humans was in 1931 in India where Dr. Lucy Wills found that her patients who were

suffering from a lack of red blood cells due to a B12 deficiency ("pernicious anemia") during pregnancy benefitted from vitamin B supplements[2]. Since then, millions of women have benefitted from the use of folates in pregnancy related anemia. However, it wasn't until an article was published in the Lancet in 1991 by Sir Nicholas Wald[3] that the connection was made between folic acid and spina bifida and anencephaly. Wald conducted a randomized control trial to show that these neural tube defects can be prevented in pregnant women who take supplemental folic acid. This study ignited a fire under policy makers and the Food and Drug Administration and ultimately led to a requirement that all enriched grains be fortified with 140 micrograms of folic acid per 100g of flour by January 1st, 1998. This level of fortification led to almost all Americans consuming about 138 micrograms of folic acid from eating products that the FDA required to be fortified. Fortification efforts have led to an increase in the serum folate levels and a decrease in the prevalence of anemia related to folate deficiency[2]. When consumption of fortified foods is augmented with folic acid supplementation, the likelihood of having a child born with spina bifida or anencephaly may be lessened. In countries such as the United States and Canada, where there has been mandatory folic acid fortification programs, the population consumes nearly one-third of the recommended daily dose of folic acid and the large majority of spina bifida and anencephaly have been prevented. In the United States, fortification programs exist and so the focus shifts away from fortification and towards ensuring that women are increasing their intake of folic acid supplements. In countries lacking a nationwide fortification plan, the combination of efforts to implement folic acid fortification as well as encouraging the intake of supplements is preferred.

After Wald's study was published, the Centers for Disease Control and Prevention recommended that any woman who has previously had a child born with spina bifida or anencephaly should consume 4000 micrograms of folic acid daily in order to prevent future children from being born with folic acid preventable neural tube defects[4]. Since this fortification mandate, public health officials noticed that there was a 27% decrease in pregnancies affected by spina bifida and anencephaly due to the initiation of fortification efforts[5]. Today, the Centers for Disease Control and Prevention has recommended that all women of childbearing age capable of becoming pregnant consume 400 micrograms per day of folic acid to decrease their risk of having a child born with spina bifida or anencephaly[4]. The health of future generations has been improved by the implementation of this nutritional intervention.

Statement of the Problem

In the United States, 1,500 babies are born each year with spina bifida[6]. In order to magnify the effects of folic acid on preventing neural tube defects, it is recommended that all women of childbearing age who are capable of becoming pregnant should consume 400 micrograms of folic acid daily. However, at least half of all pregnancies in the United States are unplanned, meaning these women would not begin taking folic acid supplements until they are aware that they are pregnant[2]. By this point, the baby's neural tube has already been formed and the presence or absence of spina bifida or anencephaly is already decided. Taking 400 micrograms of folic acid before becoming pregnant and into the first trimester decreases the risk of spina bifida and anencephaly and so the message of the importance of folic acid needs to be taken seriously among all women. However, there is lack of knowledge among women in the United States on the role of folic acid supplements and the

implications of not taking folic acid supplements daily, regardless of whether they are currently planning a pregnancy or not.

Purpose of the Study

The purpose of the study is to understand the beliefs and attitudes of women of childbearing age who are capable of becoming pregnant towards folic acid and its importance in the prevention of birth defects.

Research Questions

- What do women of reproductive age understand about the role of folic acid in preventing neural tube defects?
- How do women's beliefs about folic acid shape their decisions to take folic acid supplements?

Importance of the Study

Understanding women's beliefs and attitudes of folic acid is important to determine why they choose to take folic acid supplements or not and how their beliefs shape their health behaviors in this way. This qualitative study will help to understand women's knowledge and perceptions on folic acid and its role in preventing neural tube birth defects among women in the United States. Health professionals promote the importance of folic acid for women of childbearing age, but this study will illuminate gaps in knowledge in the understanding among women themselves that could influence how to promote these important public health messages. These gaps could lead to more effective communication

between health care professionals and the general public about folic acid which could augment the effects of fortification efforts. This study will provide insights that could lead to hypotheses for future quantitative research and will inform decision makers about the importance of folic acid in the prevention of neural tube defects.

Chapter 2: Literature Review

Introduction

Many research articles and reviews have been written about folic acid and how it relates to neural tube birth defects. This literature review will focus on the burden of neural tube defects, the connection between folic acid and neural tube defects, current knowledge about intake of folic acid, and issues of compliance from the most salient research studies over the last 30 years. Such a literature review will provide the context for the analysis conducted in this thesis and how the results might contribute to continuing guidance for women in preventing neural tube defects.

The Burden of Neural Tube Defects

Neural tube birth defects are the most common debilitating human birth defect[7]. This embryonic defect presents itself by the 28th day of pregnancy, which in many cases is before a woman is aware she is pregnant. Not only do these birth defects have emotional costs associated with them, but they are also economically costly. For one child born with a neural tube defect, it is estimated that the annual medical costs will be $294,000[11]. In the United States specifically, the average lifetime cost to care for a person with a neural tube birth defect is $500,000 to $1 million[8]. As stated in the introduction chapter, as many as 1,500 children in the United States are born each year with a neural tube defect. This adds up to a significant financial impact for both households and the health system. Unless there are effective folic acid prevention programs in place, neural tube defects can become a public health emergency[9].

Folic Acid and Neural Tube Defects

The earliest study seeking to link folate to neural tube defects was in 1981 by Laurence, K.M., et al. This study[10] was a prophylactic randomized control trial in which 905 women who had previously had a child with a neural tube defect between the years of 1954 and 1969 and were currently planning another pregnancy were recruited. These women were randomized into a treatment group and a placebo group. The treatment group received a 2mg tablet of folic acid to be taken twice a day which was to begin at the time birth control measures were stopped. Each woman was asked to report back within 6 weeks of a missed period to inform researchers about their diet and compliance. After the child was born, the women were revisited by researchers to evaluate the outcome of the pregnancy. The study found that six of the women gave birth to a child with a neural tube defect. Of these six, none were women who were a part of the treatment group and who complied with the recommendations. However, two of the children with neural tube defects were born to women who were in the treatment group but did not comply with the treatment and the remaining 4 children were born to women in the placebo group.

This study provided the highest level of evidence through a double-blind, randomized control trial to show that women with folate deficiency are at an increased risk for having a child with a neural tube defect when compared with women with who are not folate deficient. The study's conclusion states that women who do not have a proper diet and have had previous pregnancies affected by neural tube defects should either improve their diet by eating healthier foods or take a folic acid supplement in order to improve the chances that future children will be born without neural tube defects.

In 1989, Milunsky, A., et al[11] addressed the research question, what is the relationship between multivitamin intake in general and folic acid in particular to the risk of neural tube

defects? The subjects in this study were a cohort of 23,491 women who were recruited due to their involvement in alpha-fetoprotein screening or amniocentesis around the 16th week of their pregnancies. Each of the women was interviewed by trained nurses who contacted them by telephone at the time that the labs received results from their prenatal tests. Most of the interviews occurred in a double-blind manner, in which neither the interviewer nor the informant knew of the status of the lab results. The questions in the interview asked about the women's family, medical and genetic history, diet, medications and the presence or absence of illnesses during the first trimester of pregnancy.

Of the initial cohort of 23,491 women recruited to be in the study, information about the outcome of the pregnancy was gathered for 22,776 women. Of the women in which the pregnancy outcome data was collected, 49 pregnancies resulted in a neural tube defect. The study found that in the group of women who had never used multivitamins or had only used them before conceiving their child had a prevalence of neural tube defects of 3.5 per 1000. In women who used multivitamins that contained sufficient folic acid during the first few weeks of pregnancy, the prevalence of neural tube defects was 0.9 per 1000 (prevalence ratio, 0.27; 95% confidence interval, 0.12-0.59 compared with those who had not used multivitamins).

One of the most compelling studies to connect folic acid to neural tube defects built on the previous two studies and broadened the scope to include seven countries and seven other vitamins besides folic acid to determine if these vitamins had any connection with neural tube defects. This study[12], published in The Lancet in 1991by the Medical Research Council Vitamin Study, led health professionals to firmly state that folic acid supplementation is needed before pregnancy for all women who have had pregnancies affected with neural tube birth defects. The research question being studied was does

supplementation with folic acid or a mixture of seven other vitamins (A, D, B1, B2, B6, C and nicotinamide) surrounding the time of conception prevent neural tube defects? A randomized double-blind prevention trial was conducted in seven countries. Eligibility requirements for the study were that women must be at high risk for having a child born with a neural tube defect due to a previous child being born with this condition, must be planning another pregnancy and maintain the same diet and habits as in the previously affected pregnancy. As many as 1817 women were recruited and randomized into four supplement groups – folic acid, other vitamins, both, or neither. The women were to take the assigned supplement until the 12th week of their pregnancy. Doctor's visits, in which blood was drawn and further supplements were given, occurred every 3 months until the baby was born. The outcomes of the pregnancies were recorded and evaluated for the presence or absence of neural tube defects.

The results of the study found that there were 27 children born with neural tube defects, 6 of which were from the folic acid supplement group and 21 of which were in the vitamin supplement group. This data shows that there is a 72% protective effect for those in the folic acid supplement group (relative risk, 0.28; 95% confidence interval 0.12-0.71) while those in the vitamin supplement group showed no protective effect (relative risk, 0.80; 95% confidence interval 0.32-1.72). The results further indicated that folic acid supplementation prevents neural tube defects by finding that 72% of neural tube defects in this study were prevented (95% confidence interval 0.29-0.88). The evidence from the study leads to the conclusion that the prevention of neural tube defects is due to folic acid and not the other vitamins tested in the study.

Another study[13] which provides compelling evidence for the relationship between folic acid and neural tube defects was published in 1992 in the New England Journal of

Medicine by Czeizel, A.E. and I. Dudas. This article tested the research question, what is the extent to which folic acid supplementation can reduce the first occurrence of neural tube defects? This study recruited women who were planning their first pregnancy, did not have delayed conception or infertility, were not currently pregnant and who were under 35 years of age. The research took place in Hungary and all of the women were recruited through their participation in the Hungarian Family Planning Program. A total of 4753 women were included in the study and were randomly assigned to either receive a vitamin supplement containing folic acid or a trace-element supplement that did not contain folic acid. There were 2104 women randomized to receive the folic acid vitamin supplement and 2052 randomized to receive the trace-element supplement. The remaining 597 women failed to report the outcome of their pregnancy and therefore, were not included in the results. The women were instructed to take supplements daily from one month prior to conception until their second missed period. The outcome of the pregnancy with information about the presence or absence of a neural tube defect was recorded.

The results of this study found that children born with neural tube defects were more common in the group of women who received the trace-element supplement than in those who received the folic acid vitamin supplement (22.9 per 1000 versus 13.3 per 1000, $p = 0.02$). Further evidence to prove the connection between folic acid and neural tube defects was that out of the 2052 women who were randomized to the trace-element supplement group, six reported having a child born with a neural tube defect compared to none of the women randomized to the folic acid vitamin supplement group reporting the presence of a neural tube defect ($p = 0.029$).

One of the most cited articles connecting folic acid to neural tube defects was published in 1999 by Berry, R.J., et al.[14] which looked into the differences in outcomes of

pregnancies between women in two regions of China – one region with a high prevalence of neural tube defects (the northern region) and one with a low prevalence (the southern region) – when asked to take a folic acid supplement before conceiving and until the first trimester of their pregnancy. The women recruited for the study were women who were pregnant at some point between October 1, 1993 and December 31, 1996, as confirmed by a pregnancy monitoring system which collected data about structural birth defects. Each of the women had to be able to confirm the presence or absence of a neural tube birth defect after their child was born. The women were then asked to take a 400 microgram supplement of folic acid daily.

The study identified 130,142 women who took folic acid supplements before and up until the first trimester of their pregnancy and 117,689 women who did not take folic acid supplements. In the women who took the folic acid supplements, 102 had a pregnancy affected by a neural tube defect and in the women who did not take folic acid supplements, 173 had an affected pregnancy. To stratify by region, the rates of neural tube defects for women who took folic acid were 1.0 per 1000 pregnancies in the northern region and 0.6 per 1000 in the southern region. For women who did not take folic acid supplements, the rates of neural tube defects were 4.8 per 1000 pregnancies in the northern region and 1.0 per 1000 in the southern region. The study concluded that for women living in the northern region who took folic acid pills at least 80 percent of the time, the reduction in risk of having a child born with a neural tube defect was the largest. In both regions, there was a reduction in the rates of pregnancies affected by neural tube defects if the woman took folic acid supplements.

Folic Acid Intake and Knowledge

A more recent article was published in 2010 in the American Journal of Preventative Medicine by Tinker, S. C., et al.[15] The study answered the question of how different sources of folic acid contribute to achieving the recommended daily intake. To research this question, the National Health and Nutrition Examination Survey (NHANES) from 2003-2004 and 2005-2006 were used to collect data on 2617 women aged 15-44 years who were not pregnant. Information regarding their intake of folic acid and dietary habits was estimated using a questionnaire. If the informants admitted to using dietary supplements, the bottles of the supplements were examined to determine the exact dosage of folic acid being consumed. The frequency of supplement intake was recorded as well as two 24-hour dietary recalls. The first of the two recalls was conducted in person and the second was conducted via telephone 3-10 days after the initial interview. The total amount of folic acid consumed by each woman was calculated from the data from the supplements and the data from their diets.

The study found that nearly 75% of non-pregnant U.S. women aged 15-44 years did not receive the recommended amount of folic acid needed per day (95% confidence interval, 0.20-0.27). However, 72% of the women who did take folic acid supplements received the recommended dosage (95% confidence interval, 0.65-0.79). Of the women who did not take folic acid supplements, upwards of 95% did not receive the recommended dosage, regardless of their consumptions of cereals that contained folic acid. It was found that the strongest predictor of women receiving the recommended amount of folic acid was the use of dietary supplements.

An article published in the Journal of Public Health in 2012 by Rofail, D.[16] assesses the existing folic acid public health campaigns to identify common themes and barriers in

these interventions. PubMed, PsycInfo and Embase were used to search for articles that focused primarily on folic acid education and consumption. The articles that were included in this systematic review were required to have folic acid as the central focus. As many as 166 articles were initially found and 38 were included in the review. The information from these 38 articles was synthesized and condensed into summary charts to assess trends that exist among the data.

The information gathered from this review showed that before a public health campaign, only 34% of women were aware of folic acid compared to 41% after the campaign. When asked about how women learned about the importance of folic acid, the media was the primary source, followed by healthcare professionals, then family and lastly, friends. Common barriers to the uptake of knowledge about folic acid were found in the articles studied. The barriers were incomplete outreach (meaning that many women are not being reached by the campaigns), prior awareness (which meant that women who had heard about the importance of folic acid were more likely to act in a way that increased their consumption), closeness to pregnancy (women who are currently planning a pregnancy are more likely to consume folic acid compared with women who are not planning a pregnancy) and demographic and other personal characteristics. Women who took folic acid were found to have many similar characteristics such as being older, Caucasian, married, educated and non-smokers.

Compliance

Compliance to vitamin regimes is often complicated due to the multitude of factors that contribute to whether or not the recommendations are followed. Often times, cost, side effects and lack of knowledge are barriers that keep compliance low. Below are four studies

conducted that seek to determine compliance to specific programs and evaluate things that could be done to improve compliance.

A 1993 study done by Schultink et al.[17] investigated the efficiency of a program targeted to increase iron supplementation in pregnant women in Jakarta, Indonesia. Initial blood work was done before the program began on 45 pregnant women to determine baseline values of hemoglobin, serum ferritin and packed cell volume. Two months later, the same blood work along with stool samples were conducted on the same individuals to determine their compliance with the iron supplementation. Questionnaires were also conducted on these women asking about their compliance. The results from the questionnaire showed that 64% of the women claimed to have been compliant with the iron supplementation regime, but blood work and corresponding stool samples only showed that 27% of women were truly compliant. This study shows the difficulties in measuring compliance and emphasizes the need for not only qualitative reports of compliance but also randomized measurements of blood work to give a true estimate of supplementation compliance.

A more recent study addressing iron supplementation compliance was conducted in 2012 by Zavateta, et al.[18]. This double-blind study monitored the patterns of compliance to iron supplementation in 985 pregnant women in Lima, Peru. The women were given various vitamin supplements and asked to begin taking them before conception and continue until 4 weeks after their child was born. The median compliance was found to be 79%. This study used a model that incorporated weekly visits by health workers to assess compliance to the supplement regime, which may have led to a higher percentage of pregnant women taking supplements than would occur without frequent monitoring.

Reasons for noncompliance for iron supplements may differ to that of folic acid supplements due to differences in cost, side effects or the breadth of knowledge among the general public that is circulating in the media about iron supplements compared to folic acid supplements. To narrow the focus to folic acid compliance, a study[19] was conducted by the Motherisk Team at the Hospital for Sick Children in Toronto, Canada looking at the issue as it relates to prenatal counseling. The study was conducted with pregnant women and set out to see whether compliance to a folic acid supplement program could be improved through counseling. Of the counseled women included in the study, the study found that 71% were compliant compared with 17% of the control group. As was the case in the Schultink et al. study[18], the reasons behind compliance and noncompliance were not emphasized.

Another study that addresses folic acid compliance is a national study conducted in Denmark in 2000 by the Danish National Birth Cohort[20]. This study set out to understand compliance with the nationwide recommendations that women planning a pregnancy should take 400 micrograms of folic acid daily prior to conception. An informational campaign regarding folic acid supplementation was implemented in the second half of 2001; the information collected at the end of the study showed that only 22.3% of the women in the study had complied with the recommended daily intake of folic acid. The study concluded that the current strategies to reach women are not effective and need significant revisions in order to increase awareness and compliance of folic acid.

Each of these studies was internationally based, although similar problems are likely to exist within the United States. A significant gap that exists in these studies is that the reasons for non-compliance are not the primary focus of the studies, due to their quantitative study design. Research to determine strategies to increase compliance is limited.

Conclusion

There exists a gap in the current research about folic acid. None of the aforementioned studies included qualitative analysis to determine what women currently know about folic acid and how this information shapes their decisions to comply with folic acid recommendations. My study seeks to answer this question and evaluate the motivation and barriers present in the decision to take folic acid supplements.

The relationship between the intake of knowledge and behavior change among women of child-bearing age taking folic acid supplements is shown in Figure 1. When behavior change in the form of increased intake of folic acid supplements is combined with a mandatory fortification program of folic acid in all enriched grains, the reduction of folic acid preventable neural tube defects is imminent. My study focuses on the middle circle using a qualitative methodological approach. By answering the research questions articulated above, there is hope for a more direct future dialogue between women and health care professionals surrounding the importance of folic acid in preventing neural tube defects.

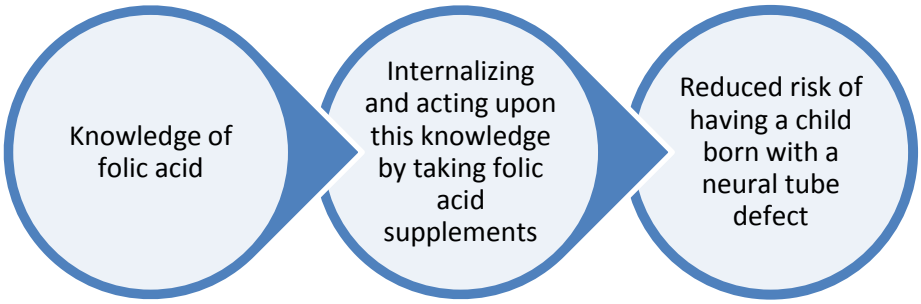

Figure 1: The conceptual framework showing the relationship between the intake of knowledge and behavior change.

Chapter 3: Methodology

Study Design

This study is a secondary analysis of qualitative data collected in St. Louis, Missouri and Atlanta, Georgia in 2010 to identify women's perceptions of folic acid supplements. The study is cross sectional, consisting of 16 focus group discussions, 8 in each location. Focus group discussions were used for this study because they allowed for the collection of in-depth data on the range of perspectives on folic acid supplements. Further, focus group discussions were beneficial because they promote discussion between participants which often leads to participant's opinions being challenged, justified and elaborated upon, which leads to greater depth and nuance in the data collected. Focus group discussions were the most appropriate method to use in this study because the group environment captures a range of beliefs about folic acid and also uncovers normative community views on the issue of folic acid and neural tube birth defects.

In order to ensure a variety of women in each focus group, women were assigned to a focus group based on whether or not they were planning to become pregnant within the next year and also whether or not they took a multivitamin at least four times per week. Each of the focus group sessions occurred in the evening and lasted 1 hour.

The data for this research were provided by the CDC's National Center for Birth Defects and Developmental Disabilities, Prevention Research branch. De-identified transcripts of focus group discussions were provided for analysis. The study from which the data were used sought to answer the following questions: How do women in the United States understand the importance of folic acid and its preventative effects for neural tube

birth defects? How do women's beliefs about folic acid shape their decisions to take folic acid supplements?

The protocol for this study was determined to be exempt from the IRB review process because due to the de-identification of the data in the focus group transcripts, it is not classified as human subject research. The exemption letter can be found in Appendix A.

Study Context

A set of 8 focus groups was conducted in two study cities, St. Louis, Missouri and Atlanta, Georgia, in the United States for a total of 16 focus group discussions. These study sites were selected by the study leaders for two main reasons. First, the sites were chosen to reflect the diversity that exists within each city's population as well as the different characteristics across the two cities due to their respective locations within the United States. According to the United States Census Bureau, the two cities chosen for the study ranked in the top 20 largest metropolitan areas in the United States in 2009[21]. Large cities allow for a more diverse population and therefore, the individuals selected to be a part of the focus groups may provide a diverse range of views on the issues of the interest to this study. Secondly, these sites were chosen for the practical reason that St. Louis and Atlanta were locations of the CDC headquarters (Atlanta) and a CDC contract office (St. Louis). The Centers for Disease Control and Prevention collaborated with the Battelle Centers for Public Health Research and Evaluation, the world's largest non-profit research and development organization, to conduct the focus groups[22].

Study Population

This study is a secondary data analysis, therefore information about the study design and implementation are provided in this chapter for context purposes only.

Women eligible to participate in the study were of childbearing age (18-45) and capable of becoming pregnant. All socioeconomic groups and ethnicities were eligible to participate in the study. Taking a vitamin supplement was common among the participants, but was not a requirement for participation. This population is appropriate for the study because any woman of childbearing age who is capable of becoming pregnant is at risk for having a pregnancy affected by folic acid preventable neural tube defects. Exclusion criteria were women currently pregnant or women who had a previous pregnancy affected by a neural tube defect.

Data Collection

The method of data collection selected was focus group discussions due to their ability to identify a range of opinions about folic acid and to discover common themes in the understanding of folic acid amongst women in the study population. The Battelle Centers for Public Health Research and Evaluation recruited participants for focus group discussions via phone calls and a screening guide which is found in Appendix B. To recruit participants, Battelle used a membership list from a formal network of people who have registered to be a part of focus group discussions. Names were drawn from these lists and were randomized to different focus group discussions. Each of the women was called to assess their interest in participating and to confirm their eligibility. In order to recruit 4 to 5 participants per group, 6 women were recruited to allow for non-attendance. The number allowed for a group discussion in which a variety of perspectives may emerge. This number of participants was

chosen in order to foster diversity of opinions. There were a total of 85 women who participated in the study.

The study's eligibility criteria meant that participant characteristics were largely similar. This is beneficial to the study since participants are more likely to share their opinions if the fellow group members are similar to themselves[23]. Characteristics that allowed for variance in group composition were race, socioeconomic status, marital status and whether or not the women had children. In each focus group, the recruited women were strangers which increased anonymity and allowed for more honest contributions to the discussions[23].

There were 8 focus groups conducted at each location over a period of 4 days. The focus group discussions in Atlanta were held August 13-16, 2012 and the groups in St. Louis were held August 27-30, 2012. Each woman was given $60 as an incentive for participation and all of the data were collected during focus groups sessions. The information from these focus groups was transcribed by a subcontractor and compiled by the CDC.

Focus Group Discussions

The focus group discussion guide was developed by the Centers for Disease Control using questions adapted from earlier instruments and surveys. The discussion guide was not pilot tested, however changes were made based on its passage through CDC clearance. The discussion guide can be found in Appendix C. Focus group discussions were tape-recorded and a note-taker was present for verification purposes and to capture information difficult to pick up on a recording. The moderator was trained in focus group facilitation by Battelle Center for Public Health Research and Evaluation and the groups were conducted in English. Each group was observed by an additional Battelle staff member and one or more

CDC staff members. As is the norm for focus group research, privacy and confidentiality were the main ethical issues to be considered in this study. To ensure that privacy and confidentiality were maintained, participants were required to sign a consent form. This consent form is found in Appendix D.

Each focus group began with the moderator asking for introductions of the members. The participants were then asked which vitamins they considered to be important for women in particular. This led the discussion onto the topic of prenatal vitamins in each case, specifically folic acid. The women were asked about their current knowledge of folic acid, its role for women who are currently planning a pregnancy, pregnant or not planning a pregnancy. The women spoke in each case about where they had heard about folic acid, the facts that were memorable from folic acid campaigns, barriers to taking folic acid and the best approaches to informing women in the general public about folic acid. Three educational brochures about folic acid that had been created and used in the past by CDC were shown and the women evaluated each of them with regards to what was helpful, what should be changed and offered advice about how the information could be communicated in a more effective manner in order to enhance uptake of knowledge. The format, the design and most importantly, the educational content, were discussed in each focus group and provided feedback for future educational campaigns.

Following the focus group discussions, a post-session question and answer session was administered by CDC professionals in order to clarify the importance of folic acid, answer questions that the women had about folic acid and to ensure that they did not leave with any misinformation. This was done following the focus group to avoid any bias that could be introduced by discussing the facts beforehand.

Data Analysis

Textual data came from 16 focus group discussions which were transcribed verbatim and de-identified by researchers at the Battelle Center for Public Health Research and Evaluation. The qualitative analysis software package MAXQDA10 (Marberg, Germany, 2007) was used to manipulate the textual data for analysis. Thematic analysis was used to analyze the textual data. Analysis involved reading each of the focus group discussions and annotating the main themes raised in the data. A codebook was then created whereby themes were listed and defined. This codebook can be found in Appendix E. The codes were developed and defined based on the main issues raised in the transcripts. The codes were validated for inclusion in the codebook if they were repeated across transcripts or emphasized to be of importance to the participants. For example, if an issue led to detailed discussion it was deemed valid for inclusion in the codebook. Both inductive and deductive codes were developed. Inductive codes emerged from reading the transcripts and deductive codes were based on concepts from the literature and research question. Codes were used to label data in MAXQDA10. An analysis plan was developed and structured around the core research questions. In the analysis plan, each research question had a list of associated codes that were used to search data to answer a dimension of each research question. Search output was read in relation to a specific research question, taking notes of the main points, themes and quotations that were raised in the data. This led to a thick description of the core issues that helped to answer the research questions. Comparisons of issues were conducted between study locations (St. Louis versus Atlanta), however, no differences or patterns were found in the research issues. Therefore, the results as presented are not stratified and instead are presented as a whole unit of women of childbearing age capable of becoming pregnant. The key findings that came from the description of themes of the coded data were

summarized by research question and quotations were used to illustrate the main themes reported. A narrative approach was used to identify the storyline that was told by the data. I then compiled the data into a coherent plot that answered each of the research questions.

Data Quality and Study Limitations

A strength of using the focus group discussions to collect data is that is allows the participants to discuss a topic area and expound on fellow participants comments that they may not mention on their own without prompting. Other strengths of focus group discussions is that they allow for a large volume of diverse information and the opinions presented can be debated and justified[23]. Limitations of focus group discussions in general include the influence of social pressures, strong voices dominating conversation and the presence of hierarchies that could arise. These potential limitations were minimized in this study by the moderator's skills in managing the discussion and the group dynamics.

Chapter 4: Results

Due to the study design, all focus group participants in this study had similar characteristics, even though they were recruited from different study locations. Despite doing comparisons on all issues by location, no distinct differences were found. Therefore, the study results are presented by the collective themes raised across all focus group discussions.

Current Knowledge of Folic Acid

Participants were asked about their knowledge of folic acid at the beginning of the focus group discussion. A few participants had heard of folic acid through conversations relating to prenatal vitamin intake. However, the majority of women were unaware of the role of folic acid in the prevention of neural tube defects. Women appear to have little or no knowledge of the importance of taking folic acid during pregnancy.

Among the few women who had heard of folic acid, their knowledge reflected a range of myths or misunderstandings on the role or importance of folic acid during pregnancy. Many women questioned the importance of taking folic acid supplements, as they had not taken these supplements in the past and not experienced birth defects. These women did not perceive themselves to be at risk of birth defects in the future, and thus felt they did not require folic acid supplementation. Women also believed that folic acid contributed to conditions such as asthma, allergies and developmental disabilities. Additionally, statements were made about folic acid supplements and birth control pills having the same goal of preventing pregnancy. This led to the false assumption that the two could be interchanged without risk of pregnancy or birth defects occurring. Furthermore,

women believed that they could receive sufficient folic acid through eating a healthy diet and felt that supplementation was unnecessary.

Sources of Knowledge

Women reported that they received information about folic acid from a range of formal and informal sources. The majority of women gained information about folic acid through informal sources such as family members and friends. This information was often in the form of anecdotal evidence of children being born with neural tube defects and discussions of etiology. A small number of women learned about folic acid through formal sources such as doctors, health professionals or in health communication materials. These women stated that they had initiated a discussion of folic acid with a health professional or sought health promotion materials when planning a pregnancy. For example, when asking a doctor which prenatal vitamins were important, women reported that folic acid was mentioned, but rarely was this discussion initiated by a doctor. An important issue was that many women reported first hearing about folic acid only <u>after</u> a positive pregnancy test. One woman quoted her doctor as saying, "It's too late to take folic acid. You're already pregnant." Many of the women who by their own initiation sought out pregnancy information in the form of brochures, journal articles or magazines reported first learning about folic acid from these materials. Only seven women (8% of study participants) reported that their doctor emphasized the importance of taking folic acid supplements before conception.

Desired Information about Folic Acid Supplementation

The lack of information about folic acid among this population was not due to disinterest among women themselves. The women involved in this study wanted to receive basic knowledge about folic acid. Their requests were often that doctor's speak in plain language to ensure their understanding of the issue. On many occasions throughout each focus group discussion, women asked basic questions about the recommended daily dose of folic acid, natural sources of folic acid, potential side effects and how frequently supplements should be taken. Women did not look for detailed information, but rather wanted only surface level, rudimentary facts about folic acid's role in preventing neural tube defects. This suggests a lack of information from other sources.

Reactions to Facts on Folic Acid

During each focus group discussion, participants were provided with factual information about folic acid and its role in preventing neural tube defects and were asked to respond to the information. There were three types of responses that were typical of the participants upon hearing the facts about folic acid – surprise, empowerment and skepticism. All types of responses occurred among women in each of the 16 focus group discussions.

The majority of women were surprised to hear of the severity of neural tube defects and the ease with which they can be prevented. This was determined based on quotations and in some cases, statements by the moderator about the women's disposition. While the focus group could not pick up on facial expressions that could depict a feeling of surprise, the moderator was reported saying statements like, "you look surprised – what are you feeling?" This, along with statements made by the participants, reflected a feeling of surprise.

For example, when the moderator mentioned the importance of taking folic acid before and during pregnancy, the following responses were typical:

> "It's surprising to me that all women – or it's my first time hearing that all women – should take it. Again, I just thought it was a vitamin that, you know, a supplemental vitamin or something that you could take and that would just help you. I didn't know that it was recommended that you take it all the time during those years. And I think if women did know that, they would take it."

> "I had no idea. I'm completely shocked by it. I had no idea that this was a connection."

Other responses reflected women feeling empowered by their new understanding of folic acid. It seemed that the information that they learned served as fuel for behavior change. These women reported feeling strengthened by the knowledge they obtained and wanted to increase the awareness of friends and family about the issue. One woman said,

> "Folic acid could prevent up to 70% of some types of serious birth defects. That's huge. 70% - that's an enormous number. I feel like I've learned something today. I can go away from this knowing about – a little bit more about folic acid and stuff."

Other responses reflecting women's empowerment include the following:

> "I think that it would definitely be worth doing some more research on it and definitely worth looking into because it could – based on the information given, it seems like it'll be beneficial, whether I was trying to get pregnant or not. Like you said, most pregnancies are unplanned anyway. It's definitely piqued my interest, as far as wanting to learn more about it."

> "Hearing this information once is going to make me want to go out and do it."

> "Any precaution that I could take against that, I would want to."

Still, some women remained skeptical even after hearing the facts. There was mention of doubt of the facts presented, such as statements like, "I wouldn't necessarily take this information as serious." The skepticism seemed to stem from distrust of medical information due to inconsistencies in doctor's recommendations, as shown by the following quote:

> "You get some doctors that are really – you really, really need this; you need extra. And other ones are – you know, the findings show that it might not really that big of a deal."

Each of these three types of responses points back to the lack of information that women have regarding folic acid and neural tube defects. If women were aware of folic acid prior to the focus group discussion, their responses to the facts may have been more phlegmatic or diluted in nature. Women desired information that could better their health as

well as the health of their unborn children; therefore, an increase in educational materials about folic acid is needed.

Current Habits of Folic Acid Intake

Participants were asked about the ways that they currently get folic acid and other vitamins. Most of the women took a multivitamin that contained folic acid, but not regularly. Other women believed that eating a healthy diet gave them all of the vitamins that their body needed, and therefore, did not take vitamin supplements. Women reported that they were more inclined to take supplements regularly after a positive pregnancy test, but not before. When asked about the frequency of which vitamin supplements are taken, almost all of the women responded by saying that they do not take the supplements daily. Many responses were similar to, "I take a vitamin a couple times a week maybe." The inconsistency in intake was common among women across all focus groups.

Barriers to Taking Folic Acid

The barriers to taking folic acid generally fell into three categories – financial, health and knowledge barriers. Each of these barriers impeded women from ingesting the recommended dose of folic acid daily.

A few women mentioned the cost of purchasing additional supplements to be problematic. One of the women spoke about the cost barrier by saying, "I'm already on a lot of medication and one more pill to buy is a problem. That's what it is for me." Other women sought out cheaper vitamins, such as children's vitamins or juices, so that they could still get vitamins, even if the dosage was lower than recommended. An example of this is illustrated in the following quote: "But the other thing is I used to take – kind of just for

financial reasons– but I was on what they call Juice Plus, which is kind of a food supplement." These supplements do not contain the daily recommended daily dose of 400 micrograms of folic acid, but women are taking these instead of folic acid supplements or multivitamins that contain the full amount of folic acid because they are cheaper. Regardless of the health benefits, the price of supplements kept some women from getting the necessary daily dosage of folic acid.

Other women mentioned health issues as a barrier to taking multivitamins, including folic acid. Reports of nausea, gastrointestinal upset and allergies were mentioned as obstacles to taking vitamin supplements. These side-effects were severe in some women, even leading to job loss in some cases. One participant said, "The multivitamin made me very sick. They said, again, it doesn't matter how sick it makes you, you have to take it every day. I ended up having to lose the job I was at because I was so sick taking the vitamin." Some women had less severe side effects with the only main concern being swallowing large pills. One woman demonstrated this by saying, "I've always had problems swallowing big vitamins." These women resorted to taking chewable vitamins, if they took vitamins at all. This is shown by the following quote: "I hate the vitamins. They're huge, so I did the gummy bears." As previously stated, the children's chewable vitamins often do not contain the appropriate amount of folic acid needed per day; therefore, women were still not getting the appropriate dose. Whether it was the side effects or swallowing a large supplement, health issues were often reported as a barrier to taking folic acid.

The final barrier that arose from the focus group discussions was the lack of knowledge about dosage, frequency of intake and remembering to take the vitamins amid a busy schedule. Many women were unaware or confused about the recommendations of taking folic acid supplements daily. This uncertainty created angst and kept many women

from taking supplements because of their concerns about the dosage, and that they may take too much or too little of a dose. Comments like the following were typical: "Quantities are rarely discussed, so you never know how much is good enough." Women also seemed to have trouble remembering to take a vitamin each day. Some women reported that unless the vitamins were on the kitchen counter, they would not remember to take them. A few women relied on their children to remind them to take vitamins daily. Forgetfulness led to inconsistency in the intake of folic acid supplements and meant that women were not getting the appropriate daily dose.

Ultimately, cost, side-effects and a lack of knowledge were the main barriers preventing women from taking folic acid supplements. These themes were repeated across all focus group discussions and hindered women from having optimum blood folate levels prior to conception.

Motivators for Folic Acid Supplementation

After the women were told about the importance of folic acid, they became motivated to be more intentional about taking this supplement. Many of the women seemed to internalize the newly learned facts and discussed their goal to take folic acid when thinking about becoming pregnant. Suddenly, when the knowledge sought about folic acid was given to the women, they become motivated to take supplements and be more aware of a daily intake of vitamins.

Women were also motivated to take folic acid supplements after hearing stories of other participants who had first trimester miscarriages that could be attributable to a folic acid deficiency. These two examples – a newfound understanding of the importance of folic

acid and stories from women similar to themselves – motivated women to admit to being more likely to take folic acid supplements in the future.

Summary of Findings

The first research question in this study focused on identifying women's understanding about folic acid and its role in the prevention of neural tube defects. This study showed that women of reproductive age were widely unaware of the role of folic acid in preventing neural tube defects. There was a significant lack of knowledge among the participants and often, the knowledge that the women did have was inaccurate. In addition, a range of myths existed which involved a misperception of personal risk, fears of the side effects of folic acid, confusion with birth control measures and the misconception that the total amount of folic acid needed per day could come entirely from diet. Many of these myths came from informal sources such as family members and friends, while many formal sources of knowledge – such as doctors and healthcare professionals – initiated conversations about folic acid only after a woman was already pregnant. Women desired simple, factual information about folic acid and its role in preventing neural tube defects but had difficulties finding this information.

The second research question sought to explore any connection between women's personal beliefs about folic acid supplements and positive behavior change through the implementation of a folic acid supplement regime into their daily lives. When women were taught the importance of folic acid during the focus group discussions, their responses were typically ones of surprise, empowerment or skepticism. This range of reactions reflects that women have not previously heard folic acid information and recommendations. The skepticism specifically points to a lack of trust in the medical establishment. Current habits

of vitamin intake were inconsistent and often required cues to action. The barriers that kept women from acting on their knowledge of folic acid fell into three main categories: financial, health and knowledge barrier. However, women felt motivated to incorporate folic acid supplements into their daily schedule after learning about the way folic acid supplements affect their health and the health of their unborn children. Women first need to be aware of the facts that exist about folic acid before positive behavior change can be implemented, and as of now, women know very little about these facts. Once educated on this issue, barriers existed that kept the link from knowledge to behavior change disconnected. Motivation can help in assuaging the difficulties that come with the barriers, but it will need to be in a combination with a reduction of barriers in order to lead to positive behavior change.

Chapter 5: Discussion

Implications of Results

A lack of knowledge about folic acid was mentioned multiple times throughout each focus group discussion. This means that women are not receiving health communication materials or having conversations with health professionals about folic acid supplementation. It is imperative that women understand the importance of folic acid in a timely manner so that they can consume supplements prior to pregnancy and avoid having a child born with a neural tube defect. It is the responsibility of healthcare professionals to educate women on the importance of folic acid. To ensure that women get accurate and timely information about folic acid, it is important that health care providers initiate a dialogue with women about folic acid supplementation.

For some women, the conversation about folic acid supplements with a healthcare professional came only after a positive pregnancy test. By this point in the pregnancy, the baby's brain and spinal cord have already been formed and it is too late to avoid a neural tube defect with folic acid supplements. To avoid beginning the conversation when it is too late, doctors should consider mentioning folic acid supplements to all women of childbearing age capable of becoming pregnant at all regular doctor visits. An honest conversation about how folic acid could impact a woman's life would increase awareness of folic acid and could be a positive force in dispelling myths that may come from informal sources.

Further, health professionals should speak in plain language and ensure throughout the conversation that women understand the risks that folate deficiency can have on their own health as well as the health of their unborn children. Speaking in plain language to ensure

understanding would reduce the likelihood of myths or gaps in understanding. Additionally, doctors or healthcare professionals should consider creating a folic acid supplementation plan for each woman tailored to her lifestyle. Many women reported wanting to know the means of getting enough folic acid based on their current lifestyle. These doctor-initiated plans would take into account diet, vitamin intake and could account for barriers that come up during the discussion. Women in this study wanted to know how to avoid neural tube defects, and so a dialogue with healthcare professionals would be an effective way to increase their knowledge about folic acid. As stated in the results, the lack of information about folic acid among this population is not due to their disinterest. Participants desired basic knowledge from informed sources, but were not finding it. Increasing the quantity and quality of conversations about folic acid and neural tube defects with healthcare professionals, as well as lifestyle plans tailored to each woman's current habits, would grant women this important knowledge.

To further enhance this recommendation, there needs to be an increased supply of health communication materials about folic acid that are easy to read and straight to the point. Women mentioned that many health communication materials were too wordy or unclear. The women requested bullet points of facts about folic acid. It was implied that women became completely disinterested and did not take time to read health communication materials if the text was dense. This means that the women are not getting any information on folic acid and neural tube defects because the dense information required more mental energy than they were willing to expend to learn about folic acid. They may have been interested to learn about how folic acid could affect their lives, but the energy required to obtain this knowledge outweighed the benefits. It is important that folic acid educational materials are concise, easy to read and to the point. An increase in the design of

health communication materials is needed. By increasing the amount of valid, concise information about folic acid and neural tube defects, may dispel the myths and rumors that currently exist about folic acid supplements. Concise information would increase the uptake of knowledge due to a growth in the number of readers which would lead to more people knowing the facts about folic acid. These suggestions would also ensure that the primary sources of folic acid information are trained healthcare professionals.

Many women were surprised to hear about the severity of neural tube defects and the ease with which they can be prevented. Others responded with empowerment from their newfound knowledge and others remained skeptical of the facts. These three reactions, as previously stated in the results, would be much more diluted if the women had heard of folic acid in the past. Again, this shows that women are unaware of the basic information about folic acid and the importance of folic acid supplementation. The skepticism points to a lack of trust in the medical establishment, which seems to come from differing recommendations made by doctors. The lack of consistency in the medical information given to women creates cynicism and doubt, which often leads to the hesitancy to comply with any recommendation made by a doctor. In order to address this skepticism, more trusted information needs to be circulating.

A main concern that was reported frequently in the focus group discussions was inconsistency in the intake of multivitamins. This comment surfaced frequently as a major barrier to women getting the appropriate dosage of folic acid. Inconsistency in vitamin intake means that women are not getting the recommended daily dose of folic acid and, therefore, are at risk of having a child born with a neural tube defect. Mandatory folic acid fortification programs assure all women of reproductive age consume folic acid whether or not they have inconsistency in multivitamin intake. An additional way to address this issue of

inconsistency is a free mobile application that serves as a daily reminder to take multivitamin supplements could be a very effective tool. In an age of increasing technology use, it was reported in late 2012 that 86% of American women own a cell phone, with 42% owning a smartphone capable of downloading applications[24]. This percentage is increasing yearly and therefore, more and more women have access to downloading health education applications. A main goal of the folic acid application would be a daily reminder to take folic acid supplements. Many of the participants stated that they only remember to take a multivitamin if they are on the kitchen counter or if reminded by a family member. This result points to the need for a cue to action that would be incorporated into the mobile application. This cue to action would potentially increase consistency in intake of folic acid supplements among users which would, in turn, reduce the risk that these women will have a child born with a neural tube defect.

A further goal of the mobile application would be to serve as a source for the basic, concise information about folic acid that women are requesting. Information on doses, a list of foods high in folic acid, locations of stores that sell folic acid supplements within driving distance from the user's current location, coupons for supplements as well as a risk calculator for folate deficiency could also be useful parts of the application. This application would account for all of the information that this study found that women want about folic acid supplements and would serve as a cue to action for healthy behavior change. The financial barrier that kept women from purchasing supplements would be addressed through a list of the coupons available at local pharmacies for folic acid supplements. The barriers involving side-effects and lack of knowledge would be addressed through the list of foods that would increase the folic acid in a woman's diet and the information on dosages of supplements. Tips to decrease the severity of side effects from multivitamins would be

available, as well. Having factual material on folic acid available at your fingertips makes the information quick, accessible and easy.

Including a networking aspect within the mobile application would increase accountability of vitamin intake and promote healthy relationships by means of peer support. Joining with friends or peers in the area who are interested in taking vitamin supplements regularly would allow for an increase in social capital. Skepticism of doctors' recommendations about folic acid supplements was a theme raised in the focus group discussions. While it can be challenging to regain trust of the medical community, connecting a woman to a network of individuals who, like her, want to prevent birth defects through folic acid supplementation will allow for dialogue, support and connectivity. Working towards a common goal of healthy pregnancies would increase community among women and would also increase dialogue about folic acid supplements.

Further Research

There is still a lot that remains unknown about women's understanding of folic acid and how this affects their behavior. While this study provided important context about women's perspectives of folic acid, using qualitative research, more qualitative studies are still needed to further understand the issues. Qualitative research seeks to grasp an understanding of a behavior. With a multitude of quantitative studies confirming the connection between folic acid and neural tube defects, additional qualitative data are needed to understand the context of health behaviors that would promote folic acid supplementation.

This study design did not stratify participants by age group, race or socio-economic status, so, differences in the knowledge and understanding of folic acid by these

characteristics were not able to be identified. In order to identify potential patterns by these characteristics, future research needs to stratify focus groups by socio-demographic characteristics to understand any further patterns. Another option would be to conduct a series of in-depth interviews on the knowledge and understanding of folic acid. These interviews allow the researcher to compare one individual to another based on differing characteristics.

Future research should also examine current knowledge of doctors and health professionals about folic acid and neural tube defects. Many of the women in the study mentioned hearing conflicting information from doctors about the importance of folic acid, while others mentioned that doctors initiated the conversation about folic acid after a confirmed pregnancy. In order to gain women's trust about the issue, doctors need to be well versed in the facts. Potential barriers that might keep doctors from speaking to women about folic acid supplements would also be useful to know.

Chapter 6: Conclusion

We are lucky in this country because mandatory folic acid fortification of enriched cereal grain products has prevented most of the folic acid preventable spina bifida and anencephaly. The difficulties in communications about the need for folic acid and the low level of folic acid supplement consumption found in this qualitative research fortunately have not impaired the prevention of these birth defects. In countries where there is no mandated folic acid fortification, my research suggests ways to increase consumption of folic acid supplements.

An increase in the quantity and quality of conversations between women and healthcare professionals about folic acid and its role in the prevention of neural tube defects may increase consumption of supplements. These conversations should be in plain language and in a way that facilitates the uptake of knowledge. Additionally, women need to encounter trusted information about folic acid on a regular basis in order to dispel myths and increase awareness of the severity of neural tube defects and the ease with which they can be prevented. Along with candid conversations with healthcare professionals and a push for increased intake of folic acid supplements, mandatory folic acid fortification programs should also be initiated. Further, an increase in health communication materials giving basic facts about folic acid would aid in the ongoing dialogue. To augment these dialogues, a free mobile phone application serving as a cue to action and a hands-on resource for trusted, concise information on folic acid would be an effective tool to encourage women to take folic acid supplements. Ultimately, women need to be educated on how the consumption of folic acid supplements affects their own health as well as the health of their unborn children.

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Appendix A – IRB Letter

Institutional Review Board

December 13, 2012

RE: **Determination: No IRB Review Required**
eIRB#: n/a
Title: *Supplements*
PI: Katherine Lean

Dear Dr. Katherine:

Thank you for requesting a determination from our office about the above-referenced project. Based on our review of the materials you provided, we have determined that it does not require IRB review because it does not meet the definition of "research" involving "human subjects" as set forth in Emory policies and procedures and federal rules, if applicable.

Specifically, in this project, you will be analyzing de-identified data from focus group transcripts. Research using such information is not considered research involving human subjects. Please note that this determination does not mean that you cannot publish the results.

This determination could be affected by substantive changes in the study design, subject populations, or identifiability of data. If the project changes in any substantive way, please contact our office for clarification.

Thank you for consulting the IRB.

Sincerely,

Martha C. Patterson, BA
Research Protocol Analyst
This letter has been digitally signed

Appendix B – Eligibility Screener

SCREENER

INTRODUCTORY STATEMENT:
Hello, my name is _____ and I am calling on behalf of the Battelle Centers for Public Health Research and Evaluation. This project is being sponsored by the Centers for Disease Control and Prevention, also called CDC. We are going to be conducting discussion groups to better understand women's beliefs about women's health and vitamins. We would like to speak with you about your thoughts and opinions about this topic. We are looking for women to participate in these discussions. The discussions will be with other women from your community. They will last one hour and a half. If you are eligible to participate, you will receive $60 at the end of the discussion as a thank-you for sharing your thoughts about women's health and vitamins. Would you be interested in participating?

If she is NOT interested:
Thank you very much for taking the time to speak with me.

If she is interested:
May I ask you a few questions to see whether you are eligible to participate in the discussion group?

ELIGIBILITY QUESTIONS:
1. What is your age? _____ If *under 18 years old or 45 or older* [SKIP TO **CLOSE**]

2. Are you currently pregnant?
   Yes (contemplator)..... ❑[SKIP TO **CLOSE**]
   No (pre-
   contemplator).....❑[CONTINUE]

3. Are you planning to become pregnant in the next 12 months?
   Yes..... ❑[CONTINUE]
   No/Don't know ..... ❑[CONTINUE]

4. Do you have any children?
   Yes..... ❑[CONTINUE]
   No .....❑[CONTINUE]

5. Have you ever had a pregnancy that resulted in a child with a birth defect such as spina bifida or anencephaly?

Yes..... ❑[**READ STATEMENT BELOW**]
No ..... ❑[CONTINUE]

[If "Yes" to Q5, read this statement] Thank you for taking the time to answer my questions. I am sorry that I am not able to include you in a discussion group because you already have knowledge and experience with (spina bifida/anencephaly). The discussion group is more for women who do not have that first-hand experience.

6. How often do you take a multivitamin?
4 times per week, or more (user)..... ❑[CONTINUE]
Fewer than 4 times per week (non-user)..... ❑[CONTINUE]

7. What is the highest level of education you have completed? (Read options below; only mark one response)

Less than High School.....❑[CONTINUE]
High School Graduate/ GED..... ❑[CONTINUE]
Some college.....❑[CONTINUE]
College Graduate.....❑[CONTINUE]
More than Graduate School.....❑[CONTINUE]

(ELIGIBLE)

Thank you for answering my questions. Based on your answers, you are eligible to participate in the study. I would like to invite you to participate in the discussion. This is not a sales meeting. No one will try to sell you anything. We are only interested in your opinions. Your opinions will help us better understand what women think about vitamins and health. This discussion will last one hour and a half and we will give you $75 taking the time to participate. Would you be interested in participating?

❑ No [**THANK YOU AND END CALL**]
❑ Yes [CONTINUE TO SCHEDULING]

(SCHEDULING)

Great! In the next few days, we will send you a packet of information with the details about where the discussion group will be held, as well as a reminder of the date and time of the group. I want to thank you again for your participation. We will call you the night before the group to remind you. It is very important that you arrive on time. Thank you for accepting our invitation. We look forward to hearing your opinions and comments. Have a nice day.

CLOSE (INELIGIBLE ONLY)

Thank you for answering my questions. I am sorry that I am not able to include you in a discussion group because you are not eligible. I appreciate your interest and taking the time to answer my questions.

Appendix C – Moderator's Guide

Moderator's Guide for Written Materials

I. INTRODUCTION AND ICEBREAKER (10 minutes)

A. Introduction and Purpose

Thank you for coming. Your presence and participation today are very important. My name is _____ and I will be moderating today's discussion. This project is being sponsored by the Centers for Disease Control and Prevention, also called CDC.

The goal of this project is to better understand the attitudes that women have about vitamins and women's health. We want to talk to you about your thoughts, feelings, and opinions about some educational materials being used by CDC.

The feedback you will give us today is information we could not get anywhere else. Thank you for your willingness to come and give us your opinions.

B. Procedure

Before we begin, I would like to start with some ground rules for our discussion today:

1. There are no right or wrong answers. Please be completely honest. We're as interested in learning what you don't like as we are in learning what you do like.

2. Everyone's participation is important. Part of my job as moderator is to make sure we get a chance to hear from everyone, so, at times, I may call on you, or ask you to shorten your remarks so someone else has the chance to speak.

3. We want this to be a group discussion, so you don't need to wait for me to call on you to speak, and please feel free to respond directly to other people's thoughts and ideas.

4. Our discussion will be kept totally secure. We will not use your names in any report.

5. Our discussion today is being tape recorded. These recordings allow us to write a more complete report, and to make sure we accurately reflect your opinions. However, please only speak one at a time, so that the tape recorder can pick up all your comments. We will destroy all recordings after we are done writing our report.

6. I am working with some other people on this project, and they will be observing our conversation from the other side of this mirror. They are taking notes and may ask a follow up question at the end. At the end of our discussion, someone will be available to answer your questions. If you have health questions, please save them to the end.

7. As moderator, my job is to keep the discussion focused on the subject. If I see that we are getting off the topic, I will bring us back to the topic so we can finish on time.

8. If you have a cell phone with you, please turn it off or silence the ringer. Thanks.

C. Introductions

Before we begin, I would like each of you to take a few moments to introduce yourself. Please tell the group:

- Your first name
- How long you have lived in this area

II. DIET AND VITAMINS (10 minutes)

Let's start by talking about the role of vitamins and helping women stay healthy.

9. Are there any vitamins that you think are especially important for women? Which ones? Why are they important? [Probe: What vitamins, if any, are important for pregnant women? Why? What about when a woman is planning a pregnancy? Why?]

III. FOLIC ACID (25 minutes)

I would like to talk [MORE] about a vitamin called folic acid. It is also sometimes called Vitamin B9 or folate.

10. What, if anything, have you heard about folic acid? Anything else? [Probes: Listen for relationship to birth defects, pregnancy, foods, prenatal vitamins, side effects, fortification of food, etc.]

11. How did you learn about folic acid? From what sources? [Probes: media, doctor, friends or family, advertising]

I want to tell you more about folic acid. Folic acid is a B vitamin. The Centers for Disease Control and Prevention (called CDC) recommends that all women who could possibly become pregnant take folic acid every day, whether they are currently planning to have a baby or not. This is because folic acid can prevent serious birth defects such spina bifida and anencephaly in babies. Women need to start taking folic acid before they are pregnant to reduce these risks. These birth defects happen before most women even know they are pregnant. Because many pregnancies are unplanned, CDC recommends that all women of childbearing age get enough folic acid every day.

12. What do you think about this information? [Probes: Is this information new to you? Are you surprised?]

13. After hearing this information, do you think you need to take folic acid? Why or why not?

14. Has your doctor or another healthcare provider ever talked to you about the connection between folic acid and healthy babies? If yes, what did you hear?

15. What about friends or family members, have you heard anything from them on this topic? If yes, what did you hear?

16. What, if anything, have you heard in the media about this topic? If yes, what did you hear? Where did you hear something? [Probe: type of media]

IV. EDUCATIONAL CAMPAIGN (40 minutes)*
[If we assume 10 minutes per product, we can ask about 4 materials.]

As I said before, CDC recommends any woman who could become pregnant, whether she is intending to become pregnant or not, needs to take folic acid every day. I want to show you [#] of educational materials currently being used to educate women about folic acid. CDC is interested in learning whether these materials still work to communicate to women about the benefits of folic acid, or whether they need to be changed. I am going to pass out the first material we are going to look at today. Take a few minutes to look at the material and read what it says and then we will discuss. [repeat the set of questions for each of the materials the group will review]

17. What is the main message of this [brochure]? [Probes: Is this information new to you? Are you surprised?]

18. Would you pick up this [brochure] if you saw it in your doctor's office or clinic? Why or why not?

19. Do you like the colors in this [brochure]? Do you like the pictures in this [brochure]? [Probe: Layout (tri-fold versus back-and-front card)? Design?] What would you keep? What would you change? [Probe whether they prefer drawings to real photos? Would they want to see actual photos of the neural tube defects?]

20. Was there anything unclear from this [brochure]? [Probe: Is it easy to read and understand? Is the font easy to read? What about the length of it? Is it too long or too short? Too much information/too little information?]

21. Do you think women can do what this [brochure] says? Why or why not?

22. What changes would you make to the [brochure]? What would you definitely not change?

Thanks for your feedback! We just have a few final questions.

V. FINAL COMMENTS AND THANK YOU (5 minutes)

23. Do you have any other questions about these materials or about folic acid that we did not discuss today?

24. Finally, do you have any other questions or is there anything else you would like to say?

[____] is here to give you additional information about folic acid and to answer any questions you may have. Thank you for coming! Your feedback and thoughts have been very important, and we appreciate your assistance. Your comments will help CDC and Prevention to promote women's health. As a reminder, all of your comments today will be kept secure.

Appendix D – Informed Consent Form

Informed Consent to Participate in a Study

Introduction

Battelle Centers for Public Health Research and Evaluation, a non-profit organization, is conducting focus group discussions on behalf of the Centers for Disease Control and Prevention, also called CDC. This project is being sponsored by the Centers for Disease Control and Prevention, also called CDC. The objective of the study is to help CDC understand women's opinions and practices related to their health.

You have been invited to participate in a focus group discussion with other women. It will last one hour and a half. Before you agree to participate, please review and consider the information listed below.

1. Participation in this interview is completely voluntary.

2. Any questions you have about this study will be answered before the interview begins.

3. The discussion will be audio taped and a report will be prepared for the CDC.

4. Your name will not be used in the report about the interview and no quotes will be linked to you.

5. The interview may be observed by project staff from Battelle and CDC.

6. We ask you to avoid using your last name during the interview.

7. You may choose not to answer questions that you do not want to answer.

8. You may choose to leave the interview at any time for any reason.

9. Thank you for your participation in this study..

10. **Are there any risks to my being in this project?**

The risks and discomforts associated with your participation are minimal and limited to those that may occur in a conversation about health problems. This project only involves your opinions about what you do to stay healthy.

11. **What are the benefits to being part of this project?**

There are no direct benefits to you. The information from this study will provide you with some health information and may be used to develop future programs that help women like you improve their health.

For more information about this study

If you have questions about your rights as a research participant in this study, please call 1-800-584-8814, leave a message including your name and phone number, and your call will be returned as soon as possible. For specific information about the study, you may call Carlyn Orians at Battelle at 206-528-3320. You will receive a copy of this form.

Your signature below indicates that you were told about the study and agree to participate.

The content of this consent form has been explained to me. I have had the chance to ask questions about this project and understand that I can ask questions at any time. I have received a copy of this form.

Signature _____ Date_____
Witness_____

Appendix E – Codebook

Code	Definition	Example
Source of Knowledge	Use this code when an informant mentions where they have heard of folic acid in the past.	Commercials, family, books, printed materials in doctor's offices, television shows, radio, magazines, online.
Intake of Folic Acid	Any discussion of how they get their daily intake of folic acid.	Leafy, green vegetables, fruits, multivitamins
Doctor's Comments	Use this code when there is any mention of what they have heard from their doctors about folic acid.	"My doctor did not ever mention it," not a big deal, very important
Knowledge Wanted	Use this code when women mention the information about folic acid that they currently do not know and/or want to know.	Foods that contain folic acid, further health benefits of folic acid, deficiency status, how much folic acid to take, when to take it
Health Barrier	Use this code when a woman mentions a health issue as a barrier to taking folic acid.	Multivitamins lead to sickness, fear of drug interactions with current medicine
Financial Barrier	Use this code when a woman mentions a financial issue as a barrier to taking folic acid.	Multivitamins/supplements are too expensive, could lead to job loss if vitamin makes me sick
Knowledge Barrier	Use this code when a woman mentions a lack of knowledge as a barrier to taking folic acid.	Can't remember to take them, unsure of how or where to get them, confusion with birth control, unknown side-effects.
Myths	Any false information stated about folic acid in the focus group.	getting 100% of folic acid through foods alone, folic acid doesn't affect people who aren't pregnant, previous child born healthy without mother taking folic acid so next child will be also.
Health Habits	Use this code when women talk about their current daily health habits.	Take multivitamins irregularly, take prenatal vitamins, calcium, vitamin D, vitamin C
Helpful Materials	Any discussion of how women want to obtain/would be open to learning information about folic acid.	Facebook, electronic ads, television commercials, brochures
Unhelpful Materials	Use this code when a woman mentions what kinds of educational materials would not work in educating her about the importance of folic acid.	Too lengthy, outdated, scare tactics, negativity, patronizing
Motivating Factors	Use this code when a woman mentions why she would be likely to take folic acid.	Doctor's orders, family history of birth defects, heard it was good for the baby, scared of NTD's.