Formative Research with Consumers, Couples, and Innovators about Reproductive Life Planning and Preconception Health

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A. Justification

A.1 Circumstances Making the Collection of Information Necessary

On January 9, 2009, CDC received OMB approval for the generic concept of health marketing (Health Marketing, 0920-0798) to provide feedback on the development, implementation and satisfaction regarding public health services, products, communication campaigns and information.

Under Health Marketing, OMB has agreed to expedite review of proposals for data collections for survey/informative materials development and customer satisfaction surveys only. OMB will generally review such requests within ten business days.

Background

Although infant mortality rates have declined over time, national data indicate that improvements have stalled (National Center for Health Statistics, 2007), and other indicators of infant or maternal health have eroded as well. For example, babies born preterm, low, or very low birth weight have increased (CDC, 1999). In addition, in 2002 low birth weight, congenital anomalies, preterm delivery, and maternal complications accounted for 46% of infant deaths. These statistics have led the Centers for Disease Control and Prevention (CDC) and other experts to call for changes in the public's notion of maternal and prenatal care to one that is more comprehensive and developmental in its approach.

CDC and other advocates have called for "preconception care" (PCC) to supplement "prenatal care," because evidence shows that changes in maternal behavior and information provided to women and couples in need has a positive impact on birth and infant outcomes. Early prenatal care is often too late to make these changes (Atrash et al., 2006). The challenge, however, is that promotion of "preconception care" or related terms like "reproductive life planning," or "interconception health" would likely not be effective, because these are unfamiliar terms to women or couples who are planning pregnancy or likely to become pregnant. Findings from the HealthStyles survey developed by Porter Novelli, indicated that half of the total respondents had not heard of PCC with almost one-third doing "nothing" to prevent pregnancies. The gap between understanding what PCC means and efforts to prevent pregnancies could result in poor outcomes for babies, mothers, and families.

In 2005, the Centers for Disease Control and Prevention (CDC) convened a Select Panel on Preconception Care. Posner, Johnson, Parker, Atrash, and Beirmann (2006) present the

strategic plan for improving women's health and pregnancy outcomes developed by the panel. The strategic plan identifies four overarching goals:

1) to improve both men's and women's knowledge, attitudes, and behaviors related to preconception health (PCH);
2) to ensure that all U.S. women of childbearing age receive preconception care services —screening, health promotion, and interventions—that will enable them to begin a pregnancy in optimal health;
3) to reduce risks indicated by a prior adverse pregnancy outcome through interventions during the interconception (inter-pregnancy) period that can prevent or minimize health problems for a mother and her future children; and
4) to reduce the health disparities in adverse pregnancy outcomes (Posner et al., 2006).

This plan includes 10 key recommendations to improve preconception health (Appendix A). Action steps to address consumers' awareness of PCC include the following:

- Conduct consumer-focused research necessary to develop messages and terms for promoting preconception health and reproductive awareness.
- Design and conduct social marketing campaigns necessary to develop messages for the promotion of preconception health knowledge, attitudes, and behaviors among men and women of childbearing age (Posner et al., 2006, p. S201).

To address individual responsibility across the lifespan, the panel recommended the following action step:

- Conduct research leading to development, dissemination, and evaluation of individual health education materials for women and men regarding preconception risk factors, including materials related to biomedical, behavioral, and social risks known to affect pregnancy (Posner et al., 2006, p. S201).

To address preventive visits, the panel recommended the following action step:

- Increase health providers' (including primary and specialty care providers') awareness regarding the importance of addressing preconception health among women of childbearing age.

The CDC panel's recommendations regarding PCC research among both men and women recognizes that mutual joint effects in couples—that is, how knowledge, skills, motivations of each partner affect his or her own and his or her partner's preconception health—may play a particularly important role in stimulating PCC behaviors in the context of couple relationships (Lewis et al., 2002; 2006a; 2006b). However, little is known about how couples communicate surrounding PCC behaviors, what terms they use, or what would make PCC appealing. Interdependence theory indicates the ways that spouses/partners can influence each other's preconception health by highlighting important patterns of influence in the couple relationship. They can both engage in the same behaviors to achieve the same outcomes—a healthier baby. They can each engage in different behaviors to achieve the same outcomes—she

takes supplements or changes nutritional behavior and he helps her by providing social support. Moreover, the factors that influence spouses' individual and collective behavior may vary not only within couples, but also between couples.

In order to change the public's notions of the care and planning needed for healthy babies, it is vital to understand first how important target audiences—women and couples—think about and define these concepts in order to frame messages and implement interventions effectively. This project proposes to examine how women and couples think about PCC in an effort to inform the development of communication messages that can lead to increased awareness, knowledge, skills, and motivation for PCC, thereby increasing the likelihood of a healthy baby.

Authorization to conduct this activity is contained in the Public Health Service Act (42 USC 241) Section 301. A copy of the legislation is included as Attachment 1.

Overview of the Data Collection System

Data collection for this effort will consist of three parts:

- 10, 90 minute focus groups with women
- 75, 60 minute telephone interviews with couples
- 18, 60 minute interviews with innovators or stakeholders in the field of PCC

Attachments 2-4 contain interview guides for the focus groups, telephone interviews, and innovator/stakeholder interviews. At the end of the focus group discussions only, participants will complete an 11-question paper-and-pencil questionnaire (see Attachment 5 – Focus Group Participant Questionnaire). Questions are either multiple-choice or write-in responses.

RTI International will conduct the focus groups and interviews and will store resulting data for only one year after the completion of data collection.

Items of Information to be Collected

The types of information to be collected include information about the participants' demographics, such as age, education level, marital status, race/ethnicity, health insurance status, and income. Discussion questions focus on awareness of healthy behaviors during pregnancy, prior to pregnancy, and preconception health; factors that may motivate or present barriers to preconception health behaviors; communicating information about preconception care to others; and preferred information sources.

Notes, discussion transcripts, and questionnaires from the focus groups will not be in an identifiable form. However, the recruitment firm (Schlesinger Associates, Inc.) will collect limited information in identifiable form (IIF) through the screener (see Screening Instruments – Attachments 6-7) in order to categorize female consumers and couples according to the five audience segments.

A.2 Purpose and Use of Information Collection

The National Center for Birth Defects and Developmental Disabilities (NCBDDD) at the CDC is requesting approval to conduct formative research with female consumers, couples, and preconception stakeholders/innovators to learn more about their knowledge, attitudes, beliefs and behaviors regarding the collection of services and behaviors represented by the concept of preconception health (PCH). Findings from the formative research will be used to develop and test messages related to PCH. If we do not conduct this formative project, CDC will not have the information it needs to create up-to-date and effective educational and communication materials.

We will use the consumer focus groups to address the following general questions:

- What does PCC and PCC behaviors need to look and feel like to make this product appealing to women?
- What strategies for promoting PCC and PCC behaviors are needed for women?
- What factors influence the price (e.g., benefits and costs) of PCC and PCC behaviors?
- What is the optimal placement of PCC or PCC behaviors for women?

We will use the couples-based interviews to address the following general questions:

- What does PCC and PCC behaviors need to look and feel like to make this product appealing to couples?
- What strategies for promoting PCC and PCC behaviors are needed for couples?
- What factors influence the price (e.g., benefits and costs) of PCC and PCC behaviors?
- What is the optimal placement of PCC or PCC behaviors when it comes to couples?

We will use the stakeholder-based interviews to address the following general questions:

- What does an effective PCC model look like to you?
- What are the facilitators and barriers to an effective PCC model?
- How should PCC be funded/reimbursed?
- How can the PCC movement advance forward?

<u>Privacy Impact Assessment Information</u>

The screening questionnaires to determine eligibility, the consumer focus groups, the couple interviews, and the exit questionnaire (consumer focus groups only) will include some questions on sensitive information such as planning for pregnancy and reproductive health. However, data will be treated in a secure manner and will not be disclosed, unless otherwise compelled by law (see section A-10).

Identifying information through the screener will be collected by the professional recruiting firm, but only for recruiting purposes and will not be attached to findings. Limited identifying information from stakeholders who work in the preconception health field will also be collected, but this information will not be attached to findings and will only be reported in a summary report.

<u>Recruitment</u>

The data collection will not use statistical methods to select respondents. We will use a professional recruitment firm, Schlesinger Associates, Inc. to recruit participants for the focus groups and telephone interviews. A variety of methods will be used to recruit participants, including the recruitment firm's existing databases of potential participants, advertisements, and flyers.

Recruitment for innovator interviews will use a snowball technique beginning with CDC-provided contacts. After conducting interviews with the original set of contacts, RTI will ask these contacts for recommendations for other noteworthy stakeholders and innovators in the field continuing until data saturation is reached or the maximum number of interviews is conducted. When recruiting, RTI will emphasize that participation is completely voluntary.

Segmentation Strategy

The segmentation strategies for the focus groups and telephone interviews participants are based on findings that poor birth outcomes are more likely among low income and racial minority populations (CDC, 1999). The income limits indicated in the screeners were selected with a goal of increasing recruitment in low and middle income categories.

A.3 Use of Improved Information Technology and Burden Reduction

Due to the nature of this project, incorporating improved information technology for the purpose of data collection is not feasible. We will employ telephone-based interviews with stakeholders and couples to gather information.

Upon consent from the participants, we will audio record the discussions to capture all information and assist with the preparation of reports. The use of electronic reporting is typically not feasible for this form of qualitative work.

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

There have been no formal efforts to identify duplication because program staff, through extensive contacts with organizations and individuals in both the private and public sectors, know that there are no similar data available. RTI International, the CDC contractor for this project, conducted a comprehensive scientific literature review of multidisciplinary fields, including medicine, public health, communication, and behavioral science. In addition to reviewing published information, the literature review included "gray" literature obtained from CDC funded projects, and literature obtained through the use of Internet and other search engines (such as Google and Medline). This project builds on the information found through the literature review, but the information currently available has significant gaps, is out-dated, and does not adequately address the topics of interest. There is no other project that duplicates the proposed efforts.

A.5. If the collection of information impacts small businesses or other small entities (Item 5 of OMB Form 83-I), describe any methods used to minimize burden.

There is no burden on small businesses or small entities. No small businesses will be involved in this activity. We will schedule all focus groups and interviews at the convenience of the participant and will not impact the participant's employer.

A.6 Consequences of Collecting the Information Less Frequently

This is a one-time request; therefore, it is not possible to ask participants to participate in the focus groups or interviews less frequently. There are no legal obstacles to reduce the burden.

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

This request fully complies with the regulations regarding the guidelines of 5 CFR 1320.5. There are no special circumstances contained within this application.

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

A. The 60-day Federal Register Notice (FRN) for 0920-0798 was published in the Federal Register on May 14, 2008, Vol. 73, No. 94, pp. 27833-27834. The 30-day FRN was published on July 24, 2008, Vol. 73, No. 143, pp. 43241-43242. No public comments were received.

B. The CDC team collaborated with RTI International staff (contractor) on the design, screening instruments, focus group and interview guides, and exit questionnaire (focus groups only). RTI staff is trained and experienced in focus group moderation and telephone interviews.

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

We will give participants in the focus groups and interviews a monetary incentive to thank them for their time, effort, and transportation costs for participating in the study. The incentive amounts are as follows:

Women	$75.00
Couples	$35.00/individual
Stakeholders/Innovators	$75.00

This proposed payment of $75/participant (women and stakeholders/innovators) and $35/participant (couples) is intended to recognize the time burden placed on the participants, encourage their cooperation, and to convey appreciation for contributing to this important activity. Numerous empirical studies have shown that incentives can significantly increase response rates (e.g., Abreu & Winters, 1999; Shettle & Mooney, 1999; Greenbaum, 2000). This level of reimbursement for the target audiences also helps to support additional costs participants may incur such as transportation and/or childcare in order to participate.

<u>Consumer Focus Groups</u>

The firm that will recruit the women for the focus groups, Schlessinger Associates, Inc, recommends a minimum payment of $75 per participant (see Attachment 8 – Recruitment Firm Letter). In their experience, they find a drop off in respondent commitment with any lower amount. In response to offering this level of incentive, respondents are much more likely to honor their commitment of participating in the focus group or interview. Lower incentives could actually result in higher recruiting costs due to the need to over recruit by higher percentages (Krueger & Casey, 2009). Additionally, this focus group will last up to 90 minutes, which averages out to $35/hour of participation.

Couples Interviews

This research is important and needed because research with low and middle income couples regarding their knowledge, attitudes, and behaviors surrounding preconception care has not been conducted before. This study will be an important first step in developing programs to help women and their partners achieve better health for themselves and during pregnancy. The couple interviews provide an opportunity to gain insight into a critical information gap that will help develop these programs.

Previous studies have noted challenges with recruiting couples and have found that financial incentives can assist with recruitment (Pappas-DeLuca et al., 2006; Preloran et al., 2001). The recruitment of couples is more difficult than recruitment for individuals because both couple members need to be receptive and agree to participate. Sensitive topics such as preconception health require both members of the couple to be willing to discuss and share their opinion with their partner present. Interviewing couples requires couples to coordinate their schedules, thus imposing an additional effort on each potential participant (Pappas-DeLuca et al., 2006). While financial incentives may not be the decisive factor in determining couple participation, Preloran et al. (2001) found that incentives resulted in couples responding to invitations to participate in studies more positively. For couples who have children, paying for childcare during the interview is an additional barrier to participation. Additional dollars beyond that which is preferred by OMB for individual interviews can offset this barrier and burden to participants.

Interviews with Stakeholders

The stakeholders we propose to interview consist of physicians and other professionals in the preconception health field. Given that the U.S. Department of Labor lists an average hourly wage for obstetricians/gynecologists of $95.84 (http://www.bls.gov/oes/2008/may/naics4_621100.htm), we propose offering a $75.00 honorarium for participation in the interview. While honoraria for physicians are usually much higher, we feel that stakeholders who are interested in this nascent field will be willing to participate with this incentive out of professional courtesy.

A.10. Assurance of Confidentiality Provided to Respondents

CDC and RTI will take many precautions to secure participants' identifiable information (see Privacy section of Consent Forms – Attachment 9-11). The information participants provide during the interviews will not be linked to the respondents' identities. Participants will use only first names or pseudonyms during the focus group discussions and interviews. Transcripts and

notes will not include participants' names. The exit questionnaires (focus groups only) will be anonymous (i.e., it will not contain any identifying information and will not be linked to individual participants). Audio files of the interviews will be stored by RTI on a secure share drive and password-protected computers. Reports will not include any identifiable information.

Identifying information (name, address, telephone number) will be used to send confirmation letters/e-mails and to make reminder calls to respondents (see Attachments 12-14). This information will be kept by the recruiting firm separately from any information collected in the interviews. Screeners will be kept in a locked file cabinet at the recruitment firm or in password-protected computer files. The recruiter will only provide RTI and CDC a summary of participant information on the recruitment grids, which will be stripped of identifiable information, such as the last names, addresses, and telephone numbers of the participants. The professional recruiting firm will be instructed to destroy their project-related records at the conclusion of the project.

The precautions taken by CDC and RTI have been evaluated by the Institutional Review Board of RTI and found to be acceptable (see RTI IRB approval – Attachments 15-16).

A.11. Justification for Sensitive Questions

Sensitive questions including those concerning pregnancy plans are necessary to determine eligibility for consumer participation in the focus groups and telephone interviews. Respondents will be asked to answer questions regarding their current plans for a pregnancy in the future, which includes a response option for those who are unable to become pregnant due to a diagnosis of infertility or any type of sterilization (e.g., tubal ligation, hysterectomy, or vasectomy).

During the screening process, potential participants will also be told that they will be asked some questions to see if they qualify for the groups. Verbal consent from the potential participants will be obtained before the potential participants are screened for eligibility over the phone.

In the event a participant finds any question to be objectionable, the participant can easily skip that question.

A. 12. Estimates of Annualized Burden Hours and Costs

A. Annualized burden hours are based on the estimated time it will take to complete the screener (12 minutes), and to participate in the focus groups (90 minutes) or interviews (60 minutes).

For the couples interviews, the number of respondents for the screener is estimated at 320, since not all of those who respond to the screener will be eligible to participate. The maximum number of respondents for the interviews with couples is 150 (75 couples).

For female consumers, the number of respondents for the screener is estimated at 300, since not all of those who respond to the screener will be eligible to participate. The maximum number of respondents for the focus groups with women is 120.

For the innovator interviews, the number of respondents who receive a request to participate is estimated at 25. The maximum number of respondents is 18.

The estimated total annual burden for all three participant groups is 472 hours.

Table 1: Estimated Annualized Burden Hours

TYPE OF RESPONDENT	FORM NAME	NUMBER OF RESPONDENTS	NUMBER OF RESPONSES PER RESPONDENT	AVERAGE BURDEN PER RESPONSE (in hours)	TOTAL ANNUAL BURDEN (in hours)
Couples - Potential Participant	Screener (Attachment 7)	320	1	12/60	64
Couples - Interview Participant	Consent Form (Attachment 10)	150	1	5/60	12.5
Couples - Interview Participant	Interview Guide (Attachment 3)	150	1	55/60	137.5
Women - Potential Focus Group Participant	Screener (Attachment 6)	300	1	12/60	60
Women – Focus Group Participant	Consent Form (Attachment 9)	120	1	5/60	10
Women – Focus Group Participant	Focus Group Guide (Attachment 2)	120	1	80/60	160
Women – Focus Group Participant	Demographic Questionnaire (Attachment 5)	120	1	5/60	10
Innovator - Interview Participant	Consent Form (Attachment 11)	18	1	5/60	1.5
Innovator - Interview Participant	Interview Guide (Attachment 4)	18	1	55/60	16.5
Total					472

B. Annualized cost estimates to potential respondents, presented in Table 2, are based on mean (average) hourly wage estimates obtained from the U.S. Department of Labor, Bureau of Labor Statistics at http://www.bls.gov/oes/current/oes_nat.htm#b29-0000. Since these activities will take place all over the country we used the mean hourly wage for all occupations to obtain the estimates for consumers provided in Table 1 ($20.32). We used the mean hourly wage for obstetricians/gynecologists to obtain the estimates for stakeholders/innovators ($95.84). The total

number of burden hours for respondents to complete their responses is 472 hours. The total annual respondent cost is $10,950.40.

Table 2: Estimated Annualized Burden Costs

TYPE OF RESPONDENT	NUMBER OF RESPONDENTS	NUMBER OF RESPONSES PER RESPONDENT	AVERAGE BURDEN PER RESPONSE (in hours)	TOTAL ANNUAL BURDEN (in hours)	AVERAGE HOURLY WAGE RATE	TOTAL ANNUAL RESPONDENT COST
Couples - Potential Participant	320	1	12/60	64	$20.32	$1,300.48
Couples - Interview Participant	150	1	1	150	$20.32	$3,048.00
Women - Potential Focus Group Participant	300	1	12/60	60	$20.32	$1,219.20
Women – Focus Group Participant	120	1	90/60	180	$20.32	$3,657.60
Innovator - Interview Participant	18	1	1	18	$95.84	$1,725.12
Total	933			472		$10,950.40

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

Respondents participate on a purely voluntary basis and, therefore, are subject to no direct costs other than their time to participate; there are no start-up or maintenance costs. We do not require any additional record keeping.

A. 14. Annualized Cost to the Government

The total cost of this 1 year project is $512,856.

Table 2: Governmental Costs

Expense Type	Expense Explanation	Annual Cost
Government Salaries:	CDC Project Officer: GS-14, 6% time	$6,780
	CDC Behavioral Scientist: GS-13, 3% time	$2,250
	CDC Fellow: GS-12, 6% time	$3,300
Contractor Costs	1 year at $156,739 For information collection (including travel to Atlanta),	$350,526

	design, development, printing forms, mailing, editing, transcription, coding, tabulation, analysis and publication of results.	
	Total Annualized Cost:	$512,586

A. 15. Explanation for Program Changes or Adjustments

This is a new data collection.

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

OMB Submission	
Implementation of Interviews and Focus Groups	Within 2 months following OMB approval
Completion of Interviews and Focus Groups	Within 6 months following OMB approval
Manuscript Initial Draft	Within 9 months following OMB approval
Manuscript Final Draft	Within 11 months following OMB approval
PowerPoint Presentation	Within 11 months following OMB approval

Verbatim transcripts, debriefing notes, and digital recordings will be completed for each interview. The analysis team will review these materials and then analyze them using the following steps (adapted from Krueger & Casey, 2000).

1. Assign each respondent in the group an identification number.
2. Code the responses according to a set of predeveloped codes that represent key theoretical constructs (preconception behaviors, motivators/barriers to PCC, communication about PCC, preferred channels/sources of information).
3. Develop and assign emergent codes for responses that do not fit the pre-existing coding scheme.
4. Using these pre-established and emergent codes, identify the key themes and determine the degree of consensus or discordance with a particular view; the goal of a focus group is to focus on what the group thinks, not on what the individual thinks.
5. In a cross-group matrix, organize the key themes in accordance to the project question most closely addressed by group, noting particularly relevant quotes.
6. Using the cross-group matrix, identify cross-cutting themes and areas lacking consensus.

All exit questionnaire data (focus groups only) will be compiled and analyzed using descriptive statistics.

Within 3 months of completion of the interviews, RTI will prepare and submit to CDC two draft manuscripts: one that presents key findings from the women and innovator data collection and one that presents key findings from data collection with couples. The manuscripts will be

formatted for submission to a peer-reviewed publication. Within 2 weeks of receipt of CDC comments, RTI will submit a final version of the manuscripts. RTI will also prepare a draft PowerPoint presentation that will highlight key findings, and offer recommendations for message development; we will submit this to CDC for review simultaneous to the manuscript submission.

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

No exemption is requested.

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

There are no exceptions to the certification.

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