Supporting Statement Part A

Assessing Knowledge, Attitudes, and Practices (KAPs) of Hispanic or Latina Women of Reproductive Age about Folic Acid Fortification and Supplementation

New

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Supporting Statement Part A. Justification

A. Justification

Goal of the project: The purpose of this project is to conduct formative research with Hispanic/Latina women of reproductive age to examine folic acid and fortified food awareness, food and supplement use practices, as well as messaging and channels to reach Hispanic/Latina women.

Intended use of the resulting data: The resulting data are expected to be used for developing new messaging and communication products to improve knowledge, awareness, and practices regarding folic acid fortification and supplementation among Hispanic/Latina women of reproductive age. Additionally, the findings from the project will inform future intervention activities to prevent neural tube defects among babies born to Hispanic/Latina women.

Methods to be used to collect: Nine focus groups will be conducted in Spanish, in both in-person and virtual formats.

The subpopulation to be studied: Hispanic/Latina Women of Reproductive Age

How the data will be analyzed: Deductive and inductive coding will be used to analyze focus group findings. Using deductive coding, a set of predetermined codes will be created from the interviewer's guide and then transcript excerpts will be extracted to fit those codes. Using an inductive, "bottom-up" approach, codes will also be developed as we analyze the transcripts. Analysts will meet to agree on salient themes related to focus group feedback to arrive at consensus on conclusions and recommendations.

Section A.1. Circumstances Making the Collection of Information Necessary

This Information Collection Request is submitted under the classification "New" request. The length of data collection requested for OMB-PRA approval is 3 years. The National Center on Birth Defects and Developmental Disabilities (NCBDDD) at the Centers for Disease Control and Prevention (CDC) is making this request as authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241) **(Attachment 1)**.

Background

Consuming 400 micrograms (mcg) of folic acid daily in the periconceptional period can reduce the risk of having a pregnancy affected by a neural tube defect (NTD), a severe birth defect of the brain and spine. To increase the amount of folic acid consumed in the U.S. population, the U.S. Food and Drug Administration (FDA) mandated fortification of enriched cereal grain products with folic acid in 1998. Although strides have been made in preventing neural tube defects, ethnic disparities remain. Hispanic women in the U.S. have the highest risk

of having a child affected by a NTD, with birth prevalence of approximately 7 NTDs per 10,000 live births[1]. In addition, Hispanic women:

1. Have lower levels of folate in their blood compared to non-Hispanic white women;
2. Are more likely than non-Hispanic white and non-Hispanic black women to have the MTHFR C677T gene variant;
3. Are less likely to know about the benefits of folic acid;
4. Are less likely to get folic acid from fortified foods or take a multivitamin with folic acid in it, particularly those women who primarily speak Spanish, were born outside of the United States, and have lived in the United States for a shorter period of time[1].

To effectively reach Hispanic women of reproductive age (WRA) and increase their knowledge and intake of folic acid for NTD prevention, a contemporary understanding of cultural factors in the decision-making process and how these women obtain information is needed. Previous research highlighted important nuances in potential cultural beliefs regarding folic acid. A study of Spanish-speaking Hispanic women in the southwest U.S. found no cultural barriers to incorporating folic-acid rich foods into their diets; however, focus groups of Mexican American women did find several cultural barriers. These included misperceptions of the term folic acid as an illegal substance, as the word "acid" is similar to LSD; its importance for NTD prevention since their healthcare providers did not talk to them about folic acid; its absence in injectable form at the pharmacy; and mistaken belief that birth defects are not preventable (resulting from an act of God).[2] Habek and colleagues (2003) found contradictory findings, suggesting that Mexican American women have increased awareness of the association between folate and birth defects compared to English-speaking women.[3] More current research is needed to determine cultural factors in the decision-making process around folic acid intake for Hispanic WRA.

[1] CDC. "Folic Acid Data and Statistics." Retrieved May 3, 2022 from https://www.cdc.gov/ncbddd/folicacid/data.html.
[2] Quinn, G. P., Hauser, K., Bell-Ellison, B. A., Rodriguez, N. Y., & Frías, J. L. (2006). Promoting pre-conceptional use of folic acid to Hispanic women: a social marketing approach. *Maternal and Child Health Journal*, *10*(5), 403-412.
[3] Habak, P. J., Coonrod, D. V., Brady, M. J., Bay, R. C., & Mills, T. E. (2003). Knowledge regarding preconceptional folic acid use in a Mexican-American patient population. Primary care update for ob/gyns, 10(6), 274-277.

Section A.2. Purpose and Use of Information Collection

This new information collection will be requested for use within three years. Information will be collected through focus groups with Hispanic/Latina women of reproductive age. CDC's Prevention and Health Disparities (PHD) Team's health equity goal is to enhance the prevention of neural tube defects among Hispanic/Latina women of reproductive age in the United States. Despite mandatory folic acid fortification of enriched cereal grain products (like bread and cereal), research shows that some U.S. women still do not get enough folic acid to prevent neural tube defects (NTD), which are severe birth defects of the brain and spine. To better understand

these issues and improve this disparity, the PHD Team plans to assess awareness of appropriate interventions among intended audiences to help guide future activities. Prior activities that CDC funded more than a decade ago to assess knowledge, awareness, and behaviors related to folic acid use among Hispanic populations included: 1) qualitative and quantitative research to guide the development of new educational materials to reach Latinas, which was highlighted in a publication titled, *But I've Already Had a Healthy Baby: Folic Acid Formative Research with Latina Mothers* (2008), and 2) formative research to understand barriers and motivators to folic acid consumption and guide materials development for young Latina adults, which was highlighted in a publication titled, *Preparing for a Healthy Future Today* (2010). To effectively reach Hispanic/Latina women of reproductive age (WRA) to increase their knowledge and intake of folic acid for NTD prevention, a contemporary understanding of cultural factors in the decision-making process and how these women obtain information is needed.

Section A.3. Use of Improved Information Technology and Burden Reduction

Focus groups will be conducted both online and in person by EurekaFacts staff, who have been contracted by CDC to complete data collection. All qualitative data will be collected via moderator's notes and transcribed recordings captured during the focus groups. Participants in online focus groups, particularly those in rural areas, will be able to participate without needing to drive long distances and if applicable, will not have to arrange childcare. This will also allow data to reflect more diverse geographic locations and help reduce the burden to participate in the study. Additionally, the focus groups will be moderated completely in Spanish (**Attachment 30 and 31**) to match the primary language that participants use in their daily lives.

Prior to collection of qualitative data, participants will be sent an email invite or letter (**Attachment 8 and 9**) to participate in a conversation (or focus group) to share their experiences. If there are not enough responses, a follow-up invitation (**Attachment 10 and 11)** will be sent with a final/second follow-up (**Attachment 12 and 13**), if needed. Once an agreed upon date and time has been determined, EurekaFacts staff will send a scheduling email (**Attachment 16 and 17**) to confirm attendance for their selected focus group format (i.e., online or in person). Upon response to the scheduling email, participants will then be sent a confirmation email (**Attachment 18 and 19**) with more details of the session. This will be followed up with a reminder email (**Attachment 39 and 40**). The invitation emails (**Attachments 8 and 9**) will lead the participants to the self-administered screener (**Attachments 20 and 21)**. Participants are also given the option of calling and a bilingual EurekaFacts staff member will screen (**Attachment 22 and 23**) the participant via phone call. Please reference **Attachment 35 and 36** for the screenshots of how the online screener will be presented. It is estimated that it will take up to 10 minutes to complete the screener.

Due to the nature of the study, EurekaFacts will also email (**Attachment 14 and 15**) a list of community-based organizations that work with this population and supply flyers (**Attachment 33**) for advertising and Frequently Asked Questions (**Attachment 26 and 27**), as needed for potential participants. The FAQ will also be programmed into a landing page. In addition, EurekaFacts has prepared social media advertisements (**Attachment 34)** that may be used to

reach Hispanic/Latina women with the specific demographics intended for this study using platforms such as Instagram and Facebook. Social media postings are the third option for recruitment to cast a wider net and will be monitored twice a week.

Section A.4. Efforts to Identify Duplication and Use of Similar Information

Currently, no related activities exist with other federal agencies, academic institutions, or NGOs to conduct formative research with Hispanic/Latina women of reproductive age about their folic acid knowledge, awareness, and practices. The CDC's OMB Information Collection Request Tracking System was reviewed to identify any open requests for similar information. No open information collections were available to provide information related to folic acid fortification and supplementation use among the intended subpopulation of Hispanic/Latina women of reproductive age. Before the information collection began, consultants gathered feedback from subject matter experts that represented national or community-based organizations that served the subpopulation to understand the value of the information collection. In addition, to determine opportunities to work with other federal agencies a search for "folic acid" was conducted on regulations.gov to determine if other Federal Register Notices exist, and no current FRNs were found.

Section A.5. Impact on Small Businesses or Other Small Entities

The CDC is contracting with EurekaFacts, LLC, a small business based in Rockville, MD, to develop and implement the data collection.

Section A.6. Consequences of Collecting the Information Less Frequently

The consequence of not collecting the information would be to not have a contemporary body of data on the folic acid knowledge, awareness, and practices of Hispanic/Latina women of reproductive age in the U.S. to inform prevention efforts in a population that is at increased risk for a pregnancy affected by a neural tube defect.

Each respondent will be asked to respond once.

There are no legal obstacles to reduce the burden.

Section A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with regulation 5 CFR 1320.5.

Section A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. A copy of the agency's 60-day Federal Register Notice is attached (*60-day Federal Register Notice* **Attachment 2**). The notice, as required by 5 CFR 1320.8 (d), was published on November 22, 2022 (Volume 87, Issue 224, pages 71329-71330). CDC received one public comment in response to this notice (**Attachment 4)**.

Comment 1 (Attachment 4): this is a waste of american tax dollars. there is no need to racialize this comment from women on folic acid. all women would have the same views. this is not a racial issue which this agency is trying to racialize everything. all women would have the same thoughts on this issue and that survey has already been done. close down this out of control spending and the racializing of eerythign in america. this comment is for the public record. who are you leaving out with this attempt to racizlize this issue? are you leaving out brown people? are you leaving out indians? Are you leaving out whites. why are you dismising their thoughts. this is stupid govt.

Response to Comment 1: Thank you for your comment. Focus groups of Mexican American women have found several cultural barriers regarding knowledge and intake of folic acid for NTD prevention. A contemporary understanding of cultural factors in the decision-making process and how these women obtain information is needed to effectively reach Hispanic women of reproductive age (WRA) and increase their knowledge and intake of folic acid for NTD prevention.

Section A.9. Explanation of Any Payment or Gift to Respondents

Respondents will receive a $75 gift card for their participation in the focus group and a thank you letter/email (**Attachment 24 and 25**) as a token of appreciation**.** Research suggests that providing monetary incentives to study participants, either prepaid or promised, increases response rates and prevents bias, making findings generalizable to our intended population (Hispanic/Latina women of reproductive age) in the U.S.[4] The EurekaFacts IRB approval of the study **(Attachment 3)** is also included and was reviewed and approved at this level of remuneration.

[4] Yu, J., & Cooper, H. (1983). A Quantitative Review of Research Design Effects on Response Rates to Questionnaires. Journal of Marketing Research, 20(1), 36–44. https://doi.org/10.1177/002224378302000105

Section A.10. Assurance of Confidentiality Provided to Respondents

The proposed data collection will have no anticipated effect on the respondent's privacy. The CDC research determination for this project has declared it "Not Research – Public Health Surveillance" and therefore exempt from IRB review (**Attachment 5**). The contractor, EurekaFacts, completed an IRB approval (**Attachment 3**) of the study due to their role in data collection. However, this data collection effort is subject to the Privacy Act and will be managed in accordance with CDC's System of Records Notice (SORN) #09-20-0136, Epidemiologic Studies and Surveillance of Disease Problems, Department of Health and Human Services/CDC/National Center for Infectious Diseases. A privacy impact assessment

(**Attachment 6**) for this project was reviewed and approved by a CDC Senior Official for Privacy.

When focus groups are conducted online, the online platform will record the session and a back-up audio recorder will also be set to record the session. When focus groups are conducted in person, EurekaFacts will use an audio recorder to record each session. A Zoom link will also be set up and sent for remote observers; this can also be used as an additional system to record the session. Information that will be collected is qualitative responses to a set of questions, which participants have the choice to answer or not, such as experiences with healthcare providers, intake of vitamins or supplements, knowledge on folic acid, and consumption of corn masa flour (**Attachment 30 and 31**). In addition, participants will look at visuals in supplements as references or aids (**Attachment 32)** for recall when responding to questions during the focus group.

All focus group recordings will be transcribed in their original language, Spanish. EurekaFacts' bicultural/bilingual research team members will code the Spanish to English transcripts using a codebook. EurekaFacts will remove all personally identifiable information (PII) from transcripts, should they exist. Electronic data will be kept on EurekaFacts' secured server. All data (hard copy and electronic) will be scanned and stored within the project folder via SharePoint. All study materials (tapes and research notes) will be properly scanned, filed, maintained, and secured within the project folder via SharePoint.

An Informed Consent Form, either an online (**Attachment 37 and 38**) or paper form (**Attachment 28 and 29**), will be obtained from all the participants of the focus group.

Frequently Asked Questions (FAQs) will be provided to all individuals eligible to participate in the project. Completion of the informed consent form will be taken as consent to participate. Because this work presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context, we will not request written documentation of informed consent. FAQs will inform the participant about the purpose and procedures of the project. Additionally, these FAQs state that there are no known risks to the participant and all personal information will be kept private to the extent allowed under federal laws. The FAQs also state there is no benefit to completing the study, but answers may help identify unmet needs of Hispanic/Latina women of reproductive age and their families. Further, the participants will be reminded during the introductions of the study that their participation is voluntary and that they may choose not to answer a question at any time or may withdraw their input from the project. Should they decide to withdraw from the focus group discussion, they may forfeit all or a part of their incentive, proportional to their level of participation. The moderator will also orally present relevant information about the study to the participants to further enable them to make informed decisions about their involvement in the study. Respondents will be informed during the screening process that all notes and transcripts from the data collection will be used solely to write the final report. All transcripts and notes from the focus groups will only be available to project staff. In addition, this information will also be disclosed to the respondents in the informed consent form.

Section A.11. Justification for Sensitive Questions

Within the moderator guide, participants will be asked health questions (e.g., vitamin/supplement intake, health care provider interactions, pregnancy, and food consumption) which they may feel uncomfortable answering. At the beginning of this guide, within the introductions, participants are reminded that "Your participation is completely voluntary. You may refuse to answer any question asked during the discussion" (**Attachment 30 and 31**).

Section A.12. Estimates of Annualized Burden Hours and Costs

It is estimated that 81 respondents will have to be screened by telephone (**Attachment 22 and 23**) or online (**Attachment 35 and 36**) to recruit participants. Each screening will take approximately 10 minutes. The estimated response burden for the screening process is 13.5 hours.

The focus groups will have an average of up to 9 participants each and 9 focus groups will be conducted with up to 81 participants. Each focus group will take 90 minutes for a total of 121.5 burden hours.

The paper-based (**Attachment 28 and 29**) or online (**Attachment 37 and 38**) informed consent process will take approximately 2 minutes to complete for a total burden of 2.7 hours.

There are no costs to respondents other than their time.

A.12.A. Estimated Annualized Burden Hours

Type of Respondents	**Form Name**	**No. of Respondents**	**No. of Responses per Respondent**	**Average Burden per Response (in hours)**	**Total Burden Hours**
Hispanic/Latina Women of Reproductive Age	Knowledge, Attitudes, and Practices (KAPs) of Hispanic/Latina Women of Reproductive Age: Focus Group Interview Guide	81	1	1.5	121.5
TOTAL					121.5

The annualized cost burden is shown in Table A.12.B. The median hourly wage rate is based on the most recent (May 2022) National Occupational Employment and Wage Estimates for all occupations, published on the Bureau of Labor Statistics website which is $22.26.

A.12.B. Estimated Annualized Burden Costs

Type of Respondents	No. of Respondents	No. Responses per Respondent	Avg. Burden per Response (in hours)	Total Burden Hours	Hourly Wage Rate[1]	Total Respondent Costs
Hispanic/Latina Women of Reproductive Age	81	1	1.5	121.5	$22.26	$2704.59
TOTAL						$2704.59

[1] Annualized burden costs are estimated using the Bureau of Labor Statistics, National Compensation Survey, available at http://www.bls.gov/oes/current/oes_nat.htm.

Section A.13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no costs to respondents associated with either capital and startup efforts or operation and maintenance of services for this project.

Section A.14. Annualized Cost to the Government

The average annualized cost to the Government to collect this information is $346,502 for this 3-year OMB approval period that is requested.

	CDC and Contract Personnel*	FTEs	Costs* (dollars)
Federal Government Personnel Costs	CDC Project Officer/Project Lead	.1	10,747
	CDC Contracting Officer Representative	.1	9,038
	CDC Subject Matter Expert	.05	6,350
	CDC Subject Matter Expert	.05	6,350
	CDC Subject Matter Expert	.025	3,175
Federal Government Other Direct Costs	Office supplies		100

Contractor Direct Labor	EurekaFacts Consultants	1	310,742
TOTAL COSTS			346,502

Section A.15. Explanation for Program Changes or Adjustments

This is a new data collection.

Section A.16. Plans for Tabulation and Publication and Project Time Schedule

A.16.—Project Time Schedule				
Activity	**Timeframe**		**Estimated Start**	**Estimated End**
OMB Approval	Estimated: December 4, 2023			
Implementation of Formative Research Plan (Recruitment and Data Collection)	Recruitment	2 weeks - 1 month after OMB approval	12/11/2023	4/1/2024
	Conduct focus groups	1 -2 months after OMB approval	1/22/2023	4/8/2024
	Notes/transcripts/ audiotapes from focus groups	5 months after OMB approval	5/6/2024	6/3/2024
Analysis and Development of Final Products	Analyze Results	5 months after OMB approval	5/13/2024	6/7/2024
	Draft Report	7 months after OMB approval	6/10/2024	7/1/24
	Final Report	8 months after OMB approval	7/15/2024	8/2/2024
	Draft PowerPoint	9 months after OMB approval	8/5/2024	8/16/2024
	Final PowerPoint	10 months after OMB approval	8/26/2024	9/16/2024

Section A.17. Reason(s) Display of OMB Expiration Date Is Inappropriate

NA

Section A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.