

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

(OMB no. 0920-0612, exp. date 03/31/2013)

Change Request and Justification

December 22, 2010

Background

Cardiovascular disease, which includes heart disease, myocardial infarction, and stroke, is a primary contributor to mortality, morbidity, and decreased quality of life, especially among older women. Addressing such risk factors as elevated blood cholesterol, high blood pressure, obesity, sedentary lifestyle, diabetes, and smoking greatly reduces a woman's risk of CVD-related illness and death. The WISEWOMAN program was established to reduce cardiovascular disease risk factors among at-risk low-income women aged 40 to 64 by providing preventive services. CDC collects information from funded WISEWOMAN programs for program monitoring and evaluation.

Summary of Change Request

The WISEWOMAN Reporting System consists of three information collections:

- Screening and Assessment Minimum Data Elements (MDE)
- (Lifestyle) Intervention Minimum Data Elements (MDE)
- Progress Report

CDC requests OMB approval to implement minor changes to the Screening and Assessment MDE and the Intervention MDE. No changes to the Progress Report are proposed. The program scope, purpose, burden, protocol, methodology, and planned analyses remain unchanged from the previous approval. An overview of proposed changes is provided in Exhibit 1. Exhibits 2, 3 and 4 provided detailed information on proposed changes. Attachment 3 is the revised data collection instrument for Screening and Assessment MDE. Attachment 4 is the revised data collection instrument for Intervention MDE.

Impact on Burden to Respondents

None. The planned deletions, additions, and minor changes in the wording of questions are not expected to change the overall burden to respondents.

Justification

This request is the result of a review of the WISEWOMAN MDE by program staff at CDC. We reviewed national surveys, consulted with the WISEWOMAN funded programs and the CDC National Breast and Cervical Cancer Early Detection Program (which collects similar information for women who receive services through NBCCEDP), CDC's Division of Diabetes Translation, and CDC's Office of Smoking and Health. We identified a number of opportunities for improving WISEWOMAN data quality and for aligning WISEWOMAN data with evaluation data collected for other chronic disease programs at CDC. Harmonizing data elements across information collections will improve CDC's ability to make comparisons between the health of women nationally and WISEWOMAN's at-risk and underserved population of women between the ages of 40 and 64. WISEWOMAN oversamples this at-risk population in the services it provides. Whereas, 21% of women reside in rural areas nationally, 39% of the women WISEWOMAN serves reside in rural areas. Access to health care services is often limited in rural areas.

A few changes are proposed to harmonize WISEWOMAN data elements with data elements used for the National Adult Tobacco Survey (OMB No. 0920-0828, exp. 10/31/2010) and/or the National Health Interview Survey (OMB No. 0920-0214, exp. 1/31/2013). Potential changes to the MDE were discussed with grantees during the WISEWOMAN annual grantee meeting in September 2010. This Change Request reflects the feedback CDC received from grantees.

Implementation Schedule

CDC plans to provide implementation guidance to programs for the MDE changes in February 2011 for implementation effective July 2011.

Exhibits

- Exhibit 1. Overview of Proposed Changes
- Exhibit 2. Deletions from Current Elements/Questions (detail)
- Exhibit 3. Modifications to Data Elements/Questions or Response Options (detail)
- Exhibit 4. New Elements/Questions (detail)

Attachments

- Attachment 3 (revised). Screening and Assessment MDE (proposed changes shown in track-changes format)
- Attachment 4 (revised). Intervention MDE (proposed changes shown in track-changes format)

Exhibit 1. Overview of Proposed Changes

TYPE OF CHANGE	ELEMENTS EFFECTED	NUMBER OF ELEMENTS
Delete from Current MDE Requirements	Disposition status; sixth race; assessment date; height and weight measurement date; height measurement unit, weight measurement unit; blood pressure alert prescribe treatment; cholesterol alert prescribed treatment; and glucose alert prescribed treatment	9
Modifications to Data Elements/Questions or Response Options	1 smoking status; high cholesterol medication personal history; high blood pressure medication personal history; diabetes medication personal history; diabetes status; glucose measurement; contact type	7
New Elements/Questions	1 second hand smoke exposure and 1 provider counseling for smoking cessation	2

Exhibit 2: Deletions from Current MDE

We propose to remove from reporting requirements nine MDEs that were determined not to be useful for analysis. The rationale for no longer requiring each one of the eight MDEs is provided in the column to the far right titled *Rationale*.

<u>MDE Field Name and File Position Location</u>	<u>Reference Document</u> <i>Current Information Collection</i>	<u>Changes Document</u> <i>Proposed Changes</i>	<u>Rationale</u> Brief description of intent of change
<p>Item 1 Current Location: S&A File</p> <p>Proposed Location: <u>NO LONGER REPORT</u></p>	<p>2b. Disposition Status</p> <ol style="list-style-type: none"> 1. Open (additional data expected) 2. Closed (complete) 	<p><u>NO LONGER REPORT</u></p>	<p>We propose to eliminate the Disposition Status field. This data is not meaningful because it is not standardized and the definitions of “open” and “closed” vary greatly between funded programs.</p>
<p>Item 2 Current Location: S&A File</p> <p>Proposed Location: <u>NO LONGER REPORT</u></p>	<p>3k. Sixth Race:</p> <ol style="list-style-type: none"> 1. White 2. Black or African American 3. Asian 4. Native Hawaiian or Other Pacific Islander 5. American Indian or Alaska Native 7. Unknown 9. No answer recorded 	<p><u>NO LONGER REPORT</u></p>	<p>WISEWOMAN Programs collect separate ethnic and racial information from patients as outlined by OMB. The race information allows up to 5 races to be selected. In the current file reporting layout there is an extra field (6th race). This is a hold-over from the earlier combined ethnicity and race question. Programs must currently report this field as data missing. We proposed to eliminate this extra field for reporting.</p>
<p>Item 3 Current Location: S&A File</p>	<p>4a. Assessment Date MM/DD/CCYY Date</p>	<p><u>NO LONGER</u></p>	<p>We propose to collect only one date to reflect when the office visit occurred. This</p>

<u>MDE Field Name and File Position Location</u>	<u>Reference Document</u>	<u>Changes Document</u>	<u>Rationale</u>
	<i><u>Current Information Collection</u></i>	<i><u>Proposed Changes</u></i>	<i><u>Brief description of intent of change</u></i>
Proposed Location: <u>NO LONGER REPORT</u>		<u>REPORT</u>	visit date will be the date the blood pressure measurement is taken.
Item 4 Current Location: S&A File Proposed Location: <u>NO LONGER REPORT</u>	9a. Height and Weight Measurement Date MM/DD/CCYY Date	<u>NO LONGER REPORT</u>	We propose to collect only one date to reflect when the visit date occurred. This visit date will be the date the blood pressure measurement is taken.
Item 5 Current Location: S&A File Proposed Location: <u>NO LONGER REPORT</u>	9c. Height Unit 1. Inches 2. Centimeters	<u>NO LONGER REPORT</u> Allow only inches as measurement unit for reporting	We propose to eliminate the metric height measurement units. Measurement units have only been reported in inches. The choice to report in metric measures is duplicative.
Item 6 Current Location: S&A File Proposed Location: <u>NO LONGER REPORT</u>	9e. Weight Unit 1. Pounds 2. Kilograms	<u>NO LONGER REPORT</u> Allow only pounds as measurement unit for reporting	We propose to eliminate the metric weight measurement units. Measurement units have only been reported in pounds. The choice to report in metric measures is duplicative.
Item 9 Current Location: S&A File	13c. If average SBP>180 or average DBP>110, what type of treatment is prescribed? 1. Medication	<u>NO LONGER REPORT</u>	We propose to eliminate this field. This data cannot be meaningfully analyzed because of the very small

<u>MDE Field Name and File Position Location</u>	<u>Reference Document</u> <u>Current Information Collection</u>	<u>Changes Document</u> <u>Proposed Changes</u>	<u>Rationale</u> <u>Brief description of intent of change</u>
Proposed Location: <u>NO LONGER REPORT</u>	2. Therapeutic Lifestyle Change (TLC) – this is NOT the same as the lifestyle intervention offered to WISEWOMAN participants 3. Both Medication and TLC 4. Nothing prescribed 5. Already on meds 6. Not an alert reading (SBP>180 or DBP>110) 7. No blood pressure value recorded (SBP1 and DBP1=777, 888, 999) 8. Client refused treatment 9. Lost to follow-up		percentage of women with alert values.
Item 10 Current Location: S&A File Proposed Location: <u>NO LONGER REPORT</u>	13f. If TOTCHOL>400, what type of treatment was prescribed 1. Medication 2. Therapeutic Lifestyle Change (TLC) – this is NOT the same as the lifestyle intervention offered to WISEWOMAN participants 3. Both Medication and TLC	<u>NO LONGER REPORT</u>	We propose to eliminate this field. This data cannot be meaningfully analyzed because of the very small percentage of women with alert values.

<u>MDE Field Name and File Position Location</u>	<u>Reference Document</u> <u>Current Information Collection</u>	<u>Changes Document</u> <u>Proposed Changes</u>	<u>Rationale</u> <u>Brief description of intent of change</u>
	4. Nothing prescribed 5. Already on meds 6. Not an alert reading (SBP>180 or DBP>110) 7. No blood pressure value recorded (SBP1 and DBP1=777, 888, 999) 8. Client refused treatment 9. Lost to follow-up		
Item 11 Current Location: S&A File Proposed Location: <u>NO LONGER REPORT</u>	13i If GLUCOSE>375, what type of treatment was prescribed 1. Medication 2. Therapeutic Lifestyle Change (TLC) – this is NOT the same as the lifestyle intervention offered to WISEWOMAN participants 3. Both Medication and TLC 4. Nothing prescribed 5. Already on meds 6. Not an alert reading (SBP>180 or DBP>110) 7. No blood pressure value recorded (SBP1 and DBP1=777, 888, 999) 8. Client refused treatment	<u>NO LONGER REPORT</u>	We propose to eliminate this field. This data cannot be meaningfully analyzed because of the very small percentage of women with alert values.

<u>MDE Field Name and File Position Location</u>	<u>Reference Document</u> <i><u>Current Information Collection</u></i>	<u>Changes Document</u> <i><u>Proposed Changes</u></i>	<u>Rationale</u> <i><u>Brief description of intent of change</u></i>
	9. Lost to follow-up		

Exhibit 3: Modifications to Elements/Questions or Response Options

Changes Related to Elements/Questions. We propose to replace 4 existing questions with questions designed to improve validity and consistency of data. The first question to be replaced is the current question used to determine smoking status of all WISEWOMAN participants. Smoking is a risk factor for heart disease and stroke. Upon further review, conducted from July 2010 to September 2010, we determined that the smoking question currently in use in the WISEWOMAN Reporting System is not reliable and valid. In addition, the current question is not found in the National Adult Tobacco Survey (OMB control no. 0920-0828). We plan to replace the existing *Smoking Status* question with a question used in the National Adult Tobacco Survey to oversample and determine prevalence for this at-risk and underserved WISEWOMAN population.

The three remaining questions to be replaced are all *medication personal history* questions for high cholesterol, high blood pressure, and diabetes. WISEWOMAN grantees, at the annual grantee conference in September 2010, suggested that the present wording of the three medication questions does not provide reliable responses. This is because WISEWOMAN participants often report the use of non-prescribed medicines or herbal medicines. The grantees asked the WISEWOMAN data reporting system to adopt specific language reported in the table below.

Changes in Response Options. We also propose to change response options for three MDE questions. These changes will result in more accurate reporting and improved data integrity.

We propose to clarify the existing MDE to assess “health history of diabetes” by adding a response option for gestational diabetes (or diabetes during pregnancy). This change is consistent with the 2010 National Health Interview Survey Adult Questionnaire (OMB No. 0920-0214).

Based on the feedback from WISEWOMAN funded programs, we propose to add response options to fasting or non-fasting “glucose” test to allow for reporting A1C test for diabetes. Recently updated recommendations by the American Diabetes Association in *Diagnosis and Classification of Diabetes Mellitus (2010)* support the use of an A1C test as an alternative to a glucose test for diabetes screening.

Finally, we propose to add two response options to “contact type” to identify when participants are referred or linked to community based resources that do not fall under the definition of a WISEWOMAN funded Lifestyle Intervention program. These two response options will allow the reporting of confirmed and non-confirmed referrals to community based resources.

* **response options are presented in RED** while recording options are presented in GRAY and will not appear on any self-report forms

<u>MDE Field Name and File Position Location</u>	<u>Reference Document</u> <u>Current Information Collection</u>	<u>Changes Document</u> <u>Proposed Changes</u>	<u>Rationale</u> <u>Brief description of intent of change</u>
<p>Item 12 Current Location: S&A File</p> <p>Proposed Location: Same</p>	<p>8a. Do you smoke cigarettes?</p> <ol style="list-style-type: none"> 1. Everyday 2. Some days 3. Not at all 7. Don't know 9. Answer not recorded 	<p><i>*8a. Do you now smoke cigarettes every day, some days, or not at all?</i></p> <ol style="list-style-type: none"> 1. Every day 2. Some days 3. Not at all 7. Don't Know/Not Sure 8. Refused 9. No answer recorded 	<p>We propose to replace the existing question with a standard validated question from the National Adult Tobacco Survey (OMB control no. 0920-0828). This question is used to determine prevalence.</p>
<p>Item 15 Current Location: S&A File</p> <p>Proposed Location: Same</p>	<p>7a. Are you currently taking medication for high Cholesterol?</p> <ol style="list-style-type: none"> 1. Yes, as prescribed 2. Yes, but did not take today 3. No 7. Don't Know 8. Don't want to answer 9. No answer recorded 	<p><i>*7a. Are you taking any medicine prescribed by your doctor, nurse, or other health professional for your high Cholesterol?</i></p> <ol style="list-style-type: none"> 1. Yes 3. No 7. Don't Know/Not Sure 8. Refused 9. No answer recorded 	<p>We propose to replace the existing question with a more meaningful question suggested by our grantees at the annual grantee conference in September 2010. The suggested question will limit high cholesterol medicines to only those prescribed by a doctor, nurse, or other health professional.</p>
<p>Item 16 Current Location: S&A File</p> <p>Proposed Location: Same</p>	<p>7b. Are you currently taking medication for high Blood Pressure?</p> <ol style="list-style-type: none"> 1. Yes, as prescribed 2. Yes, but did not take today 3. No 	<p><i>*7b. Are you taking any medicine prescribed by your doctor, nurse, or other health professional for your high blood pressure?</i></p> <ol style="list-style-type: none"> 1. Yes 	<p>We propose to replace the existing question with a more meaningful question suggested by our grantees at the annual grantee conference in September 2010. The suggested question will limit high</p>

<u>MDE Field Name and File Position Location</u>	<u>Reference Document</u> <i>Current Information Collection</i>	<u>Changes Document</u> <i>Proposed Changes</i>	<u>Rationale</u> <i>Brief description of intent of change</i>
	7. Don't Know 8. Don't want to answer 9. No answer recorded	3. No 7. Don't Know/Not Sure 8. Refused 9. No answer recorded	blood pressure medicines to only those prescribed by a doctor, nurse, or other health professional.
Item 17 Current Location: S&A File Proposed Location: Same	7c. Are you currently taking medication for diabetes? 1. Yes, as prescribed 2. Yes, but did not take today 3. No 7. Don't Know 8. Don't want to answer 9. No answer recorded	*7c. Are you taking any medicine prescribed by your doctor, nurse, or other health professional for diabetes? 1. Yes 3. No 7. Don't Know/Not Sure 8. Refused 9. No answer recorded	We propose to replace the existing question with a more meaningful question suggested by our grantees at the annual grantee conference in September 2010. The suggested question will limit diabetes medicines to only those prescribed by a doctor, nurse, or other health professional.

Changes to Response Options

<u>MDE Field Name and File Position Location</u>	<u>Reference Document</u> <i>Current Information Collection</i>	<u>Changes Document</u> <i>Proposed Changes</i>	<u>Rationale</u> <i>Brief description of intent of change</i>
Item 7 Current Location: S&A File Proposed Location: Same	5c. Have you been told by a doctor nurse or other health professional that you have diabetes? 1. Yes 2. No	*5c. Have you been told by a doctor nurse or other health professional that you have diabetes? 1. Yes 2. No	We propose to add a response option for gestational diabetes (diabetes during pregnancy). This is consistent with the 2010 National Health Interview Survey Adult Questionnaire (OMB No. 0920-0214).

<u>MDE Field Name and File Position Location</u>	<u>Reference Document</u> <i><u>Current Information Collection</u></i>	<u>Changes Document</u> <i><u>Proposed Changes</u></i>	<u>Rationale</u> <i><u>Brief description of intent of change</u></i>
	7. Don't Know 8. Don't want to answer 9. No answer recorded	3. Yes – Gestational (pregnancy) diabetes only 7. Don't Know/Not Sure 8. Don't want to answer 9. No answer recorded	
<u>Item 8</u> Current Location: S&A File Proposed Location: Same	12b. Glucose (fasting or non-fasting), mg/dl 666. Participant has a previous diagnosis of diabetes – glucose reading not necessary 777 Inadequate blood sample 888 Client refused 999 No measurement recorded	12b. Glucose (fasting or non-fasting), mg/dl 666. Participant has a previous diagnosis of diabetes - glucose reading not necessary 700. A1C taken for screening purposes 777. Inadequate blood sample 800. Participant has previous diagnosis of diabetes - A1C measured by another provider 888. Client refused 999. No measurement recorded	We propose to add two new response options: <ul style="list-style-type: none">• Response option 700 will allow programs to report A1C results when used for diagnosis.• Response “800-participant has previous diagnosis of diabetes; A1C measured by another provider. This will allow programs to use A1C results from another provider.
<u>Item 19</u> Current Location: LSI File Proposed Location: Same	5a. Type of contact 1. Face-to-Face 2. Phone 3. Evidence that mailed materials were opened and reviewed	5a. Type of contact 1. Face-to-Face 2. Phone 3. Evidence that mailed materials were opened and	We propose adding a response option to allow more accurate reporting of contact type for data integrity. This option was requested by programs to make the data more accurate and meaningful.

<u>MDE Field Name and File Position Location</u>	<u>Reference Document</u> <i>Current Information Collection</i>	<u>Changes Document</u> <i>Proposed Changes</i>	<u>Rationale</u> <u>Brief description of intent of change</u>
	<p>4. Evidence that audiotape or DVD was opened or reviewed</p> <p>5. Evidence that computer based session was completed</p>	<p>reviewed</p> <p>4. Evidence that audiotape or DVD was opened or reviewed</p> <p>5. Evidence that computer based session was completed</p> <p>6. Referral to community based resources with no WISEWOMAN LSI – referral confirmed</p> <p>7. Referral to community based resources with no WISEWOMAN LSI – referral not confirmed</p>	

Exhibit 4: New Elements/Questions

We propose to add one new question to assess exposure to secondhand smoke and one new MDE to track smoking cessation counseling. Smoking and exposure to secondhand smoke are risk factors for heart disease and stroke. We propose to add one validated question from NATS to the WISEWOMAN MDE. The question aims to assess exposure to second hand smoke. This allows the CDC to compare second hand smoke exposure nationally to the second hand smoke exposure in the at-risk and underserved WISEWOMAN population. The Institute of Medicine report titled *Secondhand Smoke Exposure and Cardiovascular Effects: Making Sense of the Evidence* (October 15, 2009) findings update evidence that exposure to second hand smoke increases the risk the cardiovascular disease by up to thirty percent.

Smoking is a risk factor for heart disease and stroke; smoking cessation is an important part of the WISEWOMAN program. The MDE to track smoking cessation counseling reflects this importance. Currently WISEWOMAN grantees do not have a way to report health care provider counseling for smoking cessation. There are MDEs for nutrition (6a – LSI file) and physical activity counseling (6c – LSI File). This new MDE will track smoking cessation intervention(s). The proposed language for this new MDE mirrors that used for nutrition and physical activity counseling.

* response options are presented in RED while recording options are presented in GRAY and will not appear on any self-report forms

<u>MDE Field Name and File Position Location</u>	<u>Reference Document</u> <i>Current Information Collection</i>	<u>Changes Document</u> <i>Proposed Changes</i>	<u>Rationale</u> <i>Brief description of intent of change</i>
<p>Screening File Item 13 Current Location: New question</p> <p>Proposed Location: 8b in S&A File</p>	<p><u>NO CURRENT QUESTION</u></p>	<p>*8b. Not counting decks, porches, or garages, during the <u>past 7 days</u>, on how many days did someone other than you smoke tobacco inside your home while you were at home?</p> <p>01-07. Number of Days 00. None 77. Don't</p>	<p>Second hand smoke is a major risk factor for cardiovascular disease. We suggest adding a question to assess second hand smoke exposure. The question was taken from the validated NATS (OMB control no. 0920-0828).</p>

<u>MDE Field Name and File Position Location</u>	<u>Reference Document</u> <i>Current Information Collection</i>	<u>Changes Document</u> <i>Proposed Changes</i>	<u>Rationale</u> <u>Brief description of intent of change</u>
		Know/Not Sure 88. Refused 99 No answer recorded	
Item 6 Current Location: New Question Proposed Location: 6g in LSI File	<u>NO CURRENT QUESTION</u>	6g. Indicate whether the participant received smoking cessation counseling during lifestyle intervention session? 1. Yes 2. No 7. Unknown	We propose to add this new MDE to track smoking cessation counseling. Smoking cessation is an important part of the WISEWOMAN program. Currently WISEWOMAN grantees do not have a way to report health care provider counseling for smoking cessation. There are MDEs for nutrition (6a – LSI file) and physical activity counseling (6c – LSI File). The language proposed for this new MDE mirrors that used for nutrition and physical activity counseling.