Non-Substantive Change Request to OMB Control No. 0920-1118: Emergency Zika Package V: Assessment of Interventions Intended to Protect Pregnant Women in Puerto Rico from Zika virus Infections

Program Contact

Lee Samuel
National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)
Office of Policy
1600 Clifton Rd, C-12
Atlanta GA 30333

Submission Date: January 23, 2021

Circumstances of Change Request for OMB 0920-1118

CDC requests approval for a non-substantive change to OMB Control No. 0920-1118: Emergency Zika Package V: Assessment of Interventions Intended to Protect Pregnant Women in Puerto Rico from Zika virus Infections.

These changes are being made to improve comprehension of questions and flow of the interview. The project protocol has not changed. IRB review is not required.

Estimates of annualized burden hours for this change request remain the same. Average length of interviews is coming in well under the time allotted for each of the interviews so no additional burden hours are needed. The burden estimate for the forms included in OMB Control No. 0920-1118 is 892 hours for the overall assessment.

Description and Justification of Changes

Attachment C: Initial Telephone Interview

Changes to the questionnaire were based on two waves of information collection that have resulted in identifying patterns from open-ended response options (which now can be added to the list of response options) and on-going training and feedback with interviewers to ensure that scripts flow well and are written clearly in order to minimize interviewer explanations, if the question was not understood by the pregnant woman, which can unintentionally influence the answer the respondent provides. On August 11, the bi-lingual behavioral science team leader and the team of interviewers met to reflect on the first two waves of interviews and to review and refine/revise instruments to improve their cultural competency, clarity, flow, and question's intent/purpose. We believe proposed changes are necessary to improve the quality and utility of the information collected.

Below we describe changes to the questionnaire and provide the rationale for changes. Additionally, a table is provided which shows the old version of questions side by side with the new version.

- Introductory script: We edited text to clarify that the interviewers are from the Puerto Rico Department of Health and not CDC, to ask how many months pregnant they are to so that our quotas for pregnancy trimester are more accurate, to shorten introduction, and improve clarity of language.
- Added a question before question 1: We have relied on WIC data to tell us about the pregnancy trimester of participants and have found inaccuracies in their data. Because we have a quota sample by pregnancy trimester, we need to ask this question to be sure that we fill our quota accurately and categorize respondents in the correct pregnancy trimester.
- Questions 1, 4, 6, 8, 17, 18, 19, 20, 22, 28, 41, 46, and 47: Response options were added based on qualitative analysis of open-ended and "other, please specify" responses from interviews completed to date.
- Moved description of Zika Prevention Kits to the beginning of section 3 and removed the follow-up question to question 15, "what have you heard" and the direction to capture verbatim responses.
- Question 16: Deleted because almost all women had received a Zika Prevention Kit from WIC and interpreted this question to mean does she know where to go to get another free Zika Prevention Kit. There are no plans to give out multiple kits to pregnant women.
- Question 21: Edited the question stem to be clearer and flow better. Also, deleted the "least important" response option because pregnant women said that they are all important and would not provide an answer.
- Questions 24 & 25: We added two response options that represent items that educational materials in the Zika Prevention Kit stress as important but that are not items currently included in the kit, but that are under consideration for inclusion (e.g., a coupon for clothing or screens)
- Question 26: Incident managers want more information about why pregnant women are reporting "never or almost never" use of items included in the kit. So, interviewers will capture verbatim responses.
- In Spanish interview scripts only, we moved section 5 about insecticide services to the end of the interview to address concerns that pregnant women might end the interview because of the negative news coverage and protests about NALED use and aerial spraying. So the section after Zika Prevention Kit is now mosquitoes and the environment followed by risk perceptions followed by necessary actions to protect pregnant women followed by insecticide services. So, questions 1-28 are the same in both instruments but after that the sequence changes to put the questions about insecticide services at the end.
- Added Questions 34 (a) English/Question 50A in Spanish version: Added an opinion question about the importance of offering insecticide spraying services to Pregnant women in Puerto Rico.
- Added Question 31 (a) English/Question 47 in Spanish version: Added question about acceptance of insecticide services in addition to the question about desire for the services. One reflects motivation (want) while the other reflects a decision (acceptance).
- Question 49 (Question 43 in Spanish version): Edited the question stem to be clearer.
- Closing statement: Shortened the thank you statement.

Attachment D: Follow-up Telephone Interview

Below we describe changes to the questionnaire and provide the rationale for changes. Additionally, a table is provided which shows the old version of questions side by side with the new version.

Introductory script: We edited text to clarify that the interviewers are from the Puerto Rico Department of Health and not CDC, to confirm that they are still pregnant, [added question – "Are you still pregnant"], to shorten the introduction, and to improve clarity of the language.

Q4: Edited question 4 to remove the explanation of oral sex as "mouth-to penis." Interviewers said that this explanation was not necessary.

Added Question 4 (a): Incident managers want to know how many condoms to put in Zika Prevention Kits, but we have been unable to find data on sexual activity levels of pregnant women in Puerto Rico. Adding this question will guide decisions on how many condoms should be included in Zika Prevention Kits. A recent qualitative assessment with pregnant women in Puerto Rico showed that they are embarrassed to purchase them or pick them up from places where they may be seen obtaining them.

Edited the introductory sentence before question 14 to more accurately describe the groups we will be asking about. Instead of saying we are asking about what the "community" may or may not be doing, we will ask, what "others" may or may not be doing to prevent Zika.

Questions 14a, 15a, 16a, and 17a: During the first wave of follow-up interviews women were asked only about the "satisfaction" of the actions of family, neighbors, municipalities, and the Department of Health. Interpreting this information without knowing, from the pregnant women's perspective, are the actions they are taking, is not helpful. These questions will offer more specific feedback to each of these groups about the actions that are driving satisfaction.

Initial Telephone Interview Guide – Attachment C	
Current Question	Requested Changes - 1/23/21
	How many months pregnant are you?
	months (write number)
Question 1.What have you heard about Zika? (Do not read, tick all	What have you heard about Zika? (Do not read, tick all mentioned)
mentioned)	
	Pregnant women should try not to get it
Pregnant women should try not to get it	It causes microcephaly or brain defects in babies
It causes microcephaly or brain defects in babies	People get it from mosquitoes, so should avoid getting bitten
People get it from mosquitoes, so should avoid getting bitten	It can be transmitted by sex from a man to a woman
It can be transmitted by sex from a man to a woman	People in Puerto Rico are getting infected with Zika – the

People in Puerto Rico are getting infected with Zika – the virus	virus is here		
is here	Most people who have it, don't know it (can have Zika and		
Most people who have it, don't know it	have no symptoms)		
It causes fever, rash, and conjunctivitis	It causes fever, rash, and conjunctivitis		
There is no treatment for Zika	There is no treatment for Zika		
There is no vaccine for Zika	There is no vaccine for Zika		
It can be life-threatening – can cause paralysis, GBS	It can be life-threatening – can cause paralysis, GBS		
Other, please specify:	People should wear repellent		
Refused [DO NOT READ]	People should wear clothing that covers		
	People should eliminate standing or accumulated water		
	People should put screens on windows and doors		
	It is like Dengue and Chikungunya		
	It is dangerous		
	Haven't heard anything		
	Other, please specify:		
	Refused [DO NOT READ]		
Question 4. In your opinion, how likely do you think it is that you will	In your opinion, how likely do you think it is that you will be infected		
be infected with Zika virus during your pregnancy (or while you are	with Zika virus during your pregnancy (or while you are pregnant)?		
pregnant)?	Extremely unlikely		
Extremely unlikely	Unlikely		
Unlikely	Neutral - Neither unlikely nor likely		
Neutral - Neither unlikely nor likely	Likely		
Likely	Extremely likely		
Extremely likely	I already have Zika [DO NOT READ]		
Refused [DO NOT READ]	Refused [DO NOT READ]		
Question 6. What actions have you taken to protect yourself from	What actions have you taken to protect yourself from getting infected		
getting infected with the Zika virus since you found out you were	with the Zika virus since you found out you were pregnant? (<i>Do not</i>		
pregnant? (Do not read, tick all mentioned)	read, tick all mentioned)		
Used mosquito net at night	Used mosquito net at night		
Used mosquito net during the day	Used mosquito net during the day		
Used mosquito repellent or spray on your body	Used mosquito repellent or spray on your body		
Worn clothes that cover my arms and legs	Worn clothes that cover my arms and legs (long sleeved shirts and		
Used mosquito coil/light fires to keep mosquitoes away	pants)		
Used a condom/had my partner use a condom in all sexual	Used mosquito coil/light fires to keep mosquitoes away		
relations	Used a condom/had my partner use a condom in all sexual		
Abstained from sexual intercourse	relations		
Cleaned/scrubbed water source/storage unit/water container(s)	Abstained from sexual intercourse		

Put cover(s) over the water source/storage unit/water	Cleaned/scrubbed water source/storage unit/water container(s)			
container(s)	Put cover(s) over the water source/storage unit/water container(s) Removed accumulated water			
Removed accumulated water				
Sprayed or fumigated inside my home	Sprayed or fumigated inside my home			
Sprayed or fumigated outside of my home	Sprayed or fumigated outside of my home			
Used larvicides (like mosquito dunks)	Used larvicides (like mosquito dunks)			
Put screens on windows and doors	Put screens on windows and doors			
Cleaned household environment	Cleaned household environment			
Drank clean water	Drank clean water			
Washed I clean water	Washed I clean water			
Prayed to God	Prayed to God			
No answer	No answer			
Other, please specify:	Wore light-colored clothing (no dark clothes)			
	Don't go outside at all			
Refused [DO NOT READ]	Don't go outside at night			
	Closed windows and doors			
	Cut grass			
	Used air conditioning			
	Go to doctor			
	Got tested and/or got my partner tested for Zika			
	Looked for more information about Zika			
	Other, please specify:			
	Refused [DO NOT READ]			
Follow-up to Question 8 - Where are you hearing messages on how to	Where? (Do not read, tick all mentioned)			
prevent Zika? (Do not read, tick all mentioned)	Doctor			
Doctor	WIC			
WIC	Family & friends			
Family & friends	Community meetings/gatherings			
Community meetings/gatherings	TV public service announcements			
TV public service announcements	TV news			
TV news	Radio news			
Radio news	Printed news (newspapers)			
Printed news (newspapers)	Posters			
Posters	Billboards			
Billboards	Internet or world wide web			
Internet or world wide web	Social media			
Social media	Facebook			
Facebook	Twitter			

Twitter Instagram Other, please specify:	Instagram Church Work University Child's school Hospital Google Neighbors Family planning Laboratory Other, please specify:		
Question 16. Do you know where you can get a Zika Prevention Kit that is free (or that does not cost you anything)? Yes No Refused	MOVED description of Zika Prevention Kit to before Q 15 to eliminate open-ended responses, improve flow, and save time Description: The Zika Prevention Kit is a tote bag that contains educational information from the Puerto Rico Health Department and the Centers for Disease Control and Prevention about how to prevent Zika infection while you are pregnant along with items that could help prevent Zika virus infection. Items in the kit include: a mosquito bed net, mosquito repellent, condoms, and some include mosquito dunks (larvicide) and thermometers. DELETING this question because most women have receive a Zika Prevention Kit and think this question is about where they can get another kit for free.		
Question 17. Have you been offered a Zika Prevention Kit?	Have you been offered a Zika Prevention Kit?		
Yes	Yes		
From who or what organization?	From who or what organization?		
WIC	WIC		
My doctor	My doctor		
Other	Hospital or clinic		
No	Church		
Refused [DO NOT READ]	Pharmacy		

	Department of Health Other No Refused [DO NOT READ]	
Question 18. Have you received a Zika Prevention Kit	Have you received a Zika Prevention Kit	
Yes Who gave you your Zika Prevention Kit WIC My doctor Other	Yes Who gave you your Zika Prevention Kit WIC My doctor Hospital or clinic Church Pharmacy Department of Health Other No, skip to question 29 Refused [DO NOT READ]	
Question 19. What color was the tote bag? White Blue Green Other, please specify: Refused	What color was the tote bag? [DO NOT READ RESPONSES] White (negro) Crema Blue Green Other, please specify: Refused	
Question 20. What items were included in the kit? (<i>Do not read, tick all mentioned</i>) Repellent Bed net Mosquito dunks Condom(s) Thermometer Educational materials Other, please specify: Don't know, didn't open it [SKIP TO QUESTION 29] Refused [DO NOT READ]	What items were included in the kit? (Do not read, tick all mentioned) Repellent in Spray Repellent in Cream Bed net Mosquito dunks Condom(s) Thermometer Educational materials Other, please specify: Don't know, didn't open it [SKIP TO QUESTION 29] Refused [DO NOT READ]	

Question 21. Of the items in your Zika Prevention Kit, which one is the most important to you? (mark stated item as ranked 1 st) Which is the next most important? (mark stated item as ranked 2 nd) Which is the next most important? (mark stated item as ranked 3 rd) Which is the least important to you? (mark stated item as ranked least important) Question 22. Theinstructions that came with the Zika Prevention Kit made it easy to know what to do with all of the items in the Zika	No, why not? Refused Of the items you just mentioned, which one is the most important to you? (mark stated item as ranked 1 st) Which one follows in importance? (mark stated item as ranked 2 nd) Which one follows in importance? (mark stated item as ranked 3 rd) Which one follows in importance? (mark stated item as ranked least important) Deleted "least important" response option The instructions that came with the Zika Prevention Kit made it easy to know what to do with all of the items in the Zika Prevention Kit.
Prevention Kit. Would you say that you (strongly disagree, disagree, neither disagree or agree, agree, and strongly agree) with the statement. Strongly disagree Disagree Neither disagree nor agree Agree Strongly agree There were no instructions in the kit Refused [DO NOT READ]	Would you say that you (strongly disagree, disagree, neither disagree or agree, agree, and strongly agree) with the statement. Strongly disagree Disagree Neither disagree nor agree Agree Strongly agree There were no instructions in the kit NEW Response option: I didn't read the instructions Refused [DO NOT READ]
Question 24. BEFORE receiving the kit, when you were pregnant, how often did you use each of the following the items? a. Insect repellent b. Condoms c. Mosquito dunks for treating accumulated water d. Bed net	BEFORE receiving the kit, when you were pregnant, how often did you use each of the following the items? a. Insect repellent b. Condoms c. Mosquito dunks for treating accumulated water d. Bed net e. Long sleeved clothes and pants that cover arms and legs f. Screens on your windows and/or door
Question 25. AFTER receiving the kit, how often did you use these types of items? a. Insect repellent b. Condoms c. Mosquito dunks for treating accumulated water d. Bed net	AFTER receiving the kit, how often did you use these types of items? a. Insect repellent b. Condoms c. Mosquito dunks for treating accumulated water d. Bed net e. Long sleeved clothes and pants that cover arms and legs

f. Screens on your windows and/or door If she says "Never or Almost Never" for any item, ask why not?		
a. Insect repellent		
b. Condoms		
c. Mosquito dunks for treating accumulated water		
d. Bed net		
e. Long sleeved clothes and pants that cover arms and legs		
f. Screens on your windows and/or door		
What other items do you recommend to be included in the Zika		
Prevention Kit to help pregnant women in Puerto Rico to protect		
themselves from getting infected with Zika?		
I would include the same items that are there now		
I don't know		
I would include more (a current item) _"Tick all		
mentioned"		
Repellent – lotion		
Repellent – spray		
Condoms		
Bed net – twin-size		
Bed net – Queen size		
Mosquito dunks (larvicide)		
I would add (new items)" "Tick all		
mentioned"		
Natural repellents		
Unscented repellents (odor-free)		
Insecticide for spraying home		
Citronella candles		
Cobras		
Coupons for products		
Coupons for screens		
I would do something else entirely (specify)		
Don't know/not sure [DO NOT READ]		
Refused [DO NOT READ]		

Description: Indoor residual spraying (IRS) is when specially trained professionals spray insecticide inside of the home in and on the places that mosquitoes like to rest — usually dark and moist places. Examples of places are under tables, behind furniture, under beds and cabinets with sinks, and by dirty laundry. The spraying can be done anytime during the day and usually will kill mosquitoes for about three months. IRS is most effective when most houses in a neighborhood have their homes sprayed.	Description: Indoor residual spraying (IRS) is when specially trained professionals spray insecticide inside of the home in and on the places that mosquitoes like to rest. The spraying can be done anytime during the day and usually will kill mosquitoes for about three months. IRS is most effective when most houses in a neighborhood have their homes sprayed.
	In your opinion, how important is it to offer insecticide spraying services to pregnant women in Puerto Rico? Not at all important Slightly important Neutral (not important but not unimportant) Somewhat important Very important Don't know/not sure Refused
Question 41. Do you have the authority to decide about structural changes (like installing screens) and to fumigate your home inside and outside? No Yes Other, please specify: Don't know/not sure [DO NOT READ] Refused [DO NOT READ]	Do you have the authority to decide about structural changes (like installing screens) and to fumigate your home inside and outside? No Yes Other, please specify: Can decide only about fumigation Rental home Family member's home Public Housing Don't know/not sure [DO NOT READ] Refused [DO NOT READ]
	When services were offered to you, did you accept them? Yes, why (<i>Do not read, tick all mentioned</i>) Wanted to have fewer mosquitoes in my home They were free Want less chance of getting bitten Don't want to get Zika Because my neighbors don't remove accumulated water Other, please specify:

	N. J. (D. J.
	No, why not (Do not read, tick all mentioned)
	Don't want chemicals sprayed in my home
	I have young children in my home
	I have a sick family member
	My home does not need spraying (have screens or air
	conditioning)
	My neighbors do a good job of removing accumulated water
	Other, please specify:
	Don't know/not sure [DO NOT READ]
	Refused [DO NOT READ]
Question 46. How long did you have to wait to be told the results of	How long did you have to wait to be told the results of your Zika test?
your Zika test?	Less than two weeks
Less than two weeks	Between two weeks and a month
Between two weeks and a month	Over a month but less than two months
Over a month but less than two months	Over two months but less than three months
Over two months but less than three months	Over three months
Over three months	Never was told the results of my Zika test
Never was told the results of my Zika test	Just got tested
Other, please specify:	Other, please specify:
Don't know/not sure [DO NOT READ]	Don't know/not sure [DO NOT READ]
Refused [DO NOT READ]	Refused [DO NOT READ]
Question 47. What do you think is needed or that needs to happen in	What do you think is needed or that needs to happen in order to protect
order to protect pregnant women from getting infected with the Zika	pregnant women from getting infected with the Zika virus? [capture
virus? [capture verbatim responses]	verbatim responses]
	"Tick all that are mentioned" and write down any other responses
	Fumigate in the community
	Fumigate homes of pregnant women
	Eliminate accumulated water in the community
	Eliminate accumulated water in the community Eliminate mosquito hatcheries (breeding sites)
	Clean up communities (pick up trash/debris)
	Pick up tires
	Inspect and take care of abandoned houses
	Provide emotional support for pregnant women
	= = 0.14c constitutional support for pregnant momen

	Provide more education for pregnant women
	Provide education for everyone in the community
	Educate everyone in the community to do their part
	Keep providing Zika Prevention Kits
	Provide repellent
	Provide condoms
	Provide light colored clothes that cover
	Provide resources for women to screen their windows and
	doors
	Pick up used tires
	Educate gynecologists/physicians about Zika
Question 49. Which of the following are actions that someone can take	I will read a list of actions and you can tell me if they can be used to
to protect themselves from getting infected with Zika? [Check all that	protect from becoming infected with Zika. [Check all that apply.
apply. (Read the options)]	(Read the options)]
CLOSING STATEMENT:	Thank you for answering these questions! Your answers will help us
On behalf of the Puerto Rico Department of Health and the CDC we	in our efforts to keep pregnant women and their babies healthy.
would like to thank you for your participation in this survey. Your	in our errorts to keep pregnant women and their bables healthy.
contribution is very important for us. The information you gave us will	
help us to improve our services. Do you have any questions?	
Follow-up Telephone Interview Guide – Attachment D	- 1 ol 1 o
Current Question	Requested Changes - 1/23/21
	Are you still pregnant (Yes/No): if yes continue
	In the past three months, how many times did you have sexual intercourse?months (write number)
Question 4. Since you became pregnant, have you had sexual	Since you became pregnant, have you had sexual intercourse, that is,
intercourse (that is vaginal anal or oral (mouth-to-penis) sey) with	vaginal anal or oral sex with any male partner?
intercourse [that is, vaginal, anal, or oral (mouth-to-penis) sex] with any male partner?	vaginal, anal, or oral sex, with any male partner?
any male partner?	
, , ,	Now I'm going to ask you about what others may or may not be doing to prevent Zika
any male partner? Now I'm going to ask you about what the community may or may not	Now I'm going to ask you about what others may or may not be doing to prevent Zika
any male partner? Now I'm going to ask you about what the community may or may not	Now I'm going to ask you about what others may or may not be doing
any male partner? Now I'm going to ask you about what the community may or may not	Now I'm going to ask you about what others may or may not be doing to prevent Zika NEW: 14a. Do you know the actions that your household family members are taking to help prevent Zika?
any male partner? Now I'm going to ask you about what the community may or may not	Now I'm going to ask you about what others may or may not be doing to prevent Zika NEW: 14a. Do you know the actions that your household family members are taking to help prevent Zika? No (Go to question 15a)
any male partner? Now I'm going to ask you about what the community may or may not	Now I'm going to ask you about what others may or may not be doing to prevent Zika NEW: 14a. Do you know the actions that your household family members are taking to help prevent Zika?

	NEW: 15a. Do you know the actions that your neighbors are taking to help prevent Zika?		
	No (Go to question 16a) Yes, what actions are they taking? (Capture verbatim responses) (Go to questions 15)		
	NEW: 16a. Do you know the actions that your municipality is taking to help prevent Zika? No (Go to question 17a) Yes, what actions are they taking? (Capture verbatim responses) (Go to questions 16)		
	NEW: 17a. Do you know the actions that the Department of Health is taking to help prevent Zika?		
	No (Go to question 18) Yes, what actions are they taking? (Capture verbatim responses) (Go to questions 17)		

Estimates of Annualized Burden hours (unchanged from approved ICR)

Estimates of annualized burden hours for this change request remain the same. The burden estimate for the forms included in OMB Control No. 0920-1118 is 892 hours for the overall assessment.

Type of	Form Name	No. of	No. of	Average	Total
Respondent		Respondents	Responses per	Burden per	Burden
			Respondent	Response	Hours
Project 1					
Pregnant WIC	Initial Telephone Interview	1,800	1	20/60	600
participant	Follow-up Telephone Interview	900	1	15/60	225
Project 2					

Type of	Form Name	No. of	No. of	Average	Total
Respondent		Respondents	Responses per	Burden per	Burden
			Respondent	Response	Hours
Project 1					
	Initial Telephone	1,800	1	20/60	600
Pregnant	Interview	1,000		20/00	000
Pyle gnant	Telephone interview				
₩ ftîcipant	of cases and controls	200	1	20/60	67
participant					
					892