

Change Request

Women's Health Needs Study: The Health of US-Resident Women from Countries with Prevalent Female Genital Mutilation/Cutting (FGM/C)

(OMB Control No. 0920-1264 expires 05/31/2022)
May 5, 2020

Summary

CDC was previously approved to conduct the Women's Health Needs Study (WHNS), a study of women living in the United States who have experienced Female Genital Mutilation/Cutting (FGM/C). As planned, CDC completed a pilot study and used the results to refine the planned methodology of the primary WHNS. The purpose of this change request is to seek approval for changes based on the pilot results. These changes include: 1) changes in the language translations in which study materials will be provided; 2) modifications to the screening instrument and study questionnaire based on pilot feedback; and 3) an increase in the sample size and burden estimates. Additionally, because current COVID-19-related social distancing measures may be in place through Summer 2020 when data collection is planned to begin, we have added language to support measures to achieve social distancing in the event those are necessary. These changes, as well as a previously approved change in reimbursement amounts and an update to the total cost of the study, are reflected in Supporting Statements A and B which are included with this change request.

Background and Justification

CDC is currently approved to collect information to assess the health characteristics, experiences, and needs of women living in the United States who have experienced Female Genital Mutilation/Cutting (FGM/C) or may be at risk for FGM/C because they or their mothers were born in a country where FGM/C is prevalent. Data from this study will be used to: identify public health needs of women and communities in the United States affected by FGM/C; formulate public health strategies for meeting identified needs; and inform efforts to prevent continuation of the practice of FGM/C on women who may be at risk. Eligible respondents who consent to participate will complete a one-time, face-to-face interview using a standardized questionnaire. The study population includes US resident women aged 18 to 49 years who were born, or whose mother was born, in a country where FGM/C is prevalent.

As outlined in the current approval, over a six-week period in September-November 2019, a pilot study was conducted by the National Opinion Research Center at the University of Chicago (NORC), the contractor engaged by CDC to carry out fieldwork. NORC and local implementing partners in the Atlanta Metropolitan Area successfully recruited, consented, and interviewed 101 eligible women. Per terms of current approval, a change request is being submitted to outline changes based on pilot study results and outlined below.

Language Translations of WHNS Study Materials

Based on our experience during the pilot, the study team identified a need to modify the country of origin study eligibility criteria in order to ensure that participants were from countries with a higher

prevalence of FGM/C. The criteria were modified to include women whose country of origin or mother's country of origin are African countries with at least >65% prevalence of FGM/C. This resulted in the elimination of lower prevalence countries originally included: Kenya, Liberia, Nigeria. It resulted in the addition of West African countries with >65% prevalence of FGM/C: Burkina Faso, Gambia, Mali, and Mauritania.

We provide revisions to study materials (informed consent, screener, and questionnaire) in languages retained from original submission (Somali (**Attachments F2, G2, H2**), Arabic (**Attachments F4, G4, H4**) and Amharic (**Attachments F5, G5, H5**)). Because of inclusion of Francophone West African participants, we have added new French translations of study materials (**Attachments F3, G3, H3**). Finally, in the pilot study Tigrinya-speaking Eritreans who were eligible could not be interviewed due to the lack of Tigrinya translations. As a result, we are also adding Tigrinya translations for the main study (**Attachments F6, G6, H6**). Swahili translations provided in the pilot will not be needed for the main study due to the removal of Swahili-speaking Kenya.

WHNS Informed Consent, Eligibility Screener and Questionnaire

The pilot study identified modifications needed in the informed consent, study screener and questionnaire. The study screener can be implemented more efficiently if questions found to be unnecessary during the pilot were removed and more explicit interviewer instructions were added. Study questionnaire changes are needed to refine content and flow. Some questions were eliminated and/or replaced, open-ended response options used in the pilot were replaced with categorical response options, and some wording was simplified or corrected. To improve questionnaire administration, interviewer instructions were clarified or simplified. A change request for an increase in reimbursement amounts was approved on 01/29/2020. IRB approval for applicable changes in the informed consent, study screener and questionnaire have been obtained. Translations for these approvals are included as indicated above.

Sample Size

A major contribution of the study will be to understand and compare experiences among those who have undergone different types of FGM/C given the potential for various morbidities and negative health effects of FGM/C related to the type and severity of procedure. Pilot study data on the percentage of women who underwent each type of FGM/C was used to calculate the power to detect differences between groups who experience different types of FGM/C and consider whether the currently approved sample size was adequate. Results suggest that increasing the sample size from 1,200 (initially planned 100 in the pilot and 1,100 in the main study) to 2,000 (101 completed the pilot and a proposed increase to 1,899 in the main study) would make a substantive improvement in the ability to measure differences according to type of circumcision women have experienced.

More specifically, in the pilot study, 51 of 101 (50.5%) eligible respondents reported having undergone some type of FGM/C; 20 reported having undergone the most severe form of FGM/C (flesh removed with genital area sewn closed) and 31 reported less severe forms (nicking or flesh removed from the genital area).

Under the original main study sample size of 1,100, we would expect to detect a minimum difference of approximately 7.3 percentage points between two estimated proportions of women who did and women who did not experience some type of FGM/C. And we would expect to detect a minimum difference of approximately 10.6 percentage points between two estimated proportions of women who experienced the most severe form of FGM/C versus women who experienced less severe forms. With the increase in the main sample size to 1,899, we expect to be able to detect a minimum difference of approximately 5.6

percentage points between two estimated proportions of women who did and did not undergo FGM/C. We also expect to be able to detect a minimum difference of approximately 8.0 percentage points between women who experienced the most severe and less severe forms of FGM/C, a substantive improvement in the ability to measure differences between these two groups of circumcised women.

An increase in sample size will require an increase in the number screened for eligibility to participate in an interview. We also are requesting a further increase in the number screened to account for the rate of refusals after eligibility is determined, which was not factored into our original calculations. Based on rates during the pilot of either refusing or being unable to participate after being deemed eligible when recruited from community-based organizations, we expect that 17% of those deemed eligible will not complete a full study interview.

For a total sample size of 2,000, we need to obtain 1,899 completed interviews during the primary study (having completed 101 during the pilot). With an estimated eligibility rate of 65% and, of those eligible a refusal rate of 17%, we will have to screen approximately 3,515 women for the main study, in addition to the 229 already screened in the pilot study, for a total of 3,744 screened for the entire study. This is an increase of 1,744 women screened.

COVID-19 Social Distancing Measures

Due to the COVID-19 pandemic, we anticipate that social distancing measures implemented in March/April 2020 may continue through Summer 2020. NORC will work closely with WHNS implementing organizations to ensure that WHNS recruitment and interviews follow all state and federal recommendations for social distancing. It is possible that partners could implement WHNS recruitment and interviews using the same secure measures that they devise to provide confidential social services using secure video conferencing or telephone communication.

Effect of Proposed Changes on Currently Approved Instruments

WHNS Eligibility Screener (Attachment G1 (English), clean and track change translations provided with revisions incorporated)

The revised study screener eliminates unnecessary questions and adds more explicit interviewer instructions.

Item No. on Currently Approved Measure	Requested Change
--	At the beginning and end of the screener, we added places for the interviewer to indicate questionnaire start and end times. This change will allow us to track the length of interviews.
--	A standard introductory statement was added to the beginning of the screener. This will help the interviewer establish a connection with the respondent and help the respondent understand the purpose and content of the screener.
2	French and Tigrinya languages were added as response options; Swahili was

	removed.
5, 6, 8	These questions were removed from the screener because they are unnecessary to determine participant eligibility.
--	At the end of the screener, interviewer instructions for determining the study participant's eligibility were expanded to ensure that the interviewer made the correct determination. Changes to these interviewer instructions included modifying the list of eligible countries of origin to match the updated eligibility criteria.

WHNS Questionnaire (Attachment H1 (English), clean and track change; translations provided with revisions incorporated)

WHNS questionnaire changes eliminated and/or replaced some questions; open-ended response options used in the pilot were replaced with categorical response options; and some wording was simplified or corrected. To improve questionnaire administration, interviewer instructions were clarified or simplified. The removal, addition, and reordering of some questions resulted in renumbering of the questionnaire and skip instructions.

Item No. on Currently Approved Measure	Summary of Changes
--	At the beginning and end of the questionnaire, we added places for the interviewer to indicate interview start and end times. This change will allow us to track the length of interviews.
--	Section B Introduction: A privacy assurance statement was added to the beginning of the screener to help the respondent understand that her answers will not be shared outside the study team.
1	Question removed because it repeated a question on the screener instrument about languages spoken by the respondent.
4	Question removed because it yielded little useful information since ethnic groups or tribes were not specified and 20% of responses were "Don't Know".
6, 7	Questions were removed because countries were not specified. The two questions were replaced by a single question (New Question 5) that specifies countries where the respondent has traveled. It is useful to the study to know whether the respondents have traveled back from the U.S. to FGM/C practicing countries because this is a risk factor for FGM/C.
5	Adds the response option: "Born in the US [GO TO SECTION C]" to what is now Question 6. This replaces skip logic instructions that were confusing to interviewers.
--	New Question 7 captures age at arrival in the U.S. This information is needed to determine the immigrant generation of participants. This is an important background characteristic that will enable us to examine if FGM/C attitudes change after migration

	and how health experiences compare across generations.
--	Section B questions were reordered.
11-14, 40, 54	Throughout the questionnaire, we changed “husband” to “husband/partner” and/or included “living with a partner” in response options to accommodate women who might be co-habiting with a partner.
--	New Question 13 was added to capture the husband/partner's country of origin. Because the husband/partner's beliefs and family traditions surrounding FGM/C are often involved in a family decision on FGM/C. Information on husband/partner country of origin will provide important context.
15	Added “religious organization” to the organizations mentioned in what is now question 14. This is because the church or mosque are important community/social organizations.
16	The wording was unclear when administered in the pilot. We propose simplified language to what is now question 15.
20	During the pilot, there was uncertainty about whether “interpreter” meant “professional interpreter” (it is intended to be broader, i.e., anyone who could interpret for the woman). Also, the term “doctor” was too restrictive since women may see other types of providers. We are proposing language to address these two issues. The question (now Question 19) has been reworded and the term “doctor” replaced with “healthcare provider”.
28	Question 28 removed: Based on pilot study findings, the currently approved open-ended Question 28 did not yield useful data.
--	Introduction to Section G: Section G introductory statement is expanded to include the definition of prenatal care. This definition helps the respondent understand what is meant by prenatal care throughout this section.
--	Birth History Table: Skip instructions have been added. More rows for additional births have been added since in the pilot some women had more live births than the pilot questionnaire provided for.
39	Based on findings from the pilot study, the open-ended question probe was removed because it did not yield useful information in the pilot. What is now question 37, will remain as a simple Yes/No question.
40	We added a response option “Do not have a husband/partner” and eliminated the preceding skip logic instructions to what is now question 38.
43	During the pilot study, some women said they don’t remember their age of cutting because they were too young. This make sense since in some countries, the cutting can be done before 4 years of age. We propose the additional response option “too young to remember” to what is now question 40.
42	We replaced an open-ended question on type of FGM/C with a categorical response option (now question 44). The goal of open-ended questions on the pilot questionnaire was to determine the appropriate categorical response options. These response options refer to the three main types of FGM/C. FGM/C “Types 1, 2 and 3” are standard categories defined by the World Health Organization. The results of this question will be compared to women’s responses to questions 41-43 to determine whether women know

	the type of FGM/C they have experienced.
48	We eliminated the open-ended question and replaced it with a close-ended question that lists health problems/conditions. These options are based on pilot results from the open-ended pilot question.
52	To improve flow of Question 52 (now 50-53), we split the same content into four separately numbered questions. We reordered the rows (health conditions): Rows A-C health conditions are now in Question 53, rows D and E are now included in Question 52, rows F-I are now included in Question 50, and row J is now Question 51. We also reordered the columns (questions), placing the question about whether the condition is an ongoing problem before questions about seeking health care and satisfaction with health care received. We replaced the word “intercourse” with “sex” to simplify the language based on feedback from interviewers from the pilot. We added the response option “Don’t know” and more explicit skip instructions for interviewers. We modified skip instructions to make flow easier for interviewers.
--	Section I questions were reordered to improve flow. Based on recommendations from both the FGM/C expert advisors and pilot study interviewers, the revised order asks respondent's opinion about FGM/C before the questions about her husband's opinion.
57	A response option for “not applicable, born in the U.S.” was added to what is now question 55.
58	We eliminated the open-ended response option which did not yield useful data in the pilot.

Burden Estimate

WHNS Eligibility Screener: By examining the total number of questions and words added to and removed from the study screener, we found a net decrease of 3 questions and 12 words. We do not anticipate a change in the time to complete the screener.

WHNS Questionnaire: By examining the total number of questions and words added to and removed from the study questionnaire, we found a net decrease of 3 questions and 12 words. We do not anticipate a change in the time to complete the questionnaire.

Sample Size: We are requesting to increase the initially approved total sample size of 1,200 to 2,000 completed interviews. Because 101 pilot interviews have already been completed, we propose to interview 1,899 for the full study. In order to obtain 2,000 completed interviews, assuming that 35% of women screened will not be eligible and now including an estimated refusal rate of 17% among eligible women, we would need to increase the number of women screened from 2,000 to approximately 3,744 women.

Overall, we estimate an annualized increase of 248 burden hours (from 356 to 604 Total Annualized Burden Hours). **Estimated Annualized Burden Hours Before Proposed Changes**

Type of Respondent	Form Name	Total No. of Respondents	Annualized number of Respondents	No. of Responses Per Respondent	Average Burden Per Response (in Hours)	Total Annualized Burden Hours
Women age 18 to 49 who were born in, or whose mother was born in, an FGM/C practicing country	WHNS Eligibility Screener*	2,000	667	1	5/60	56
Women age 18-49 who were born in, or whose mother was born in, an FGM/C practicing country	WHNS Questionnaire	1,200	400	1	45/60	300
Total						356

*Burden hours calculated inclusion of informed consent process.

Estimated Annualized Burden Hours After Proposed Changes

Type of Respondent	Form Name	Total No. of Respondents	Annualized number of Respondents	No. of Responses Per Respondent	Average Burden Per Response (in Hours)	Total Annualized Burden Hours
Women age 18 to 49 who were born in, or whose mother was born in, an FGM/C practicing country	WHNS Eligibility Screener*	3,744	1,248	1	5/60	104
Women age	WHNS	2,000	667	1	45/60	500

Type of Respondent	Form Name	Total No. of Respondents	Annualized number of Respondents	No. of Responses Per Respondent	Average Burden Per Response (in Hours)	Total Annualized Burden Hours
18-49 who were born in, or whose mother was born in, an FGM/C practicing country	Questionnaire					
Total						604

*Burden hours calculated inclusion of informed consent process

COVID-19 Social Distancing Measures: Changes in recruitment and interview procedures will have no impact on study burden.

The OMB approval is requested, effective immediately.