

Change Request

Well-Integrated Screening and Evaluation for Women Across the Nation (WISEWOMAN) Reporting System

(OMB no. 0920-0612, exp. date 03/31/2025)

March 23, 2023

Background and Justification

The Well-Integrated Screening and Evaluation for Women Across the Nation (WISEWOMAN) program is a direct service program that provides clinical screening and healthy behavior support services to uninsured and underinsured women aged 40 to 64. The goal of the WISEWOMAN program is to reduce risk factors for cardiovascular disease (CVD) in a vulnerable and underserved population. Women in lower income brackets, or without health insurance, have an increased risk of CVD morbidity and mortality because they have limited access to health services such as screenings, medications, and healthy behavior support services. Through CDC's WISEWOMAN program, state governments and tribal organizations receive funding to provide these services, and report information to CDC through the funding recipient's annual progress report and an electronic dataset on clients enrolled in the program. The current dataset consists of 59 minimum data elements (MDE) that address CVD risk factors such as elevated blood cholesterol, high blood pressure, obesity, diabetes, smoking, sedentary lifestyle, and client demographics and behaviors, which are incorporated into the client's health department electronic health record. Information is collected by providers at the time of enrollment and at rescreening (a minimum of 11 months post-enrollment). The information reported to CDC is used to evaluate the effectiveness and outcomes of WISEWOMAN services and programs.

CDC requests OMB approval for 11 additional data elements that align with the current purpose and scope of existing WISEWOMAN data elements. The additional MDE will strengthen:

- **Program fidelity:** Proposed additional elements will involve ascertaining social needs and will help decipher ways to mitigate barriers that are preventing active participation in the WISEWOMAN program. These proposed changes will improve CDC's ability to improve CVD risk analysis and program efficacy.
- **Data Quality:** Proposed changes to MDEs provide companion data to existing data elements to provide a more complete picture for underserved women in the WISEWOMAN Program.

This request is a refinement of our current data approach of continuously serving underserved populations and also in line with HHS's current health equity goals. The additional data elements emanate from the Notice of Funding Opportunity announcement (CDC-RFA-DP-23-0003) that was published in late March. These additional MDEs will improve analytical utility, program fidelity, and data quality and will have a marginal effect on burden hours. Overall, if approved the total number of MDEs will be 70. No changes are being proposed to the Annual Progress Report.

This Change Request also includes:

- non-substantive changes to response option to 2 previously approved MDEs in order to improve data accuracy. Proposed response option changes involve including distinction of modality for a follow-up screening, and maternal related diseases as a part of previous medical history.
- one (1) minor change to the wording an approved MDE question that will allow for more contextual knowledge about the respondent’s primary spoken language and enhance the engagement of non-English speaking participants in the WISEWOMAN program.

An overview of the proposed change to the MDEs is provided in Exhibit 1. Details of how the updated MDEs will appear and their exact locations in the manual are provided in Exhibit 2 and Exhibit 3. The exhibits are attached.

Attachments

- Exhibits
 1. Overview of Change Request
 2. Additional Proposed Minimum Data Elements
 3. Modifications to Previously Approved Minimum Data Elements
- WISEWOMAN MDE Manual

Implementation Schedule

CDC is submitting this change request to OMB to provide Minimum Data Elements implementation guidance to programs for the new program year, which begins September 2023.

Effect on Burden Estimate

Minor change in burden is projected. Addition of 11 MDEs and non-substantive changes to 3 previously approved MDEs results in a total of 14 MDEs. Please see current and projected change in Estimated Burden Hours:

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Table 1: Number of Respondents and Current Estimated Burden Hours

Type of Respondents	Type of Collection	No. of Respondents	Annual Frequency per Response	Hours per Response	Total Hours
WISEWOMAN Awardees	Screening and Assessment and Lifestyle Program	35	2	24	1680
	MDEs				
	Annual Progress Report	35	1	16	560
	Total		3	40	2,240

Table 2: Number of Respondents and Change in Estimated Burden Hours

Type of Respondents	Type of Collection	No. of Respondents	Annual Frequency per Response	Hours per Response	Total Hours
WISEWOMAN Awardees	Screening and Assessment and Lifestyle Program	35	2	25	1750
	MDEs				
	Annual Progress Report	35	1	16	560
	Total		3	41	2,310

Exhibit 1. Overview of Change Request

Type	Elements Affected	Number of Elements
Additions to Minimum Data Elements Question or Response Options	Internet Access, Food Insecurity, Transportation Barriers, Child-Care Barriers, Housing Insecurity, Domestic Partnerships, Medication Adherence, and Referral to Social Needs	11
Modifications to current Minimum Data Elements Question or Response Options	Type of Screening Visit, Primary Language, Medical History	3

Exhibit 2. Proposed Additions to Minimum Data Elements Question or Response Options

We propose to add 11 new MDE questions. Capturing these barriers will enhance program implementation through engaging women, reducing their hypertension, and addressing barriers by making referrals to specific social support services offered by partners. This includes internet access, food, housing, transportation, childcare barriers, intimate partner violence and barriers to medication adherence.

No.	MDE Field Name and File Position Location	Reference Document Current Information Collection	Changes Document Proposed Changes	Rationale Brief description of intent of change
1	Item Current Location : New question Proposed Location :	<u>NO CURRENT QUESTION</u>	Do you own or use any of the following types of computer? i. Desktop/Laptop ii. Smartphone iii. Tablet/Other portable wireless Computer 1. Yes 2. No. 7. Don't know 8. Don't want to answer 9. No answer recorded	American Community Survey
2	Item Current Location : New	<u>NO CURRENT QUESTION</u>	Do you or any member of this household have access to the internet? 1. Yes- by paying a cell phone company or internet service provider. 2. Yes- without paying a cell phone	American Community Survey

	question Proposed Location :		company or internet service provider. 3. No access to internet in this house, apartment, or mobile home 7. Don't know 8. Don't want to answer 9. No answer recorded	
3	Item Current Location : New question Proposed Location :	<u>NO CURRENT QUESTION</u>	During the last 12 MONTHS, was there a time when you were worried you would run out of food because of a lack of money or other resources? 1. Yes 2. No 7. Don't know 8. Don't want to answer 9. No answer recorded	Food insecurity question will capture barriers to program engagement. This question is adapted from Food Insecurity Experience Scale Voices of the Hungry Food and Agriculture Organization of the United Nations (fao.org)
4	Item Current Location : New question Proposed Location :	<u>NO CURRENT QUESTION</u>	Have you ever missed a doctor's appointment because of transportation problems? 1. Yes 2. No 7. Don't know 8. Don't want to answer 9. No answer recorded	Transportation barrier question will capture barriers to program engagement. This question is adapted from Measuring Health-related Transportation Barriers in Urban Settings – PMC (nih.gov)
5	Item Current Location : New Question Proposed Location : -	<u>NO CURRENT QUESTION</u>	If you are you currently using child care services please identify the type of services you use, if not select <i>Not Applicable</i> . 1. Infant (Birth to 11 months) 2. Toddler (11 to 36 months) 3. Preschool (3 to 5 years) 4. After School Care (K-9 th grade) 5. Not Applicable 7. Don't know 8. Don't want to answer 9. No answer recorded	Childcare barrier question will capture barriers to program engagement. This question is adapted from 350-056(FCS-132P).pdf (vt.edu)
6	Item Current Location :	<u>NO CURRENT QUESTION</u>	Have you had any of these child-care related problems during the past year? (Select all that apply) 1. Cost	Childcare barrier question will capture barriers to program engagement. This question is adapted

	New Question Proposed Location :		<ol style="list-style-type: none"> 2. Availability 3. Location 4. Transportation 5. Hours of Operation 6. Other 7. Not Applicable 8. Don't know 9. No answer recorded 	<p>from 350-056(FCS-132P).pdf (vt.edu)</p>
7	Item Current Location : New question Proposed Location :	<u>NO CURRENT QUESTION</u>	<p>What is your housing situation today?</p> <ol style="list-style-type: none"> 1. I have housing 2. I have housing, but I am worried about losing my housing 3. I do not have housing 7. Don't know 8. Don't want to answer 9. No answer recorded 	<p>Housing insecurity question will capture barriers to program engagement. This question is adapted from PRAPARE-English.pdf</p>
8	Item Current Location : New question Proposed Location :	<u>NO CURRENT QUESTION</u>	<p>The following will ask about how safe you feel:</p> <ol style="list-style-type: none"> i. How often does your partner physically hurt you? ii. How often does your partner insult or talk down to you? <ol style="list-style-type: none"> 1. Never 2. Rarely 3. Sometimes 4. Fairly Often 5. Frequently 8. Response not given 9. No answer Recorded 	<p>This copyrighted IPV question can capture a barrier to actively participating in the WISEWOMAN Program.</p> <p>Question is from the Hurt, Insult, Threaten, and Scream (HITS) Tool (page 42).</p> <p>Intimate Partner Violence and Sexual Victimization Assessment Instruments for Use in Healthcare Settings 06_105344_IPV_SVB ooklet_knuth.indd (cdc.gov)</p>
9	Item Current Location : New question	<u>NO CURRENT QUESTION</u>	<p>These four items are related to medication-taking adherence:</p> <ol style="list-style-type: none"> i. Do you ever forget to take your (name of health condition) medicine? ii. Are you careless at times 	<p>This proposed question can enhance understanding of participants adherence to medication. These questions are adapted from the Medication</p>

	Proposed Location :		<p>about taking your (name of health condition) medicine?</p> <p>iii. When you feel better, do you sometimes stop taking your (name of health condition) medicine?</p> <p>iv. Sometimes if you feel worse when you take your (name of health condition) medicine, do you stop taking it?</p> <p>1. Yes 2. No 8. Response not given 9. No answer Recorded</p>	<p>Adherence Questionnaire (MAQ) The Clinical Utility of the Medication Adherence Questionnaire (Maq) in an Alcohol Pharmacotherapy Trial (nih.gov)</p>
10	Item Current Location : New question Proposed Location :	<u>NO CURRENT QUESTION</u>	Social Service ID	Identify specific resources used to address social determinant of health and barriers that impede engagement with the WISEWOMAN Program.
11	Item Current Location : New question Proposed Location :	<u>NO CURRENT QUESTION</u>	Social Service Referral Date 1. MM/DD/YYYY	Identify specific resources used to address social determinant of health and barriers that impede engagement with the WISEWOMAN Program.

Exhibit 3. Proposed Changes to MDE Questions or Response Options

We propose to alter response options to existing MDEs 2c and 3i and add three response options to existing MDE 4B to increase analytical utility and strengthen the analytical framework of the minimum data elements. The table below describes this element in further detail:

No.	MDE Field Number	Current Information Collection Phrasing	Proposed Changes	Rationale
1	<p>Item Current Location: 2c: Type</p> <p>Proposed Location: 2c: Type</p>	<p>Type of Screening Visit</p> <ol style="list-style-type: none"> 1. Screening 2. Rescreening 3. Follow-up screening LSP/HC complete 4. Follow-up screening LSP/HC incomplete 9. No answer recorded 	<p>Type of Screening Visit</p> <ol style="list-style-type: none"> 1. <i>Baseline Assessment</i> 2. <i>Reassessment</i> 3. <i>Follow-up Assessment (in-person)</i> 4. <i>Follow-up Assessment (at-home)</i> 9. No answer recorded 	<p>These modified responses can increase analytical utility and distinction between in-person and at-home follow-up screening visits.</p>
2	<p>Item Current Location: Item 3i: Language</p> <p>Proposed Location: Item 3i: Language</p>	<p>What is the primary language spoken in your home?</p> <ol style="list-style-type: none"> 01 English 02 Spanish 03 Arabic 04 Chinese 05 French 06 Italian 07 Japanese 08 Korean 09 Polish 10 Russian 11 Tagalog 12 Vietnamese 13 Creole 14 Portuguese 15 Hmong 16 Other Language 88 Don't want to answer 99 No answer recorded 	<p><i>What primary language do you speak?</i></p> <ol style="list-style-type: none"> 01 English 02 Spanish 03 Arabic 04 Chinese 05 French 06 Italian 07 Japanese 08 Korean 09 Polish 10 Russian 11 Tagalog 12 Vietnamese 13 Creole 14 Portuguese 15 Hmong 16 “___” (write in) 88 Don't want to answer 99 No answer recorded 	<p>This modified question can enhance understanding of participants' needs for appropriate translated materials where needed.</p>
3	<p>Item Current</p>	<p>Have you had any of the following? (1 for yes/2 for no):</p>	<p>Have you had any of the following? (1 for yes/2 for no): ___ Stroke/TIA</p>	<p>This modified response can increase</p>

	<p>Location: 4B: SRHA</p> <p>Proposed Location: 4B: SRHA</p>	<p>___ Stroke/TIA</p> <p>___ Heart attack</p> <p>___ Coronary heart disease</p> <p>___ Heart failure</p> <p>___ Vascular disease (peripheral arterial disease)</p> <p>___ Congenital heart disease and defects</p> <p>7. Don't know/Not sure</p> <p>8. Don't want to answer</p> <p>9. No answer recorded</p>	<p>___ Heart attack</p> <p>___ Coronary heart disease</p> <p>___ Heart failure</p> <p>___ Vascular disease (peripheral arterial disease)</p> <p>___ Congenital heart disease and defects</p> <p>* ___ <i>Gestational hypertension</i></p> <p>* ___ <i>Gestational diabetes</i></p> <p>* ___ <i>Pre-eclampsia/eclampsia</i></p> <p>7. Don't know/Not sure</p> <p>8. Don't want to answer</p> <p>9. No answer recorded</p>	<p>analytical utility as maternal diseases increase risk of CVD later in life.</p> <p>Gestational diabetes and the risk of cardiovascular disease in women: a systematic review and meta-analysis SpringerLink</p> <p>Future Cardiovascular Disease Risk for Women With Gestational Hypertension: A Systematic Review and Meta-Analysis Journal of the American Heart Association (ahajournals.org)</p> <p>Cardiovascular Disease-Related Morbidity and Mortality in Women With a History of Pregnancy Complications Circulation (ahajournals.org)</p>
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