WISEWOMAN Policy Manual

WISEWOMAN

Making Healthier Choices for a Healthier Life

Fiscal Year 2015/2016
October 1, 2015 to September 30, 2016

WISEWOMAN Program Policies
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www.michigancancer.org/bcccp/wisewomanprogram

WISEWOMAN Program Description

The WISEWOMAN Program provides chronic disease risk factor screening and healthy lifestyle behavior support to Michigan women. In order to be enrolled in WISEWOMAN, a woman must first be in the Michigan Breast and Cervical Cancer Control Navigation Program (BCCCNP). The BCCCNP provides breast and cervical cancer screening and follow-up services (including cancer treatment) to low income women aged 40-64 with no insurance. They also provide breast and cervical cancer navigation services to low income women aged 40-64 with insurance.

The WISEWOMAN Program helps participants understand their chronic disease risk factors and make healthy lifestyle choices. A healthy lifestyle can help reduce current chronic disease risk factors and symptoms. It may also prevent or delay the onset of new chronic disease risk factors.

The local WISEWOMAN Agency team includes the clinical staff and a Community Navigator. The clinical staff conduct the health risk assessment, and clinical screening for each participant. The Community Navigator conducts risk reduction counseling, assists the participant with goal setting, assists with choosing the best healthy behavior support option for her and provides on-going follow-up contact and support.

The health risk assessment allows the participant to tell us about her personal medical history as well as her current health behaviors.

At the clinical screening, the clinical staff:

1. measure the participant's height and weight in order to calculate her body mass index (BMI)
2. measure her blood pressure
3. collect a drop of blood from the participant's finger in order to determine her total cholesterol, high density lipoprotein (HDL) cholesterol, and glucose.

The program participant receives appropriate medical referrals based on the clinical screening results.

A Community Navigator at the screening site communicates the participant's risk factors to her in a risk reduction counseling session and talks with the participant to determine her readiness to make behavior changes that will lead to better health.

A participant identified with hypertension is offered the opportunity to participate in a blood pressure control program to help manage her blood pressure.

Each participant who is ready to make changes is encouraged to determine one priority area such as blood pressure control, nutrition, physical activity, or smoking cessation.

The Community Navigator works with her to develop a goal related to this area. The participant can receive one-on-one health coaching. She can also choose to participate in an evidence-based lifestyle program or a community-based program to assist her in making healthy lifestyle behavior changes.

WISEWOMAN Program Description

The WISEWOMAN program addresses the four domains of chronic disease prevention and health promotion.

1. Data Collection and Analysis: WISEWOMAN collects a variety of demographic, chronic disease risk factor, and lifestyle intervention data elements that are evaluated to help inform the evidence regarding outcomes of various types of lifestyle programs including health coaching. Program data are used in the quality improvement process to ensure program efficiency and effectiveness.

2. Environmental Approaches: Local WISEWOMAN agencies partner within their own communities to bring about environmental changes. These changes benefit the WISEWOMAN participant, but they also benefit the entire community.

3. Health Systems: Local WISEWOMAN agencies deliver clinical screening for cardiovascular disease (CVD), diabetes, and other chronic diseases, provide risk reduction counseling, and offer blood pressure control strategies to WISEWOMAN participants. The agencies are able to demonstrate, within the local health system, the feasibility of providing these evidence-based practices. Other providers in the health system may decide to offer similar services to their patients.

4. Community-Clinical Linkages: Local WISEWOMAN agencies conduct regular scans of each community where WISEWOMAN is implemented to identify community resources such as clinics, support groups, and programs able to help participants make healthy behavior changes that will prevent or delay the onset of chronic conditions or will allow them to manage existing chronic conditions.

Program Focus Areas

In addition to addressing the four domains of chronic disease prevention and health promotion, the Michigan WISEWOMAN program has three main focus areas related directly to participants.

1. Identify and communicate risk factors for cardiovascular disease (CVD), stroke, diabetes, and other chronic diseases. The participant is better able to determine where she wants to focus her change efforts if she understands her chronic disease risk factors.

2. Encourage healthy lifestyle choices. Community Navigators help each participant make lifestyle behavior changes that will positively impact her current chronic disease risk factors and symptoms as well as prevent or delay the development of new chronic disease risk factors.

3. Address Health Equity and Social Justice issues. Local WISEWOMAN agencies identify and conduct targeted outreach to underserved populations, such as people with disabilities, non-English speakers, Lesbian, Gay, Bisexual, and Transgendered (LGBT), racial/ethnic minorities, and other populations who may otherwise be missed. in order to improve the health outcomes of women in that population. Once in the program, many women find it difficult to think about making healthy lifestyle choices when they are having trouble meeting rent, paying for utilities, and buying food for their families. Michigan WISEWOMAN addresses these issues through special projects that provide participants with opportunities to earn extra money while learning marketable skills.

Local WISEWOMAN Agency Requirements

Each Local WISEWOMAN Agency (LWA) funded by the Michigan Department of Health and Human Services (MDHHS) to implement the WISEWOMAN Program must adhere to the following requirements:

Program Management

1. Identify one person as the Local WISEWOMAN Agency Coordinator. The Coordinator's responsibilities are listed in the "Local Staff Responsibilities" document.

2. Follow all WISEWOMAN program policies and procedures.

3. Meet or show significant progress toward meeting performance measures established by the Centers for Disease Control and Prevention (CDC) and MDHHS WISEWOMAN.

4. MDHHS WISEWOMAN Program staff must train all staff members involved in the implementation of the WISEWOMAN Program **prior** to their participation in the program.

5. Provide documentation to MDHHS that WISEWOMAN Program Policies and Procedures will be followed by each staff member involved in the implementation of the WISEWOMAN Program. Documentation must be provided electronically using the WISEWOMAN Program Assurances Checklist located on the WISEWOMAN website.

6. Provide and regularly update contact information for all local WISEWOMAN staff in order for the state WISEWOMAN staff to maintain contact.

7. The LWA must inform the MDHHS WISEWOMAN Program Director within one week of any WISEWOMAN Program staff changes (including extended sick leave) using the WISEWOMAN Staffing Changes form.

8. Upon request, provide documentation to MDHHS of the qualifications of staff members who will perform:
    - Cholesterol, Glucose, and Blood Pressure Screening
    - Community Navigation
    - Case Management (for women with alert values)
    - Program Coordination

9. Submit scheduled (monthly for contractual; quarterly for Master Agreements) and final Financial Status Reports (FSR) in a timely manner.

10. Provide non-federal match totaling 33% of the Coordination and Screening funding received for WISEWOMAN Program caseload.
    - Documentation of the 33% match requirement of the Coordination and Screening dollars must be provided to MDHHS on an **annual** basis using the

Matching Funds Reporting Form. The Matching Funds Reporting Form is submitted with the Final FSR.

- See the WISEWOMAN website for current fiscal year WISEWOMAN Budgeting Instructions and a sample Matching Funds Report.

11. Track earned caseload throughout the fiscal year to ensure achieving an earned caseload of at least 95% of budgeted caseload without exceeding 100%.
    - The LWA will not receive Coordination and Screening funding, Community Navigation funding, or Case Management reimbursement (if applicable) for any participants over 100% of budgeted caseload.
    - Michigan WISEWOMAN is able to amend the Comprehensive Agreement at various times throughout the year. At those times, agencies will have the opportunity to amend their budgeted caseload amount. Agencies can request a decrease or an increase in caseload. Caseload decreases will be granted. Caseload increases will be granted based on availability and past performance in meeting caseload.
    - *Any LWA clearly not on pace to meet budgeted caseload for the fiscal year at midyear (April) may have caseload taken away from them and given to other Local WISEWOMAN Agencies. An agency's past performance in achieving budgeted caseload will influence WISEWOMAN decisions and actions.*

Data Collection and Analysis

1. Collect all data elements required by MDHHS using WISEWOMAN forms.

2. Enter WISEWOMAN participant data into the WISEWOMAN module of the Michigan Breast and Cervical Cancer Information System (MBCIS). These data will be used to track progress toward meeting budgeted caseload as well as progress toward meeting other performance measures.

3. Actively participate in the WISEWOMAN Quality Improvement (QI) Process. This includes QI related to:
    - Data quality and completeness
    - Blood pressure measurement
    - Hypertension control
    - Community Navigation
    - Participant outcomes

4. Use Discoverer reports to assist in the QI process and to identify participants requiring follow-up, such as those with uncontrolled hypertension.

Environmental Approaches

1. Conduct an annual community scan of each community where WISEWOMAN is implemented.

2. Document the results of the community scan using the *Healthy Lifestyle Community Resources* form.

3. Use the community scan to identify existing resources in the community that foster healthy lifestyles, such as places for physical activity, access to healthy food, and smoke-free public places.

4. Provide relevant information about existing community resources to help WISEWOMAN participants achieve their lifestyle behavior change goals.

5. Use the results of the community scan to identify gaps in healthy environmental resources in the community related to nutrition, physical activity, and tobacco cessation.

6. Collaborate with community partners to address healthy environments that will support participants as they establish and sustain healthy eating habits, increase physical activity, stop smoking, and avoid exposure to second-hand smoke. Specific examples of collaborative efforts might include:
    - developing a community garden
    - establishing or promoting a farmers market
    - creating or expanding a walking trail
    - setting up a bicycle sharing program
    - establishing smoke-free parks and beaches

Health Systems

1. Provide WISEWOMAN screening services **at the same office visit** where BCCCP screening services occur for at least 50% of WISEWOMAN caseload. See Non-Integrated Office Visit Policy for more information.

2. Provide risk reduction counseling to all participants at the time of screening.

3. Provide to MDHHS copies of contracts or letters of agreement with health care providers who indicate willingness to:
    - See program participants who require a medical evaluation for reimbursement at the current WISEWOMAN Program rate
    - See program participants free or at reduced fees following the medical evaluation if additional care is required.

4. Ensure that health care providers to whom program participants are referred, will follow national treatment and clinical follow-up care guidelines including drug therapy and periodic re-evaluation and re-administration of laboratory tests as recommended by:
    - Adult Treatment Panel III for treatment of cholesterol (ATP III)
    - Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure (JNC 7)
    - Standards of Medical Care in Diabetes (published annually by American Diabetes Association).

5. Ensure that health care providers will refer participants newly diagnosed with diabetes to a local diabetes self-management education (DSME) program.

6. Provide to MDHHS copies of contracts or letters of agreement with diabetes self-management education programs that indicate willingness to see program participants free or at reduced fees following a diagnosis of diabetes.

7. Follow case management protocols related to alert value and hypertension case management.

8. Provide blood pressure control support for women with uncontrolled hypertension. See Blood Pressure Control Protocol for more information.

9. Obtain prescription drug assistance for women who are unable to afford their prescription medications. This may include providing prescription assistance directly and/or ensuring participating health care providers are able to secure prescription assistance for the women.

<u>Community-Clinical Linkages</u>

1. Use the community scan to identify existing evidence-based and other community programs to support WISEWOMAN participants in accomplishing their lifestyle behavior change goals.

2. Refer WISEWOMAN participants to appropriate evidence-based or other community programs depending on medical needs and goals. Examples

    - A woman identified with pre-diabetes should be referred to the Diabetes Prevention Program (DPP)
    - A woman who is interested in losing weight should be referred to a local Taking off Pounds Sensibly (TOPS) club
    - A woman who is ready to quit smoking should be referred to the Quitline or to a local tobacco cessation program

3. Collaborate with evidence-based programs to ensure a referral system and feedback loop that informs the local WISEWOMAN agency of the status of women who access services and identifies barriers to accessing those services.

4. Use the results of the community scan to identify gaps in evidence-based and other community programs related to nutrition, physical activity, and tobacco cessation.

5. Collaborate with community partners to develop evidence-based and other community programs and resources, such as DPP, TOPS Club, Enhance Fitness, community gardens, or walking groups, where needed, that will benefit WISEWOMAN participants and all members of the community.

6. Collaborate with Federally Qualified Health Centers (FQHC) and other healthcare providers to build or enhance systems to facilitate provider referrals to evidence-based and other community programs.

7. Provide to MDHHS a record of community partnerships and collaborations made on behalf of WISEWOMAN participants.
    - Agencies are expected to demonstrate **active** working relationships with community organizations/agencies
    - Examples include MSU Extension, Coalition Against Domestic Violence and Sexual Assault, YMCA
    - The Community Navigator will document the development of new resources using the Resource Development Tool.

Health Equity and Social Justice

1. Identify and document underserved populations in the geographic service area of the agency. Examples include people with disabilities, non-English speaking populations, Lesbian, Gay, Bisexual, and Transgendered (LGBT) populations, racial and ethnic minorities, and other populations who may otherwise be missed.

2. Choose at least one underserved population to target for the fiscal year.

3. Conduct outreach and provide all WISEWOMAN services to targeted underserved population(s).

4. Continuing education forms for all LCA WISEWOMAN staff must contain at least one Health Equity Social Justice educational activity not including those offered by MDHHS WISEWOMAN.

WISEWOMAN Program
Local Staff Responsibilities

Local Coordinator

- Act as the main point of contact between the local WISEWOMAN agency and the Michigan Department of Health and Human Services (MDHHS)
- Ensure adherence to all *Local WISEWOMAN Agency Requirements*
- Ensure the local WISEWOMAN agency follows all WISEWOMAN Policies, Procedures, and Protocols
    - WISEWOMAN Eligibility
    - Clinical Screening Procedures
    - Screening and Referral Protocols
    - Non-Integrated Screening Office Visit Policy
    - Case Management Protocols
    - Blood Pressure Control Protocol
    - Community Navigation Protocols
    - Take off Pounds Sensibly (TOPS) Referral Protocol
    - Diabetes Prevention Program (DPP) Referral Protocol
    - Billing and Reimbursement Protocols
    - Performance Measure Policy
    - Records Retention Policy
- Ensure scheduled (monthly for contractual; quarterly for Comprehensive Agreement) and final Financial Status Reports (FSR) are submitted in a timely manner
- Ensure timely completion and submission of the Matching Funds Report (MFR)
- Participate in the Quality Improvement Process with appropriate staff
- Ensure timely entry of data into the WISEWOMAN module of the Michigan Breast and Cervical Cancer Control Information System (MBCIS)
- Ensure timely and correct billing of WISEWOMAN Services
- Participate in WISEWOMAN conference calls, meetings, and site visits
- Work with Community Navigator to conduct community scans
- Ensure the local WISEWOMAN agency's involvement in community partnerships and collaborations made on behalf of WISEWOMAN participants
- Attend professional development trainings as required

Clinical Screener

- Conduct Health Risk Assessment
- Conduct Clinical Screening
    - Measure the participant's height and weight in order to calculate body mass index (BMI)
    - Measure the participant's blood pressure according to Clinical Screening Procedures
    - Measure the participant's total cholesterol, HDL cholesterol, and fasting glucose according to Clinical Screening Procedures
    - Measure the participant's Hemoglobin A1c using an Alere Afinion® Analyzer *(if the participant has a history of diabetes)* according to Screening and Referral Protocols
- Determine medical referrals according to *Screening and Referral Protocols*
- Participate in Blood Pressure Measurement Quality Improvement process
- Attend professional development trainings as required

Community Navigator

- Conduct community scan of community where WISEWOMAN is implemented
- Develop and regularly update a comprehensive overview of community based resources and programs based on community scan
- Deliver risk reduction counseling to every participant to communicate the participant's risk factors in a way she can understand
- Conduct Alert Value Case Management or Hypertension Case Management when needed
- Conduct readiness to change assessment to determine if participant is ready to make healthy lifestyle changes
- Encourage participants with hypertension to set blood pressure control as a priority area
- Assist participants who are ready to make change to develop a goal in their chosen priority area
- Conduct Health Coaching and regularly monitor outcomes for participants who are ready to make changes

- Conduct an Outcome Evaluation on all participants who set a goal/small step
- Identify or develop community linkages with organizations to meet WISEWOMAN requirements for community programming
- Develop a feedback loop with organizations to receive information about attendance and outcomes of WISEWOMAN participants
- Refer participants to community based and evidence-based resources that can help the women achieve their goal
- Follow-up with all community referrals to determine extent of participation and outcomes
- Participate in the WISEWOMAN Quality Improvement process
- Attend professional development trainings as required

WISEWOMAN Eligibility

Who is eligible?

1. Women receiving screening services through the Michigan Breast and Cervical Cancer Control Navigation Program (BCCCNP). This is a woman between the ages of 40 and 64 who is below 250% of the federal poverty level and does not have insurance. She must receive at least one of four breast or cervical cancer screening services.
    a. Clinical breast examination
    b. Mammogram
    c. Pap smear
    d. Pelvic examination

    She should receive her WISEWOMAN screening services, risk reduction counseling, and readiness to change assessment on the same day as her BCCCNP screening service(s).

2. Women receiving diagnostic services through the BCCCNP. This is a woman between the ages of 40 and 64 who is below 250% of poverty level who has insurance through the marketplace. Her screening uncovered an abnormality that needs more testing. Her insurance paid for the screening services. However, they will not pay for her diagnostic services. She may have a bronze plan with a large deductible. In this case, BCCCNP is paying for her diagnostic services, so she is eligible WISEWOMAN. Since BCCCNP will not provide screening services, her WISEWOMAN screening services, risk reduction counseling, and readiness to change assessment will take place when you can get her into the office. (See the WISEWOMAN *Non-Integrated Screening Office Visit Policy* for more information on the WISEWOMAN screening visit.)

3. Women receiving navigation-only services through the BCCCNP. This is a woman who is under 64 and below 250% of poverty level. She either has Healthy Michigan Plan or she has insurance through the marketplace. She has not received breast or cervical cancer screening services in the past year. The BCCCNP agency provides navigation services to her to ensure she receives at least one of the four screening services. (See the BCCCNP *Navigation Only Clients Protocol* for more information on BCCCNP Navigation.)
    a. If your agency provides the breast or cervical cancer screening services, you should provide the WISEWOMAN screening services and risk reduction counseling at the same appointment.
    b. If she receives her breast or cervical cancer screening services from another provider, and the provider **does not** provide total cholesterol, HDL, and glucose (or A1c) screening, your agency should bring the woman in to your office and:
        i. Provide the full WISEWOMAN screening
        ii. Ensure she completes the WISEWOMAN Health Intake Questions

iii. Provide risk reduction counseling, and a readiness to change assessment
iv. Conduct coordination of benefits with her insurance company to ensure WISEWOMAN is the payer of last resort. (WISEWOMAN funds can only be used to pay for services not covered by her insurance.)

c. If she receives her breast or cervical cancer screening services from another provider, and the provider **does** provide total cholesterol, HDL, and glucose (or A1c) screening, your agency will need to:
   i. Get the results of those tests from the provider
   ii. Ensure she completes the WISEWOMAN Health Intake Questions
   iii. Provide risk reduction counseling and a readiness to change assessment
   iv. Conduct any WISEWOMAN required tests the provider did not conduct

Baseline Screening

The baseline WISEWOMAN screening initiates a one-year cycle. At least 50% of WISEWOMAN screening visits **must** take place at the same time as the Breast and Cervical Cancer Control Navigation Program (BCCCNP) screening, during the same office visit.

The **Health Risk Assessment Component** evaluates the participant's medical history and current health behaviors.

- Personal Health Assessment
  - Personal history of:
    - High cholesterol
    - High blood pressure
    - Diabetes
    - Coronary Heart Disease
  - Currently taking medication to:
    - Lower cholesterol
    - Lower blood pressure
    - Lower blood sugar
  - Home blood pressure measurement

- Healthy Lifestyle Assessment
  - Nutrition
    - Fruits and vegetables
    - Fish
    - Whole grains
    - Sugar sweetened beverages
    - Sodium
  - Physical Activity
    - Weekly moderate and vigorous physical activity
  - Tobacco Use
    - Current status
    - Second hand smoke
  - Physical and emotional well-being

The **Clinical Screening Component** assesses for chronic disease risk factors and includes:

- Body Mass Index (BMI) Assessment
  - Measure the participant's height and weight, and determine BMI using a BMI wheel or chart.
- Blood Pressure Assessment
  - Measure the participant's blood pressure two times
  - Determine the category by averaging the two measurements

NOTE: CDC requires either a fasting glucose or A1c reading for every participant in order for her to count toward caseload. Refer to the Fasting Glucose & Hemoglobin A1c Protocol for your local WISEWOMAN agency to determine how to handle participants with no history of diabetes who are not fasting when they come in to be screened.

- Total and HDL Cholesterol and Blood Glucose
  - Measure the participant's fasting Glucose and Total and HDL Cholesterol using the Cholestech® LDX Machine in order to obtain immediate results.
- Hemoglobin A1c
  - For participants with a history of diabetes, measure her Hemoglobin A1c using the Afinion® A1c analyzer.
  - Participants with no history of diabetes **may** receive an A1c analysis if they are not fasting when they come in to be screened. The blood sample for the A1c analysis **must** be obtained through a venous blood draw, and the sample **must** be sent to a laboratory for analysis. **Do not use** the Alere Afinion® Analyzer for participants with no history of diabetes.

See Clinical Screening Procedures for more information.

Medical Referrals

Program participants who are identified with a disease level value will be referred for blood work (if needed) and to a health care provider for evaluation. Disease level values requiring referral are:

- BP greater than **140** (systolic) and/or greater than **90** (diastolic)
- Total Cholesterol greater than **240 and not currently being treated for high cholesterol**
- HDL less than **40 and not currently being treated for high cholesterol**
- Fasting Plasma Glucose greater than **125** (After fasting at least 9 hours) **and no history of diabetes**
- Hemoglobin A1c greater than or equal to **6.5% and no history of diabetes**
- Hemoglobin A1c greater than 7% **with a history of diabetes**

See Screening and Referral Protocols for more information.

Case Management

If a program participant's blood pressure and/or glucose measurements fall into the alert range, she will receive Alert Value Case Management. (Less than 3% of program participants will have values in the alert range.) Alert values are:

- Average BP is greater than **180** (systolic) and/or greater than **110** (diastolic)
- Glucose is less than or equal to **50** or greater than or equal to **250** (fasting or casual)

If a program participant is identified with uncontrolled hypertension, she will receive Hypertension Case Management. Uncontrolled hypertension is defined as:

- Average Blood PRessure is **140-180** (systolic) and/or **90-110** (diastolic) **AND**
- She answers "Yes" to question 6 and/or 7 of WISEWOMAN Questions indicating she has been told she has hypertension or she takes medicine to lower her blood pressure.

See Case Management Protocols for more information.

Risk Reduction Counseling

Each participant will receive risk reduction counseling at the time of screening using the WISEWOMAN *My Health Information* pamphlet, geared to low or marginal literacy readers. The pamphlet defines and identifies the participant's BMI, blood pressure, total cholesterol, HDL cholesterol, and glucose. The pamphlet also provides information about the participant's risks related to personal health history, physical activity, and smoking status.

Chronic Disease Control

Participants identified with hypertension, whether newly identified or existing, are offered help with blood pressure control.
Participants newly identified with diabetes are referred to a diabetes self-management education program.
Participants identified with pre-diabetes are referred to the diabetes prevention program.
Participants who choose not to participate in one of the chronic disease control options have the option of participating in health behavior support.

Readiness to Change Assessment

During the risk reduction counseling, the Community Navigator will assess the participant's readiness to make healthy lifestyle behavior change. Those who are ready to change will receive health coaching to assist them in making healthy lifestyle behavior changes. Women who are not ready to change will be contacted in 30 to 60 days to discuss their current situation and to see if they are ready to make changes at that time.

Health Coaching

Each participant who is ready to make changes is encouraged to determine one priority area. The priority areas include:

- blood pressure control
- nutrition
- physical activity
- smoking cessation

The Community Navigator works with the participant to develop a goal related to this area. The participant will receive one-on-one health coaching. She can also choose to participate in an evidence-based lifestyle program or a community-based program to assist her in making healthy lifestyle behavior changes.

If she chooses an evidence-based lifestyle program, such as the Diabetes Prevention Program or Taking off Pounds Sensibly (TOPS), WISEWOMAN will cover the cost of her participation in

the program as long as she attends a minimum number of sessions. She may prefer to attend a low or no cost community-based program, such as a walking group or Supplemental Nutrition Assistance Program Education (SNAP-Ed) nutrition classes.

See Community Navigation Protocols for more information.

Outcome Evaluation Contact

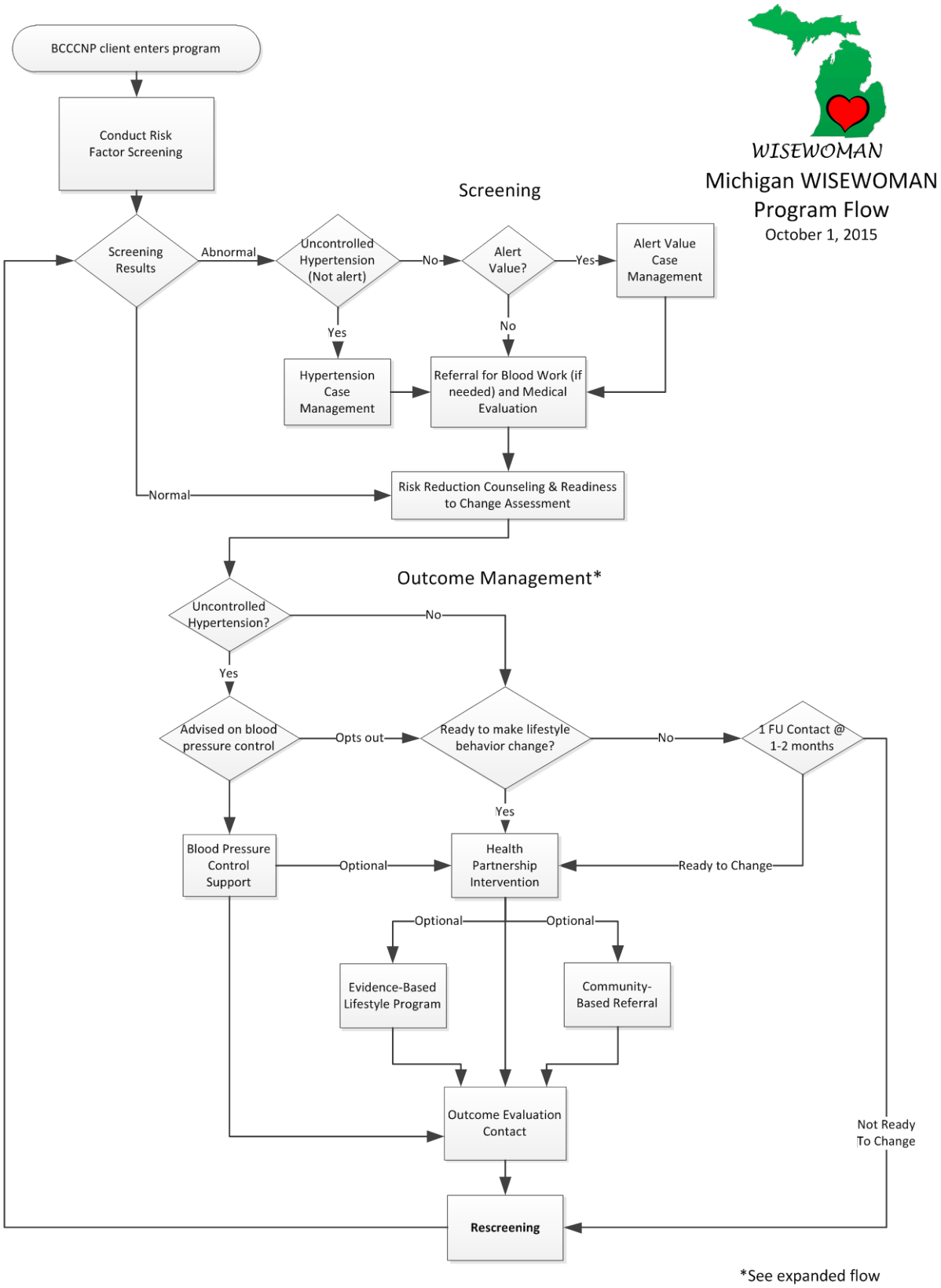
The Community Navigator will conduct an Outcome Evaluation Contact with the participant who is ready to make changes in order to assess her progress and to reinforce her chosen goal.

See Community Navigation Protocols for more information.

Rescreening

WISEWOMAN program participants who remain eligible for the program should have the opportunity to receive WISEWOMAN rescreening services 12 to 18 months after their previous screening.

See Rescreening Policy for more information.


WISEWOMAN
Michigan WISEWOMAN Program Flow
October 1, 2015
BCCCNP client enters program
Conduct Risk Factor Screening
Screening
Screening Results
Abnormal
Uncontrolled Hypertension (Not alert)
No
Alert Value?
Yes
Alert Value Case Management
Yes
No
Hypertension Case Management
Referral for Blood Work (if needed) and Medical Evaluation
Normal
Risk Reduction Counseling & Readiness to Change Assessment
Outcome Management*
Uncontrolled Hypertension?
No
Yes
Advised on blood pressure control
Opts out
Ready to make lifestyle behavior change?
No
1 FU Contact @ 1-2 months
Yes
Blood Pressure Control Support
Optional
Health Partnership Intervention
Ready to Change
Optional
Optional
Evidence-Based Lifestyle Program
Community-Based Referral
Outcome Evaluation Contact
Not Ready To Change
Rescreening
*See expanded flow

WISEWOMAN Program Flow
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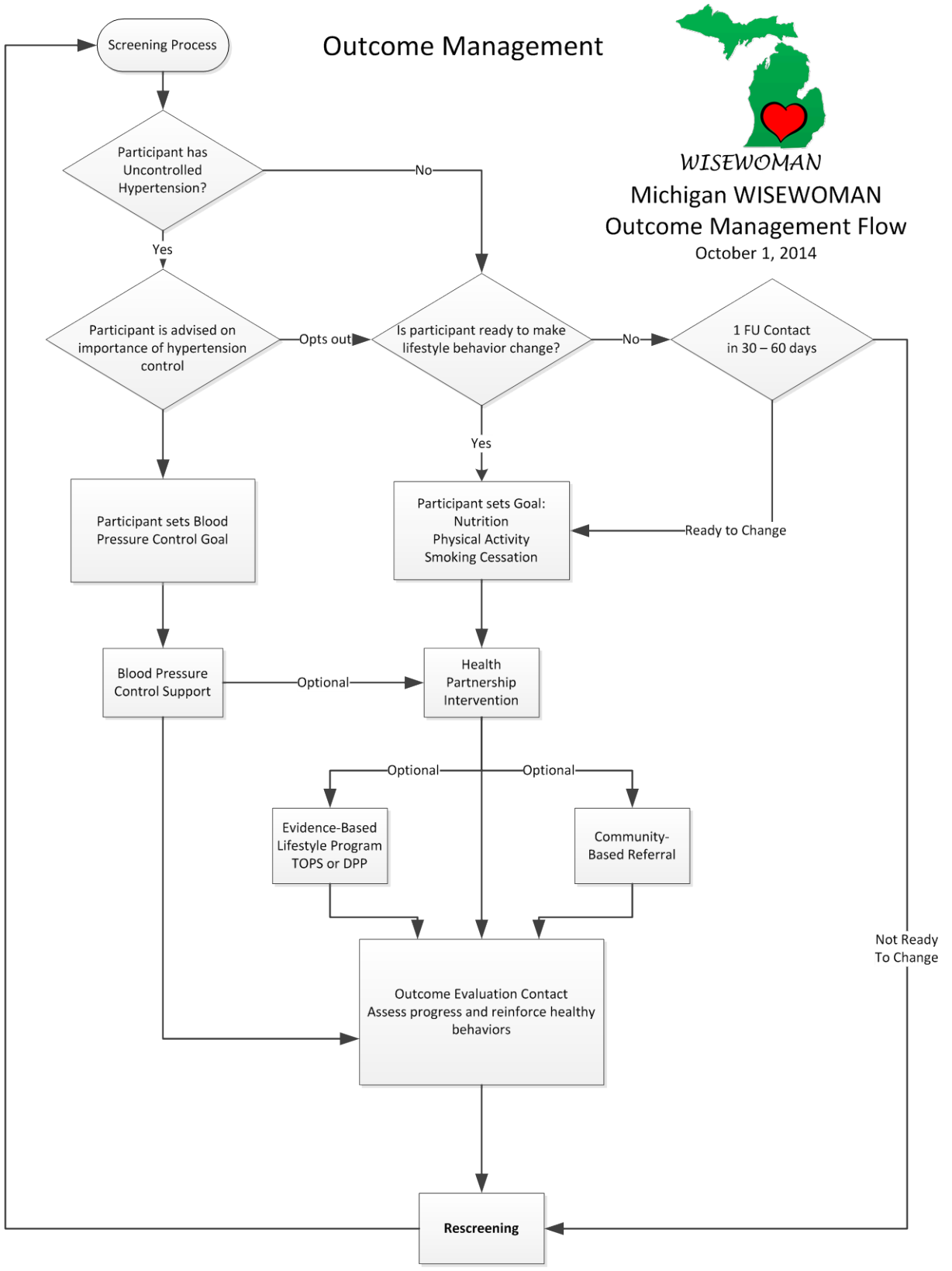


WISEWOMAN Non-Integrated Screening Office Visit Policy

Michigan WISEWOMAN requested and received permission from CDC to allow local agencies to conduct a limited number of non-integrated office visits subject to the Non-Integrated Office Visit Policy.

Non-Integrated Screening Office Visit Policy

- All women screened in the WISEWOMAN program **must** be currently enrolled in the BCCCNP
- No more than 50% of WISEWOMAN screening office visits can be non-integrated
- The local WISEWOMAN agency conducting the WISEWOMAN screening may bill for the non-integrated office visit
- Office visits will be billed using either established patient partial exam CPT codes (99211, 99212), or new patient partial exam codes (99201, 99202)

What is an Integrated Office Visit?

The WISEWOMAN Program is funded by the Centers for Disease Control and Prevention (CDC). The CDC requires WISEWOMAN screening to take place during the same office visit as Breast and Cervical Cancer Control Navigation Program (BCCCNP) services. This is known as an *integrated office visit*.

In the past, the majority of BCCCNP women received their cancer screening services through the program. That allowed the local WISEWOMAN agency to provide WISEWOMAN screening services to a subset of BCCCNP clients during an integrated office visit as required by the current CDC WISEWOMAN cooperative agreement.

When is a Non-Integrated Office Visit Allowed?

There are two circumstances when a Non-Integrated office visit is allowed:

1) A woman has an insurance plan with a large deductible ($1,000 or more). The insurance covers her mammogram and pap smear at no charge. If the cancer screening detects an abnormality, she has to pay all of her deductible before the insurance pays anything.

   If she is below 250% of poverty level, and she is not able to afford the diagnostic testing, she is eligible to receive diagnostic services through the BCCCNP. A woman who enters BCCCNP for diagnostic services is eligible for WISEWOMAN, but she will not have a breast and cervical screening office visit where WISEWOMAN services can be performed. This makes her eligible for a non-integrated office visit.

2) A woman is otherwise eligible for BCCCNP except she has Healthy Michigan Plan or some other form of insurance. However, she does not know how to access the breast and cervical cancer screening services provided by her insurance. The Michigan BCCCNP navigates the woman to those services according to BCCCNP protocol. She is now eligible for WISEWOMAN. If she receives her breast and cervical services from an outside provider, there will not be a breast and cervical screening office visit where WISEWOMAN services can be performed. This makes her eligible for a non-integrated office visit.

WISEWOMAN Program Performance Measure Policy
Fiscal Year 2016
(Effective Dates: October 1, 2015 to September 30, 2016)

Data Collection and Analysis

- **At least 95%** of participants have all screening and enrollment data. This includes all WISEWOMAN Questions, height, weight, two blood pressure readings, fasting status, cholesterol, HDL, and either fasting glucose or Hemoglobin A1C.
- **At least 95%** of participants who are ready to make changes receive an outcome evaluation contact during the appropriate time frame.

Environmental Approaches

- Organization is actively engaged with **at least 1** public or private partner organization to promote and support environmental changes for increased physical activity, access to healthy food choices, smoking cessation, or elimination of exposure to secondhand smoke.

Health Systems

- Organization screens **at least 95%** of budgeted caseload* without going over.
- **100%** of women screened receive risk reduction counseling, including appropriate referral to health coaching, community resources, or lifestyle programs.
- **At least 95%** of all participants with an alert screening value (Blood Pressure **>180** (systolic) **and/or >110** (diastolic) and/or Glucose <**50** or Glucose ≥ **250**) are seen for medical evaluation within one week of screening.
- **100%** of women with uncontrolled hypertension at screening receive hypertension case management.
- **At least 50%** of women who participate in blood pressure control are taking medication as prescribed at outcome evaluation contact.
- **At least 75%** of women who are not ready to make changes at screening receive one follow-up contact after screening.

Community-Clinical Linkages

- **At least 80%** of women who are referred to health coaching or an evidence-based lifestyle program participate in the program.
- **At least 60%** of women who participate in health coaching or an evidence-based lifestyle program complete the program.

***** In order to count toward caseload, a participant's data in MBCIS must include: date of birth; race and ethnicity; WISEWOMAN Questions 3-4, 6-7, 9-10, 13, 20-24, 26-28; height and weight; blood pressure; total cholesterol; and glucose.

WISEWOMAN Program Clinical Screening Procedures

Procedure For Measurement Of Blood Pressure

1. CHECK THE EQUIPMENT. Do not use if any problems are found.
   A. Look to see that the gauge - mercury meniscus or aneroid needle - is at zero. (Preferably, do not use an aneroid gauge with a stop-pin.)
   B. Check the cuff for any breaks in stitching or tears in the fabric.
   C. Check the rubber tubing for cracks or leaks, especially at connections.
   D. Be sure three sizes of cuffs are accessible (small, regular, large).
   E. Recommend 12-15 inch stethoscope tubing.

2. PLACE THE MANOMETER so it can be viewed straight on and within 15 inches of the viewer.

3. RIGHT ARM will be used when possible. Upper arm should be bare and unconstricted by clothing. (You should be able to get at least one finger under a rolled-up sleeve.)

4. SELECT THE APPROPRIATE SIZE CUFF. The bladder width should equal at least 40% of the circumference of the upper arm, and the length of the bladder should be 80% of the circumference of the arm, but no more than 100%.

5. PALPATE the location of the brachial artery (on the upper arm's inner aspect.)

6. POSITION the center of the cuff's bladder over the brachial artery.

7. APPLY THE CUFF evenly and snugly one-inch (2.5cm) above the antecubital fossa (bend of arm). CHECK SNUGNESS at both top and bottom of the cuff.

8. POSITION THE ARM so the cuff is at heart level. The arm should rest firmly supported on a table, slightly abducted and bent, with palm up.

9. For the first reading only, OBTAIN PALPATORY SYSTOLIC PRESSURE.
   A. Palpate the radial artery pulse.
   B. Inflate the cuff to the point where the pulse can no longer be felt.
   C. Slowly deflate the cuff, noting on the gauge the point where the pulse reappears/can again be felt. This is the estimated systolic pressure.

   Rapidly deflate the cuff. Wait at least 15-30 seconds before re-inflating the cuff to begin the first auscultatory measurement. (This allows good circulation to be reestablished.)

10. CALCULATE the maximum inflation level (MIL) by adding 30 mm Hg to the estimated systolic. (This figure will be utilized in Step #14.)

11. CHECK THE CLIENT'S POSITION. Legs should be uncrossed, feet resting firmly on the floor and the back supported while blood pressure is being measured. (Clients may need to be reminded to uncross their legs each time you are ready to take a blood pressure reading.)

12. INSERT the stethoscope earpieces, angled forward to fit snugly.

13. PLACE THE BELL OR THE DIAPHRAGM HEAD of the stethoscope lightly over brachial artery at the bend of the elbow, but with good skin contact. Avoid too much pressure, which can close off the vessel and distort the sounds, therefore altering the reading. (The bell head is preferred because it permits more accurate auscultation of the Korotkoff sounds than the diaphragm, especially in the

interpretation of diastolic readings.)

14. INFLATE the cuff as rapidly as possible to maximum inflation level (MIL), calculated in Step #10 (30 mm Hg above estimated systolic pressure).

15. DEFLATE THE CUFF SLOWLY and CONSISTENTLY at the rate of 2 mm per pulse beat. The rate of deflation should be slow enough to accurately evaluate the exact millimeter marking of the Korotkoff sounds. Once deflation has begun, never reinflate.

16. NOTE where the first sharp rhythmic sound appears in relation to the gauge's calibrations. This is the systolic pressure.

17. CONTINUE DEFLATION at the established rate. NOTE on the gauge where the last sound is heard. This is the diastolic pressure (5th Korotkoff phase) in adults.

18. CONTINUE DEFLATION for 10 mm Hg past the last sound. (This assures that the absence of sound is not a "skipped" beat but is the true end of the sound.) Then deflate the cuff rapidly and completely.

19. RECORD the readings to the nearest 2mm (round off upward). This means all readings taken with non-electronic equipment will be stated and written in even numbers.

20. MAKE NOTATIONS of cuff, arm and position only if there are variations from the standard procedure of seated, regular cuff, right arm and fifth Korotkoff phase.

21. Reporting for READINGS where examiner has questions:
    A. When an auscultatory gap is heard (at least 2 initial beats, then absence of regular beats), do not record the first disappearance of sound as the diastolic reading. The sound will soon return as decompression of the vessel continues. The sound will finally disappear, indicating true diastolic.
    B. When sounds are too soft to be certain of either systolic or diastolic readings, "discard" this reading. Institute augmentation procedures on the next attempt. Always inflate the cuff to the MIL as rapidly as possible.

AUGMENTATION PROCEDURES

Have the client raise their arm prior to inflation to drain the blood from forearm. Inflate the cuff rapidly and then have the client lower his/her arm to the standard position. Apply the stethoscope immediately and begin deflation.

or

After inflation, keep the valve closed and have the client clench fist 5-6 times. Then apply the stethoscope immediately and begin deflation.

REPEAT the measurement 30 seconds or more after the cuff is completely deflated. This allows for circulation to adequately return and permits a true reading.

NOTE: Mercury manometers are preferred because they are more accurate, easier to maintain and less likely to become decalibrated.

Source: (1) Michigan Department of Public Health and the Michigan Association for Local Public Health. *Promoting Cardiovascular Health in Michigan: Recommendations for Action*. pp 35-37, December 1991; (2) Perloff, Dorothea; Grim, Carlene; et.al..... "Human Blood Pressure Determination by Sphygmomanometry." AHA Medical/Scientific Statement: Special Report. *Circulation*. Vol. 88, No. 5, Part 1, November 1993. pp 2460-2470.

Procedure for Measuring Blood Pressure on Lower Arm

This procedure should **only be used if the upper arm is too large for a large adult cuff and an appropriate size cuff is not available**. This procedure is recommended only as a **last attempt** to get the best estimate of the blood pressure (BP) as possible.

The proportion of the bladder in the cuff to the lower arm should still meet the procedural guidelines outlined: the bladder width should be 40% and the bladder length should be 80% of the circumference of the lower arm.

Sometimes the diastolic reading may not be audible over the radial artery but the systolic at minimum could be recorded. Be sure you note that the BP was taken on the lower arm.

The procedure below is the same as the one used in the upper arm except for the changes noted in italics:

1. CHECK THE EQUIPMENT. Do not use if any problems are found.
   A. Look to see the gauge - mercury meniscus or aneroid needle is at zero. (Preferably, do not use an aneroid gauge with a stop-pin.)
   B. Check the cuff for any breaks in stitching or tears in the fabric.
   C. Check the rubber tubing for cracks or leaks, especially at connections
   D. Be sure three sizes of cuffs are accessible (small, regular, and adult large).
   E. Recommend 12-15 inch stethoscope tubing and bell/diaphragm stethoscope head.

2. PLACE THE MANOMETER so it can be viewed straight on and within 15 inches of the viewer.

3. RIGHT ARM will be used when possible. *Lower* arm should be bare and un-constricted by clothing. (You should be able to get at least one finger under a rolled up sleeve.)

4. SELECT THE APPROPRIATE SIZE CUFF. The bladder width should equal at least 40% of the circumference of the *lower* arm, and the length of the bladder should be 80% of the circumference of the arm, but no more than 100%. *Measure the circumference halfway between the wrist and elbow*.

5. PALPATE the location of the *radial* artery.

6. POSITION the center of the cuff's bladder over the *radial* artery.

7. APPLY THE CUFF evenly and snugly one-inch (2.5 cm) above the *radial artery* at the wrist. CHECK SNUGNESS at both the top and bottom of the cuff.

8. POSITION THE ARM so the cuff is at heart level. The *forearm* should *be* supported on a table, slightly abducted and bent, with palm up.

9. For the first reading only, OBTAIN ESTIMATED SYSTOLIC PRESSURE.
   A. Palpitate the radial artery pulse.
   B. Inflate the cuff to the point where the pulse can no longer be felt.
   C. Slowly deflate the cuff, noting on the gauge the point where the pulse reappears/can again be felt. This is the estimated systolic pressure.

D. Rapidly deflate the cuff. Wait at least 15-30 seconds before re-inflating the cuff to begin the first auscultatory measurement. (This allows good circulation to be reestablished.)

10. CALCULATE the maximum inflation level (MIL) by adding 30 mm Hg to the estimated systolic pressure. (This figure will be utilized in step #14)

11. CHECK THE CLIENT'S POSITION. Legs should be uncrossed, feet resting firmly on the floor and the back supported while blood pressure is being measured. (Clients may need to be reminded to uncross their legs each time you are ready to take a blood pressure measurement.)

12. INSERT the stethoscope earpieces, angled forward to fit snugly.

13. PLACE THE BELL OR THE *PEDIATRIC* DIAPHRAGM HEAD of the stethoscope lightly over the *radial* artery, but with good skin contact. Avoid to much pressure, which can close off the vessel and distort the sounds, therefore altering the reading. (The bell head is preferred because it permits more accurate auscultation of the Korotkoff sounds that the diaphragm, especially in the interpretation of diastolic readings.)

14. INFLATE the cuff as rapidly as possible to maximum inflation level (MIL), calculated in Step #10 (30 mm Hg above estimated systolic pressure.)

15. DEFLATE THE CUFF SLOWLY and CONSISTENTLY at the rate of 2 mm per pulse beat. The rate of deflation should be slow enough to accurately evaluate the exact millimeter marking of the Korotkoff sounds. Once deflation has begun, never re-inflate.

16. NOTE where the first sharp rhythmic sound appears in relation to the number or markings on the gauge. This is the systolic pressure.

17. CONTINUE DEFLATION at the established rate. NOTE on the gauge where the last sound is heard. This is the diastolic pressure (5^{th} Korotkoff phase) in adults.

18. CONTINUE DEFLATION for 10 mm Hg past the last sound. (This assures that the absence of sound is not a skipped beat but is the true end of the sound.) Then deflate the cuff rapidly and completely.

19. RECORD the readings to the nearest 2mm (round to an even number). This means all readings take with non-electronic equipment will be stated and written in even number.

20. MAKE NOTATIONS of cuff, arm and position only if there are variations from the standard procedure of seated, regular cuff, right arm and fifth Korotkoff phase. *Be sure to note lower arm used.*

21. Reporting for READINGS where examiner has questions:
    A. When an auscultatory gap is heard (at least 2 initial beats, then absence of regular beats), do not record the first disappearance of sound as the diastolic reading. The sound will soon return as record as decompression of the vessel continues. The sound will finally disappear, indicating true diastolic.
    B. When sounds are too soft to be certain of either systolic or diastolic readings, discard this reading. Institute augmentation procedures on the next attempt. Always inflate the cuff to the MIL as rapidly as possible.

AUGMENTATION PROCEDURES

Have the client raise the arm prior to inflation to drain the blood from forearm. Inflate the cuff rapidly and then have the client lower his/her arm to the standard position. Apply the stethoscope immediately and begin deflation.

or

After inflation, keep the valve closed and have the client open and close her/his fist 5-6 times. Then apply the stethoscope immediately and begin deflation.

22. REPEAT the measurement 30 seconds or more after the cuff is completely deflated. This allows for circulation to adequately return and permits a true reading.

Note: Use the same BP classification levels for high and normal cut off points.

Source (1) Michigan Department of Public Health and the Michigan Association for Local Public Health. *Promoting Cardiovascular Health in Michigan: Recommendation for* Action. pp 35-37, December 191; (2) Perloff Dorothea; Grim, Carlene; et.al... AHuman Blood Pressure Determination by Sphygmomanometry.@ AHA Medical/Scientific Statement: Special Report. *Circulation.* Vol. 88, No.5, Part 1, November 1993. Pp 2460-2470; (3) The Sixth Report of the Joint Committee on Detection, Evaluation and Treatment of _High Blood Pressure (NIH Publication No. 98-4080, November, 1997. (4) Consultation with Grim, Clarence and Carlene. December 22, 2000.

g:bplowerarm.12-00

CHOLESTECH® BLOOD COLLECTION BY FINGER PUNCTURE
FOR
CHOLESTEROL AND GLUCOSE

Purpose: To safely obtain a viable whole blood capillary specimen for processing in the Cholestech LDX System® maintaining the standards required by Occupational Health and Safety Administration (OSHA), Clinical Laboratories Improvement Amendments (CLIA'88), and clinical practices.

CLIA regulations are based on the test complexity, and are classified as waived, moderate complexity, or high complexity. Facilities performing only waived tests have no routine oversight or personnel requirements and are only required to obtain a Certificate of Waiver, pay fees and follow the manufacturer's requirements. Health Departments and other facilities must follow the requirements of the policies of their laboratory director.

I. Background and Exposure Control

a) Facilities providing services that could result in contact with human blood or other potentially infectious material must have an "OSHA-Bloodborne Pathogen Exposure Control Plan" (BPECP) outlining tasks, procedures, assigned job classifications according to exposure risk (Category A or B), engineering controls, universal precautions, and personal protective equipment (PPE) required to decrease the risk of their employees' exposure to any bloodborne pathogen.
b) Category A employees perform procedures or tasks conducted in routine situations as a condition of employment that could result in exposure to human blood or other infectious material. Employers must offer the Hepatitis B vaccine series, boosters, and antibody testing to Category A employees. If the employee initially declines, the employer must provide the vaccine if an employee changes their mind and is still in Category A.
c) Category A employees must be provided OSHA-approved lancets* and specific training as established in the Facility's BPECP on OSHA's standard "Occupation Exposure to Bloodborne Pathogens " before beginning to test and annually thereafter.

***OSHA Approved Lancets*
Authority: The Department of Consumer and Industry Services: Occupational Health Standards—Bloodborne Infectious Diseases by the authority conferred on the director of the department of consumer and industry services by: [sections 14 and 24 of 1974, PA 154, MCL 408.1014 and 408.1024, and Executive Reorganization Order Nos. 1996-1 and 1996-2, MCL 330.3101 and 4454.2001]
**** Category A, non-managerial, employees, annually, shall have direct input, documented in the "BBECP", into the identification, evaluation, and selection of effective engineering and work practice controls including commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure, including improved technology (self-retracting lancets, needleless systems, etc.)***

II. Exposure Avoidance

a) Universal precautions (a method of infection control that treats all human blood and other potentially infectious
b) material as capable of transmitting, HIV, HBV, and other bloodborne pathogens) must be followed.
c) Place sharps container close to the collection site and place contaminated lancet into the container immediately after use. Dispose of all blood collection materials and cassettes in a biohazard waste container immediately after use following the facility's BPECP. Wear intact

gloves at all times during the procedure, in addition to lab coat and other personal protective equipment as indicated.

d) Any blood spill should be cleaned immediately with a 10% bleach solution or other approved bloodborne pathogen disinfectant.
e) Materials for each client's specimen should be placed on a clean, non-permeable and absorbent surface such as a small waterproof towel.

III. Machine and Work Area Preparation

Work surface should be clean and sanitary, without direct heat or bright light, and at room temperature (68-86˚F)

Set-up machine according to the "*Cholestech User Manual®. Page 9, Getting Started".* Available online at: www.cholestech.com

IV. Materials and Equipment:

a) 10% bleach solution or other disinfectant approved for blood-borne pathogens
b) 70% isopropyl alcohol or alcohol swab
c) Cotton balls, or gauze
d) Blood lancets and/or lancet device for skin punctures
e) Capillary tubes and Micropipettes
f) Cholestech® LDX Machine Analyzer, test cassettes, Optics check cassette
g) Water-proof towels/drapes
h) Power source
i) Quality control serum vials (high and low) and recording records
j) Personal protective equipment
k) Sharps containers and biohazardous waste containers
l) Hand gel or sink
m) Band-aids (Optional)

V. Client Specimen Collection and Testing

Read the procedures in the Cholestech LDX User Manual® and Product Insert Instructions for testing patient samples.

a) Check signed consent for testing and HIPAA Privacy Statement if applicable. Identify the patient, and explain the procedure to them.
b) Assess the warmth/circulation of the patient's fingers and choose a site. The third or fourth (middle or ring) finger on the non-dominant hand is preferred for finger sticks. Do not use a finger with calluses and/or a wound. If improvement in circulation is needed, have the patient rub their hands together or hold below the level of their heart for a few minutes.
c) Choose a site that is on the side of the fingertip midway between the edge and midpoint of the fingertip. (see drawing)

d) Wash your hands before you put on your gloves. Hand disinfectant gels are acceptable unless the facility policies state otherwise.
e) Cleanse the client's finger with alcohol from a wipe or cotton ball for 15-30 seconds, rubbing vigorously. Wipe excess alcohol with sterile gauze let dry or it will sting and potentially make the reading inaccurate.

f) Using a sterile, OSHA-approved* blood lancet, make a deep enough puncture (1.5mm) to form a free-flowing drop of blood. A deep puncture will avoid needing to re-puncture.
g) To assure an accurate reading, squeeze the finger from the base moving to the top, DO NOT MILK the finger or allow air bubbles to collect in the capillary tube.
h) Hold the capillary tube horizontally by the end with the plunger. Insert the capillary tube tip in the drop of blood. The tube will fill by capillary action up to the black mark. Perform the filling of the tube within 10 seconds of the puncture to assure a good specimen.
i) If another drop of blood is needed and the same puncture site is viable, wipe the finger with gauze, and squeeze until a large drip of blood forms. If you can not obtain a large enough drop, choose another site, disinfect and re-puncture. It is not necessary to re-glove at this point if the gloves are intact.
j) Wipe off any excess blood and ask the patient to apply pressure to the puncture until the bleeding stops. Apply a band-aid to the site to prevent contamination.
k) Using the plunger, dispense the entire blood sample from the micropipette, into the cassette as soon as possible.
l) Once you have placed the sample into the cassette well, place the cassette in the drawer and press RUN immediately.
m) Dispose of lancet and capillary tube into the sharps container and other materials and into a biohazard waste container or as directed by the BPECP.
n) Remove gloves pulling one over the other, turning the contaminated side inside out.
o) Give the client the written result and counsel or send to the next station for counseling.
p) Put on a fresh pair of gloves for the next client.
q) At the end of the session, clean entire area and wipe down countertops with the 10% bleach solution or other designated disinfectant. Clean machine according to the manufacturer's instruction. Dispose of biohazardous materials container and sharps according to the facility's BPECP.

Analysis of Blood Sample

Follow manufacturer's instructions. *Cholestech User Manual® Testing Procedure".* Available online at: www.cholestech.com

Quality Control

Quality control practices assure that the system is working properly and giving dependable results. Good laboratory practice principles suggest that in addition to routine testing, (a-c below), external controls must be run if there is any question of the system integrity or operator technique, for example, if reagent storage or handling or when the machine operators have not performed a test in recent weeks.

a) Optics Check must be run on every day of testing before the first test is done.
b) Controls must be run each time a new lot of cassettes is opened.
c) Controls must be run anytime there is a question about the cassettes being stored properly.
d) The Cholestech LDX is a waived CLIA test so external proficiency tests are not required in the law; however, they are recommended and may be required by the laboratory director.
e) See facility policies for all lab related recording forms, corrective action plans, and other facility-specific requirements.

Refer to the Cholestech User Manual®. Quality Control, Available online at: www.cholestech.com

References:

- Cholestech ® Technical Service 1-800-733-0404
  Manufacturer's Website: www.cholestech.com
- Web-based MDCH Laboratory Procedure #RL.04.01
  http://www.michigan.gov/documents/RL_135815_7.04.01_Specimen_Collection_Blood_by_Finger_Puncture.doc
- OSHA-"Occupation Exposure to Bloodborne Pathogens" (29CFR 1910.1030)
- CMS CLIA Resource: http://www.cms.hhs.gov/clia/
- FDA CLIA Resource: http://www.fda.gov/cdrh/clia/
- HIPAA: http://www.hhs.gov/ocr/hipaa/
- MMWR-Recommendations and Reports Good Laboratory Practices for Waived Testing Sites [11/11/2005/Vol.54/No., RR-13]

WISEWOMAN Program Procedure
MDCH, Cardiovascular Health, Nutrition and Physical Activity Section 7/2007

Clinical Laboratory Improvement Amendments of 1988

General Program Description

Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988 establishing quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. A laboratory is defined as any facility which performs laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention, treatment of disease, or impairment of, or assessment of health. CLIA is user fee funded; therefore, all costs of administering the program must be covered by the regulated facilities, including certificate and survey costs.

The final CLIA regulations were published on February 28, 1992 and are based on the complexity of the test method; thus, the more complicated the test, the more stringent the requirements. Three categories of tests have been established: waived complexity, moderate complexity and high complexity. CLIA specifies quality standards for proficiency test (PT), patient test management, quality control, personnel qualifications and quality assurance for laboratories performing moderate and/or high complexity tests. Waived laboratories must enroll in CLIA, pay the applicable fee and follow manufacturers' instructions. Because problems in cytology laboratories were the impetus for CLIA, there are also specific cytology requirements.

The Centers for Medicare & Medicaid Services (CMS) is charged with the implementation of CLIA, including laboratory registration, fee collection, surveys, surveyor guidelines and training, enforcement, approvals of PT providers, accrediting organizations and exempt states. The Centers for Disease Control and Prevention (CDC) is responsible for the CLIA studies, convening the Clinical Laboratory Improvement Amendments Committee (CLIAC) and providing scientific and technical support/consultation to DHHS/CMS. The Food and Drug Administration is responsible for test categorization.

To enroll in the CLIA program, laboratories must first register by completing an application, paying fees, being surveyed, if applicable, and becoming certified. CLIA fees are based on the certificate requested by the laboratory (that is, waived, PPM, accreditation, or compliance) and, for moderate and high complexity laboratories, the annual volume and types of testing performed. Waived and PPM laboratories may apply directly for their certificate as they aren't subject to routine inspections. Those laboratories that must be surveyed routinely; i.e., those performing moderate and/or high complexity testing, can choose whether they wish to be surveyed by CMS or by a private accrediting organization. The CMS survey process is outcome oriented and utilizes a quality assurance focus and an educational approach to assess compliance.

CLIA and the WISEWOMAN Program

The Cholestech LDX System is in the **waived category**. All users of waived tests are required to register with CMS and obtain a **CLIA Certificate of Waiver**. Many local health departments in Michigan are part of the Regional Lab System that the Michigan Department of Community Health oversees. If the cholesterol and glucose screening are to take place at a health department that is part of the Regional Lab System, it is important to confirm that a suitable CLIA certificate has been obtained. If the cholesterol and glucose screening are to take place through an agency other than a local health department, the application for the Certificate of waiver can be obtained through the CMS website, **http://www.cms.hhs.gov/clia/ .**

Hypertension Case Management

- If a program participant has uncontrolled hypertension, she will receive Hypertension Case Management (Less than 20% of program participants should have values in the non-alert hypertension range)
- A participant is determined to have uncontrolled hypertension if:
    - Her average blood pressure is 140-180 (systolic) and/or 90 -110 (diastolic) **AND**
    - She answers "Yes" to question 6 and/or 7 of WISEWOMAN Questions indicating she has been told she has hypertension or she takes medicine to lower her blood pressure.
- For each woman who qualifies for Hypertension Case Management
    - Explain the importance of keeping her hypertension under control
    - Explain the importance of taking her medication as prescribed and encourage her to set blood pressure control as a priority area
    - Strongly encourage her to attend the medical evaluation
    - Follow up with the participant to determine whether or not she attended the medical evaluation
    - Complete a WISEWOMAN Case Management Form
    - Fax the completed form to Michigan Department of Health and Human Services (MDHHS) within five business days after the Resolution Date (MDHHS staff will enter the appropriate data and authorizations into the MBCIS WISEWOMAN module)
- For a Participant Status of *Complete*, the case manager must:
    - Contact the program participant to ensure she attended the medical evaluation
    - Record the date of the medical evaluation as the Resolution Date on the Case Management form
- For a Participant Status of *Refused referral*, the case manager must:
    - Record the date the participant refused as the Resolution Date on the Case Management form
    - Document the client's reason for refusal on the Case Management form
- For a Participant Status of *Lost to Follow-up*, the case manager must:
    - Document three unsuccessful attempts to contact the participant by phone
    - Document the date a letter was sent to the participant
    - If the participant does not respond to the letter within 14 days, she will be considered Lost to Follow-up
    - Record the date the participant was considered Lost to Follow-up as the Resolution Date on the Case Management form

- Hypertension Case Management concludes when the program participant attends the medical evaluation, refuses the referral, or is determined to be lost to follow-up
- Once Hypertension Case Management concludes, the program participant will receive community navigation services (The Community Navigator should encourage the participant to follow-through with medical care and indicated treatment)
- The organization may bill once during each cycle for reimbursement of Hypertension Case Management services provided to an eligible program participant

Alert Value Case Management

- If a program participant's blood pressure and/or glucose measurements fall into the alert range, she will receive Alert Value Case Management (Less than 3% of program participants will have values in the alert range.)
  Alert values are:
    - Average Blood Pressure **greater than 180** (systolic) **and/or greater than 110** (diastolic)
    - Glucose **less than or equal to 50 or greater than or equal to 250** (fasting or casual) **and no history of diabetes**
- For each woman who qualifies for Alert Value Case Management
    - Set up an appointment for medical evaluation within seven days from the date of the screening
    - Complete a WISEWOMAN Case Management Form
    - Fax the completed form to MDHHS within five business days after the Resolution Date (MDHHS staff will enter the appropriate data and authorizations into the MBCIS WISEWOMAN module)
- For a Participant Status of *Complete*, the case manager must:
    - Assist the program participant with addressing barriers to ensure she attends a medical evaluation
    - If the participant attends the medical evaluation after seven days, the case manager must document the reason for not meeting the deadline
    - Obtain information about the treatment prescribed and document it on the Case Management form
    - Record the date of the medical evaluation as the Resolution Date on the Case Management form
- For a Participant Status of *Refused referral*, the case manager must:
    - Record the date the participant refused as the Resolution Date on the Case Management form
    - Document the client's reason for refusal on the Case Management form

- For a Participant Status of *Lost to Follow-up*, the case manager must:
    - Document three unsuccessful attempts to contact the participant by phone
    - Document the date a letter was sent to the participant
    - If the participant does not respond to the letter within 14 days, she will be considered Lost to Follow-up
    - Record the date the participant was considered Lost to Follow-up as the Resolution Date on the Case Management form
- Alert Value Case Management concludes when the program participant attends the medical evaluation, refuses the referral, or is determined to be lost to follow-up
- Once Alert Value Case Management concludes, the program participant will receive community navigation services (The Community Navigator should encourage the participant to follow-through with medical care and indicated treatment)
- The program participant receiving Alert Value Case Management should be encouraged to set blood pressure control or blood sugar control as a priority area
- The organization may bill once during each cycle for reimbursement of Alert Value Case Management services provided to an eligible program participant

Body Mass Index

- **Obese:** BMI ≥30 Consider as risk factor for CVD.
  - No referral for Medical Evaluation
- **Overweight:** BMI 25.0-29.9
  - No referral for Medical Evaluation
- **Normal:** BMI 18.5-24.9
  - No referral for Medical Evaluation
- **Underweight**: BMI <18.5
  - No referral for Medical Evaluation

Blood Pressure Screening

Agency staff conducting the Blood Pressure Screening must follow the Procedures for Measurement of Blood Pressure and Procedure for Measuring Blood Pressure on Lower Arm included in the WISEWOMAN Program Clinical Screening Procedures.

- **Alert:** >180 (systolic) **and/or** >110 (diastolic) (Alert Value Case Management)
  - Refer for Medical Evaluation – Participant should be seen **immediately or within 1 week** depending on clinical situation and complications
  - Provide Blood Pressure Control Support
- **Stage 2 Hypertension:** 160-180 (systolic) **and/or** 100-110 (diastolic) (Hypertension Case Management if uncontrolled hypertension[1])
  - Refer for Medical Evaluation
  - Refer to Blood Pressure Control Support
- **Stage 1 Hypertension:** 140-159 (systolic) **and/or** 90-99 (diastolic) (Hypertension Case Management if uncontrolled hypertension[1])
  - Refer for Medical Evaluation
  - Refer to Blood Pressure Control Support
- **Prehypertension:** 120-139 (systolic) **and/or** 80-89 (diastolic)
  - No referral for Medical Evaluation
- **Normal:** <120 (systolic) **and** <80 (diastolic)
  - No referral for Medical Evaluation

Cholesterol and Glucose Screening

1. Screening for Total and HDL Cholesterol and Fasting Glucose must be done using a Cholestech LDX, for immediate receipt of results.

2. Agency staff conducting the Cholesterol and Glucose Screening must follow the Cholestech® Blood Collection By Finger Puncture For Cholesterol and Glucose included in the WISEWOMAN Program Clinical Screening Procedures.

[1] A participant is determined to have uncontrolled hypertension if her average blood pressure is 140-180 (systolic) and/or 90 -110 (diastolic) **AND** she answered "Yes" to question 6 and/or 7 of WISEWOMAN Questions indicating a history of hypertension or of taking BP meds.

3. Agency staff responsible for maintaining the Cholestech® LDX Analyzer must follow the Quality Control procedures outlined in the WISEWOMAN Program Clinical Screening Procedures

4. Handling error messages or "out of range" values when using the Cholestech machine.
   a. If you receive an error message saying, "Reaction Did Not Occur," repeat the test with a new cassette and a new finger stick sample. If the message reappears, refer the participant for a fasting lipid panel and/or a fasting glucose.
   b. Out of range values:
      i. Total Cholesterol <100 or >500 – Refer for a fasting lipid panel
      ii. HDL <15 or >100 – Refer for a fasting lipid panel
      iii. Glucose <50 or >500 – Refer for a fasting plasma glucose
   c. When entering the Screening Results in the WISEWOMAN module of MBCIS, leave the results that you did not obtain blank. Put a note in the Screening Notes saying "Unable to Obtain Cholesterol/HDL/Glucose Results. Referred for fasting lipid panel." Send an email to RobertsR6@michigan.gov with ONLY the MBCIS number of the participant (no personal identifiers) and a note. MDHHS will authorize the service.

Total Cholesterol

- **High:** ≥ 240 mg/dL
  - Refer for Fasting Lipid Profile and Medical Evaluation **if not currently being treated for high cholesterol**
- **Borderline High:** 200-239 mg/dL
  - Refer for Fasting Lipid Profile **if not currently being treated for high cholesterol**
  - If LDL is from fasting lipid profile is ≥ 160, refer for Medical Evaluation
- **Normal:** <200 mg/dL
  - No referral for Fasting Lipid Profile or Medical Evaluation

HDL Cholesterol

- **Undesirable:** <40 mg/dL
  - Refer for Fasting Lipid Profile **if not currently being treated for high cholesterol**
  - If LDL from fasting lipid profile is ≥ 160, refer for Medical Evaluation
- **Desirable:** 40-59 mg/dL
  - No referral for Medical Evaluation
- **Very Desirable:** ≥60 mg/dL
  - No referral for Medical Evaluation

NOTE: CDC requires either a fasting glucose or A1c reading for every participant in order for her to count toward caseload. Refer to the Fasting Glucose & Hemoglobin A1c Protocol for your local WISEWOMAN agency to determine how to handle participants with no history of diabetes who are not fasting when they come in to be screened.

Glucose

- **Alert:** <50 **or** ≥250 mg/dL Fasting or Casual **and no history of diabetes** (Alert Value Case Management)
    - Follow-up Fasting Plasma Glucose and Medical Evaluation within **1 week**
    - Refer to Diabetes Self-management Education
- **Diabetes:** >125 mg/dL Fasting OR >200 mg/dL Casual
    - Refer for Follow-up Fasting Plasma Glucose and Medical Evaluation **if no history of diabetes**
    - Refer to Diabetes Self-Management Education
- **Pre-diabetes:** 100-125 mg/dL Fasting
    - No referral for Follow-up Fasting Plasma Glucose or Medical Evaluation
    - Refer to Diabetes Prevention Program **if no history of diabetes**
- **Desirable:** 70-100 mg/dL Fasting
    - No referral for Follow-up Fasting Plasma Glucose or Medical Evaluation

A1c

Participants with a history of diabetes should receive an A1c analysis using the Alere Afinion® Analyzer.

- **Elevated**: > 7%
    - Refer to provider treating diabetes to discuss glucose control
    - If not currently seeing a provider, refer for Medical Evaluation
- **Desirable:** ≤ 7%
    - No referral for Medical Evaluation

Participants with no history of diabetes may receive an A1c analysis **if they are not fasting** when they come in to be screened. The blood sample for the A1c analysis must be obtained through a venous blood draw, and the sample must be sent to a laboratory for analysis. **Do not use** the Alere Afinion® Analyzer for participants with **no history of diabetes**.
Categories and protocols based on the laboratory's A1c analysis:

- **Diabetes:** ≥ 6.5%
    - Refer for Medical Evaluation
    - Refer to Diabetes Self-Management Education
- **Pre-diabetes:** 5.7% - 6.4%
    - No referral for Medical Evaluation
    - Refer to Diabetes Prevention Program
- **Desirable:** < 5.7%
    - No referral for Medical Evaluation

Participant Readiness to Change

- **Participant is not ready to make changes**
  - No referrals to community resources required
- **Participant is ready to make changes**
  - Conduct Expanded Health Coaching
    - Includes one-on-one goal setting and follow-up contacts
    - May refer to an evidence-based lifestyle program to support goal
      - **Nutrition/Weight Loss:** Taking Off Pounds Sensibly (TOPS)
      - **Physical Activity:** Enhance Fitness
      - **Tobacco Cessation:** MDHHS Tobacco Quitline
    - May refer to community-based program to support goal
      - Supplemental Nutrition Assistance Program Education (SNAP-Ed)
      - Walking group
      - Michigan State University Extension (MSUE) Nutrition Programming
      - YMCA
      - Other community-based programs identified in the Community Scan

Community Scan

The Community Navigator will conduct a community scan of each community where WISEWOMAN is implemented. Community scans identify resources such as clinics, support groups, and programs able to help participants make healthy behavior changes to prevent or delay the onset of chronic conditions or to manage existing chronic conditions.

Risk Reduction Counseling

Each participant will receive risk reduction counseling at the time of screening using the WISEWOMAN ***My Health Information*** pamphlet geared to low or marginal literacy readers. The pamphlet defines and identifies the participant's BMI, blood pressure, total cholesterol, HDL cholesterol, glucose and other identified risk factors.

During the risk reduction counseling, the Community Navigator will:

- Assess the participant's current risk factors by reviewing the My Health Information pamphlet with the participant.
- Advise the participant about the meaning of her risk factors and the importance of taking small steps toward better health.

Outcome Management

Readiness to Change

The Community Navigator will determine the participant's readiness to make lifestyle changes based on the ***Readiness and Confidence Ruler*** and application of Stages of Change theory.

A participant should be at least a 7 on both the readiness and confidence ruler in order to set a goal or small step. For participants less than a 7 on either scale the Community Navigator should focus on identifying what it would take for them to be a 7 on the readiness and confidence ruler and addressing those factors.

Not Ready to Make Change

For participants who are not ready to make changes, the Community Navigator will:

- Approach the client using good Motivational Interviewing techniques
- Encourage the participant to identify a small step toward better health
- Provide the participant with health education information related to her risk factors and information about community resources that can assist her with her small step toward better health
- Contact the participant 30 days after her risk reduction counseling session to see if she is ready to make a healthy lifestyle change

Ready to Make Change

For participants who are ready to make changes the Community Navigator will:

- Guide the participant through the Healthy Lifestyle Goal Development (see below) using the ***Participant Agreement*** form and the Referral Process (see below).

Healthy Lifestyle Goal Development

For participants who are ready to make a change the Community Navigator will:

- Approach the participant using good Motivational Interviewing techniques
- Encourage the participant to identify one priority area. The priority areas include:
    - Blood pressure control for women with uncontrolled hypertension
    - Nutrition
    - Physical activity
    - Smoking cessation

  Participants with uncontrolled hypertension should be encouraged to set blood pressure control as their priority area. Participants can opt out or select another priority area if they choose, but only after the Community Navigator has encouraged and emphasized the importance of medication adherence.
- Work with the participant to develop a goal/small step related to her chosen priority area using the information from the WISEWOMAN ***Health Intake*** forms.
- Encourage the participant to focus on developing a goal she is interested in achieving
- Spend at least 30 minutes face-to-face, with the participant, developing a goal and completing the ***Participant Agreement*** form

Health Coaching

For participants who are ready to make changes the Community Navigator will:

- Make regular contact with the participant to encourage success with her lifestyle change goal
- The first contact should take place within one to two weeks after the participant sets her goal.
- Document each contact using the ***WISEWOMAN Contact Form***
- Provide assistance, as appropriate, to help the participant overcome barriers to successfully reaching her goal
- Help the participant develop a new goal as she reaches and feels comfortable with her previous goal
- Provide additional educational materials and referrals to appropriate community resources related to her lifestyle behavior goal (i.e., nutrition, physical activity and smoking cessation)
- Make promotional contacts, such as calling a participant to tell her about Market Fresh coupons (**Only participants who are ready to make change and who have set a goal/small step will be eligible for Market Fresh coupons)**

Blood Pressure Control

Participants with uncontrolled hypertension should be encouraged to set blood pressure control as a priority area. Use the ***Taking Control of My Blood Pressure*** list to help the

participant set a goal that will help her get control of her blood pressure. The goal should be something she wants to do and believes she can accomplish.
See Blood Pressure Control Protocol for more information.

Referrals

For participants who are ready to make change the Community Navigator will:

- Assist participant in identifying and connecting with community resources and programs to support her in being successful at achieving her goal
- Provide participant with health education information to support her efforts at behavior change
- Refer the participant to the Michigan State University Extension Supplemental Nutrition Assistance Program – Education (SNAP-Ed)

WISEWOMAN will be able to pay for some fees related to a woman's participation in certain evidence-based lifestyle programs:

- Diabetes Prevention Program (DPP) – The DPP is a program for women identified with pre-diabetes to help prevent or delay the onset of type 2 diabetes. It includes 16 weekly classes and monthly follow-up for eight months
  See Diabetes Prevention Program Referral Protocol for more information.
- Take Off Pounds Sensibly (TOPS) – TOPS is a weight loss support and wellness education program based in the community.
  See Take Off Pounds Sensibly (TOPS) Referral Protocol for more information

Outcome Evaluation Contact

The outcome evaluation contact is required for participants who are ready to make change and have established a small step/goal. The purpose of the contact is to assess her progress and reinforce her goal.

For participants who only participate in health coaching or blood pressure control, the Community Navigator will conduct an outcome evaluation contact with the participant six to eight months after screening.

- When feasible, the outcome evaluation contact will be face-to-face with the participant to assess biometric measurements and/or lifestyle changes directly related to her goal, such as weight, blood pressure, physical activity, nutrition habits, etc.
- If a face-to-face contact is not possible, the outcome evaluation contact may take place by phone.

For participants who participate in an evidence-based or community-based lifestyle program, the Community Navigator will track when the participant completes the program and will:

- Immediately follow up with the program to determine attendance, graduation, and outcomes documented by the program
- When feasible, conduct a face-to-face outcome evaluation contact with the participant to determine biometric measurements and/or lifestyle changes directly related to the program, such as weight, blood pressure, physical activity, nutrition habits, etc.

- If a face-to-face contact is not possible, the outcome evaluation contact may take place by phone.

Navigation Contacts (tracking attendance/adherence/outcomes)
For participants who are ready to make change and are referred to an evidence-based or community-based lifestyle program the Community Navigator will:

- Work with programs to establish a mechanism for tracking a participant's attendance and completion of the program
- Use the ***WISEWOMAN Contact Form*** to track the participants attendance at programs where they have been referred

Developing Community-Based Programs to Support Behavior Change

All WISEWOMAN participants should have the opportunity to participate in programs to support their goals (e.g., smoking cessation, nutrition and physical activity). Some examples include cooking classes, community gardens, gardening classes, and walking clubs.

WISEWOMAN participants should be referred to appropriate free/low cost community programs to support identified goals. In the absence of local community programming, agencies are encouraged to work with community partners to develop programming to meet the WISEWOMAN participant's health needs and those of other community members.

Rewards

- Rewards such as Market Fresh coupons are only provided to participants who are ready to make change and have set a goal.
- Rewards provided by the Michigan Department of Health and Human Services (MDHHS) may be used to motivate program participants to make healthy lifestyle changes and assist with successful goal attainment. Agencies can determine how to use the rewards to best meet the needs of program participants.

Tracking and Quality Improvement

- Local WISEWOMAN program staff will develop and maintain a tracking system to ensure each program participant receives an appropriate number of health coaching contacts according to her motivation
- MDHHS will provide agencies with a ***Participant Contact Information*** report at the beginning of each month listing all active participants and the number of contacts they have received. This report should be used in conjunction with the agency's tracking system
- Community Navigators will participate in the WISEWOMAN Quality Improvement Process by:
    - Reviewing quality improvement reports at least monthly
    - Participating in quarterly quality improvement conference calls with MDHHS staff

Training and Professional Development

All local WISEWOMAN program Community Navigators will:

1) Be trained by WISEWOMAN staff at MDHHS. Training will consist of three parts:

   Initial Training
   - An overview of the WISEWOMAN program
   - Chronic disease risk factor screening
   - The Initial Training is available online at: http://breeze.mdch.train.org/p21diijvlqq/

   Community Navigator Training
   - Concepts of Motivational Interviewing
   - Elements of the Community Navigator role
   - The Community Navigator Training is offered monthly. The schedule is available at: http://bit.ly/wwtraining

   Follow-up Training
   - Takes place 4 – 6 weeks after the Initial Training
   - Focuses on skills needed to conduct effective health coaching and community resource development
   - The Follow-Up Training is offered monthly. The schedule is available at: http://bit.ly/wwtraining

2) Be trained in Motivational Interviewing. MDHHS will make Motivational Interviewing Training available at least once per year.

3) Maintain regular and timely communication with the MDHHS Navigation Specialist. This will allow the Navigation Specialist to provide the Community Navigators with new information related to health coaching, community resource development and to assess the changing needs of the Community Navigator.

4) Take part in training and professional development provided by MDHHS. These include:
   a. WISEWOMAN Annual Meeting
   b. Conference calls, such as quarterly Quality Improvement calls
   c. Special trainings provided by MDHHS
   d. Motivational Interviewing videos on WISEWOMAN website

5) Attend the quarterly Navigation Networking calls provided by MDHHS WISEWOMAN staff.

6) Take part in other training and professional development opportunities throughout the year. Community Navigators will keep track of the training and professional development they take part in and report them to MDHHS at the end of each fiscal year using the ***Continuing Education Tracking*** form.

WISEWOMAN Program
Blood Pressure Control Protocol

Uncontrolled Hypertension

A participant has uncontrolled hypertension if:

- Her average blood pressure at screening is 140-180 (systolic) and/or 90 -110 (diastolic) **AND**
- She answers "Yes" to question 6 and/or 7 of WISEWOMAN Health Intake Questions indicating she has been told she has hypertension and/or she takes medicine to lower her blood pressure.

According to the Centers for Disease Control and Prevention, the key elements a woman needs to effectively manage her hypertension are:

1. Being an informed, activated patient working in a productive relationship with a prepared and proactive health care team.
2. Access and adherence to medications or other treatments prescribed.
3. Lifestyle modification: Avoiding tobacco, limiting sodium, eating a healthy diet, maintaining a healthy weight, getting regular physical activity, managing stress, and moderating alcohol consumption.

If a program participant has uncontrolled hypertension, encourage her to work on getting her blood pressure under control.

Medication Adherence

Taking medication as prescribed is sometimes the only way for a participant to keep her blood pressure under control. That is why a woman who is working on controlling her blood pressure needs to do something related to medication adherence.

Review the ***WISEWOMAN Health Intake Questions*** to determine whether the participant takes medication to lower her blood pressure.

- If the participant takes medication, complete the ***Medication Adherence Questionnaire for Hypertension*** with the participant.
    - Identify the participant's barrier(s) to medication adherence
        - Behavioral – 1, 1a-1b, 5
        - Clinical – 2, 2a-2c, 2f, 3
        - Financial – 2d-2e, 4
- If the participant does not take medication, complete the ***Self-Efficacy For Appropriate Medication Use Scale.***
    - Determine the participant's potential barrier(s) to medication adherence
        - Behavioral – Questions 1-4, 6-8, and 11
        - Clinical – Questions 5, 9-10, and 12-14
        - Financial – Questions 15-16

Complete the Participant Agreement

Use the ***Taking Control of My Blood Pressure*** list to help the participant set a goal that will help her get control of her blood pressure. The goal should be something she wants to do and believes she can accomplish.

<u>Take my medicine the way the doctor prescribed it</u>

- Medication Adherence
    - Behavioral barriers and examples of ways to address barriers
        - Forgets to take medication
            - Use a pill reminder
            - Sign up for daily text alerts
        - Forgets to order refills
            - Set up automatic prescription renewal
        - Does not want to take medication
            - Provide education about the importance of blood pressure medication and how it can help
    - Clinical barriers and examples of ways to address barriers
        - Has questions about how to take medication or has concerns about medication safety
            - Refer to pharmacist or doctor to address questions or concerns
        - Stops taking medication when feeling better or because of side effects
            - Provide education about importance of continuing to use medication as prescribed
    - Financial barriers and examples of ways to address barriers
        - Can't afford medication
            - Enroll in prescription assistance program
        - Uses multiple pharmacies to get lowest prices
            - Enroll in prescription assistance program
            - Encourage participant to consolidate prescriptions at one pharmacy
        - Can't get medication (logistical issues such as transportation)
            - Set up home delivery of medications (if available)
            - Help with logistical issues
- *Pharmacy-based medication adherence support*
    - Contact local pharmacies to determine their capacity to provide medication adherence support to WISEWOMAN participants
    - Discuss Million Hearts Team Up Pressure Down resources with pharmacists http://millionhearts.hhs.gov/resources/teamuppressuredown.html

<u>Reduce Stress</u>

- Show the participant the resources listed under Stress Management on the Community Scan. Help her get connected with one of those resources.

Aim for a Healthy Weight

- Talk to the participant about the TOPS program. Give her information about local TOPS chapters or other weight management options listed in the Community Scan.

Get more physical activity

- Help guide the participant to set up small steps that will eventually help her reach 30 minutes of physical activity at least 5 days a week.
- Provide resources from the Community Scan.

Limit alcohol

- Drinking alcohol can raise your blood pressure. If you are going to drink, do not have more than one drink per day.
- Provide substance abuse resources from the Community Scan if the participant is interested.

Avoid tobacco

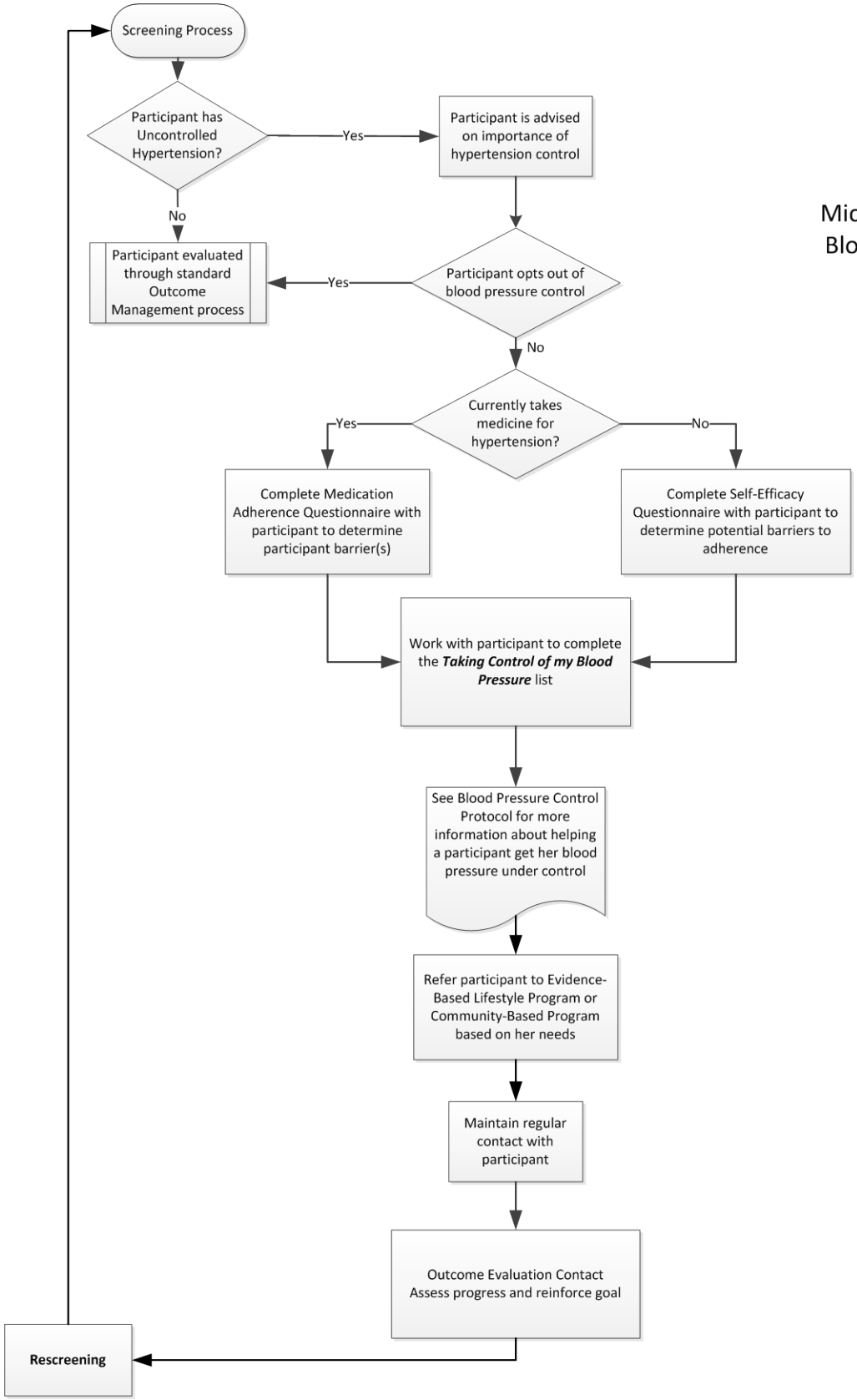
- Use the Michigan Tobacco Quitline fax referral form if the paraticipant is ready to quit smoking, or refer to other tobacco cessation resources listed in the Community Scan.
- Provide information about second-hand smoke if the participant does not smoke but is exposed to second-hand smoke.

Monitor my blood pressure at home or at the pharmacy

- Provide the participant with a WISEWOMAN blood pressure tracker and explain how to use it.

Watch what I eat

- Talk to the participant about how each of the options can help her get her blood pressure under control.
    - Sodium is a mineral your body needs for muscle contractions, nerve transmissions and staying hydrated. However, too much sodium can raise your blood pressure.
    - Americans get most of their sodium through processed foods. Processed foods are anything that comes in a package, such as potato chips, cookies, and crackers.
    - The DASH diet has been shown to lower blood pressure. You can find information about the diet at http://dashdiet.org/
    - When you cook your own meals at home you can control the amount of salt you eat, and you can cook with fruits and vegetables for a healthier meal.
- Provide information from the Community Scan about free or low cost nutrition programs, such as SNAP-Ed through your local Michigan State University Extension office.



WISEWOMAN
Michigan WISEWOMAN Blood Pressure Control Process Flow
September 5, 2014

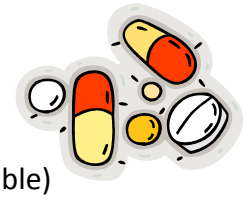
Taking Control of My Blood Pressure

Today, you were identified with uncontrolled hypertension. That means someone told you that your blood pressure was high in the past, and it is high today. Keeping your blood pressure under control is one of the most important things you can do to keep from having a heart attack or stroke.

How are you going to take control of <u>your</u> blood pressure?

☑ <u>Take my medicine the way the doctor prescribed it</u>

- ❑ Visit your doctor regularly to review your treatment and change medicines if needed
- ❑ Use a pill reminder
- ❑ Set up text, email, or phone call reminders
- ❑ Apply for prescription assistance
- ❑ Set up mail delivery of medicines (if available)
- ❑ Set up my prescriptions to renew automatically (if available)
- ❑ Talk to my pharmacist or my doctor about questions or concerns I have



❑ <u>Reduce stress</u>

- ❑ Learn and practice deep breathing exercises
- ❑ Do yoga
- ❑ Meditate

❑ <u>Aim for a healthy weight</u>

- ❑ Join the TOPS program
- ❑ Keep my waist measurement below 35 inches

❑ <u>Get more physical activity</u>

- ❑ Work up to least 30 minutes of physical activity a day at least 5 days a week
- ❑ Join a walking club

❑ <u>Limit alcohol</u>

- ❑ Drink no more than one alcohol drink per day
- ❑ Talk to your health coach about substance abuse help

❑ <u>Avoid tobacco</u>

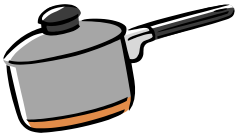
- ❑ Use the Michigan Tobacco Quitline to quit smoking
- ❑ Stay away from second-hand smoke

❑ <u>Monitor my blood pressure at home or at the pharmacy</u>

- ❑ Write down the results
- ❑ Share the results with my doctor

❑ <u>Watch what I eat</u>

- ❑ Cut back on sodium (salt)
- ❑ Eat less processed foods
- ❑ Follow the DASH Diet – (Dietary Approach to Stop Hypertension)
- ❑ Cook more meals at home



WISEWOMAN Program
Take Off Pounds Sensibly (TOPS) Referral Protocol

Establish Relationship with local TOPS Chapter(s)

When completing the Community Scan, identify the Take Off Pounds Sensibly (TOPS) Club chapters in the community. Information about TOPS locations is available at: http://www.tops.org/

The Community Navigator should contact the TOPS Club Chapter to establish a relationship. The local TOPS Club Chapter and Community Navigator will need to develop a feedback mechanism to get information about the participant's:

- Attendance
- Weight changes

TOPS Club Referral

A program participant may be referred to TOPS Club if she meets all of the following criteria:

- Has a BMI ≥25
- Indicates a readiness to change
- Has local access to TOPS Club Chapter meetings
- Has attended one local meeting and agrees TOPS Club is an appropriate option
- Commits to attending at least six local chapter meetings each three month period for the first six months

The Community Navigator will:

- Work with the participant to complete the Participant Agreement and set a weight loss goal
- Work with the participant to complete the WISEWOMAN TOPS Membership Agreement
- Provide the participant with a list of local TOPS Club chapters
- Determine eligibility based on the criteria listed above
- Maintain contact with the participant to encourage her to attend meetings
    - If she has trouble attending meetings, discuss barriers to participation
- Conduct Outcome Evaluation Contact with the participant after she has attended TOPS Club meetings for six months

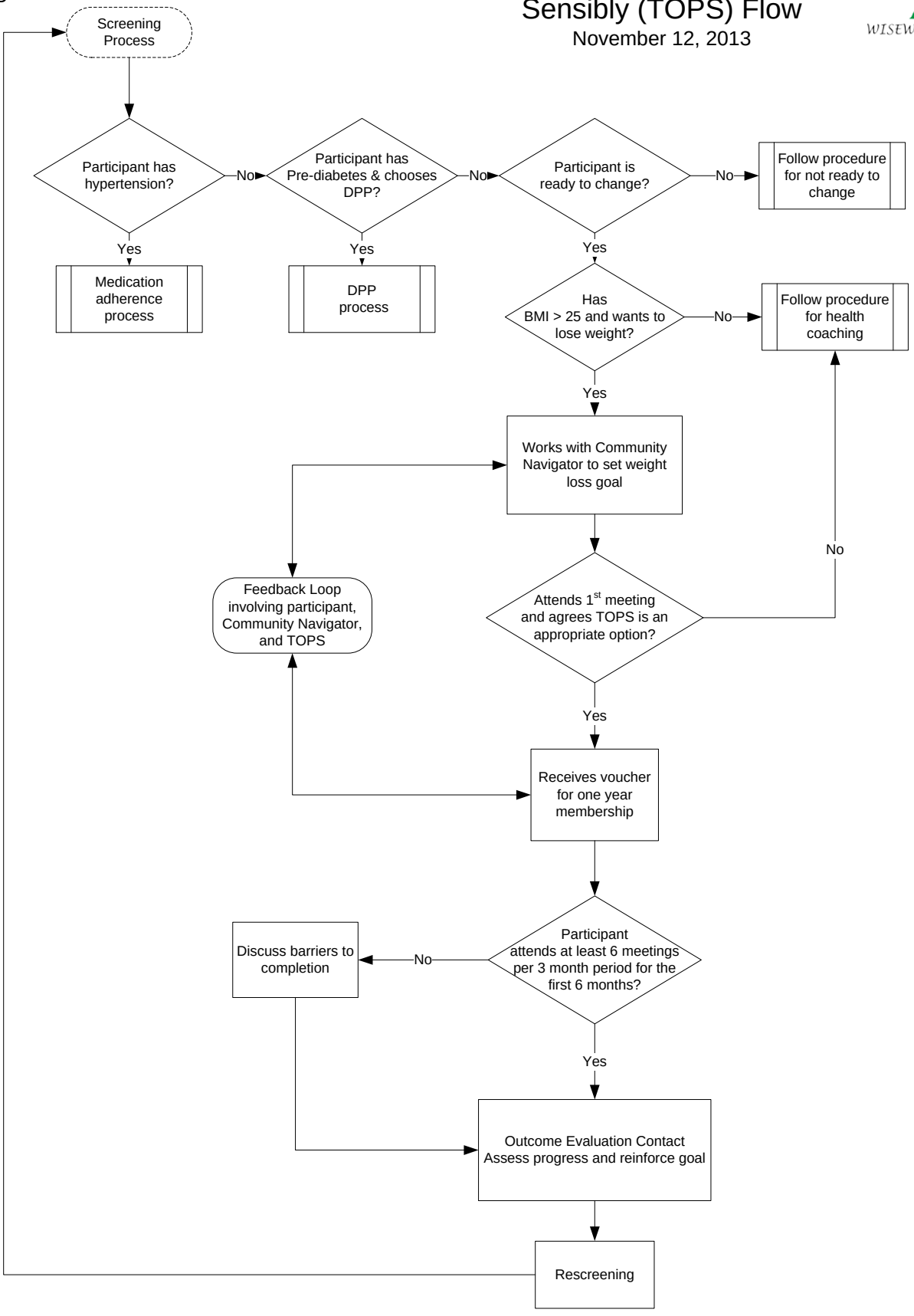
The participant will:

- Develop a Participant Agreement
- Complete and sign the WISEWOMAN TOPS Membership Agreement
- Attend one free TOPS Club meeting

- Provide the Community Navigator with the date and location of the TOPS meeting attended
- Redeem the membership voucher when she receives it in the mail
- Attend at least six local chapter meetings during each three month period for six months
- Pay monthly chapter dues

Michigan WISEWOMAN Take Off Pounds Sensibly (TOPS) Flow

November 12, 2013



WISEWOMAN Program
Diabetes Prevention Program Referral Protocol

Establish Relationship with Diabetes Prevention Program

When completing the Community Scan, determine if there is a Diabetes Prevention Program (DPP) in the community. Information about DPP locations is available at: http://www.midiabetesprevention.org.

Where there is no DPP locally, WISEWOMAN participants in that community will not have DPP as an option. There is no expectation for a WISEWOMAN Agency to begin a Diabetes Prevention Program.

If there is a local DPP in the community, the Community Navigator should contact the Program to establish a relationship. The DPP and Community Navigator will need to develop:

- A referral process
- A feedback mechanism to get information about the participant's:
  - Attendance
  - Weight changes
  - Changes in physical activity

Diabetes Prevention Program Referral

A program participant may be referred to a Diabetes Prevention Program if she meets all of the following criteria:

- Has a BMI ≥24 kg/m2 (≥22 kg/m2, if Asian)
- Is identified with prediabetes **or** has a history of gestational diabetes mellitus (GDM)
- Indicates a readiness to change
- Agrees DPP is an appropriate option
- Has local access to a DPP

The Community Navigator will:

- Work with the participant to complete the Participant Agreement and set a goal related to diabetes prevention
  - (Her goal could be to complete the DPP)
- Work with the participant to complete the WISEWOMAN Diabetes Prevention Program Agreement
- Refer the participant to the local DPP using the established referral process
- Maintain contact with the participant to encourage her to attend all sessions
  - If she has trouble attending sessions, discuss barriers to participation
- Conduct Outcome Evaluation Contact with the participant after the 16 core sessions are over to assess her progress and reinforce her behavior change(s)

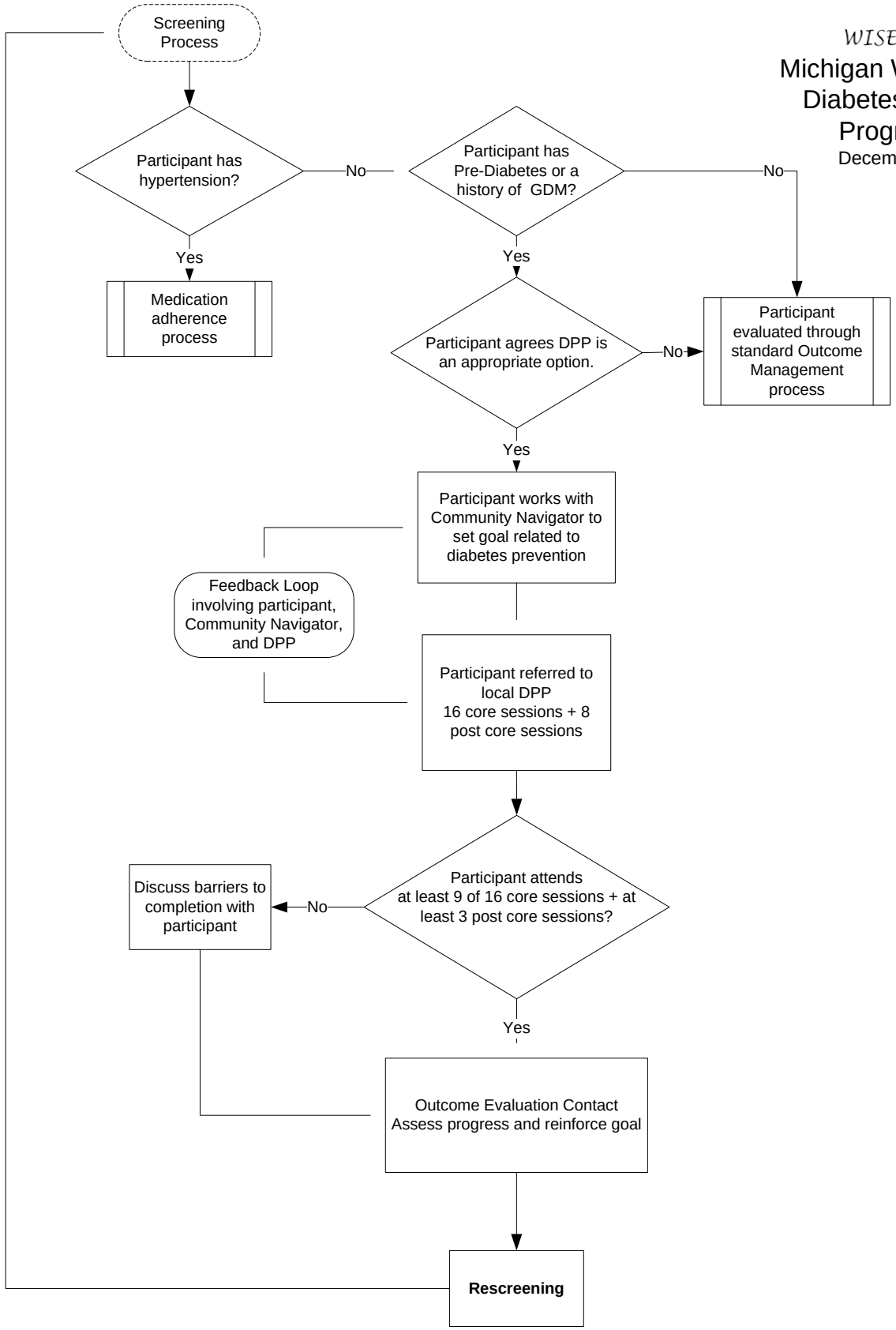
The participant will:

- Develop a Participant Agreement
- Complete and sign the WISEWOMAN Diabetes Prevention Program Agreement
- Attend Diabetes Prevention Program sessions
- Complete the Diabetes Prevention Program
    - Complete means the participant attended at least 9 of 16 core sessions and at least 3 of 8 post core sessions

WISEWOMAN

Michigan WISEWOMAN Diabetes Prevention Program Flow

December 16, 2013



WISEWOMAN Program
Billing and Reimbursement

Only Current Procedural Terminology (CPT) Codes and HCPCS Codes included in the Current Fiscal Year WISEWOMAN Unit Cost Reimbursement Rate Schedule are eligible for reimbursement. The most current Rate Schedule information is available online at: http://www.michigancancer.org/bcccp/WiseWomanProgram.

WISEWOMAN Providers can bill for the following services for each program participant during each one-year cycle:

- One screening office visit if WISEWOMAN visit is not integrated with BCCCP office visit. *See WISEWOMAN Non-Integrated Office Visit Policy for more information*
- One Medical Evaluation Office Visit if screening results for blood pressure, cholesterol, and/or glucose warrant a referral.
- One fasting lipoprotein panel (lipid panel) if cholesterol screening results warrant a referral. Lab results must be entered into the MBCIS WISEWOMAN module.
- One follow-up fasting plasma glucose (FPG) if glucose screening results warrant a referral or if participant is not fasting at the WISEWOMAN office visit. Lab results must be entered into the MBCIS WISEWOMAN module. **(If participant requires both a fasting lipoprotein panel and a fasting plasma glucose, both tests should be conducted at the same time.)**
- One glycated hemoglobin (HbA1c) test for a participant who is not fasting at the WISEWOMAN office visit. (Can only be billed by labs) Lab results must be entered into the MBCIS WISEWOMAN module.
- One venipuncture charge for the blood draw associated with the fasting lipoprotein panel (lipid panel) and/or the fasting plasma glucose (FPG) or Glycated Hemoglobin (HbA1c) when the test is NOT performed on the Cholestech Machine.
- Alert Value Case Management for a program participant with an Alert value for Blood Pressure or Glucose (one time per participant per annual cycle).
- Hypertension Case Management for a program participant with uncontrolled hypertension at screening (one time per participant per annual cycle).
    - **When billing for Alert Value Case Management or Hypertension Case Management, the date of service should be the same as the screening date.**
    - MDCH will enter the data and authorization related to Case Management.
- Once for a New Recruit if participant is new to WISEWOMAN since 2008.
- One Follow-Up Contact to a participant who is not ready to make changes at screening.
- Once for Medication Adherence for a participant who chooses medication adherence as her goal.
- One Initial Contact when a participant participates in her first health coaching session or lifestyle program encounter.

- One Contact Complete when a participant completes health coaching or lifestyle program.
    - Health Coaching – minimum of 3 contacts
    - DPP – Minimum of 9 core sessions
    - TOPS – Minimum of 12 sessions
- One Outcome Evaluation Contact after participant completes health coaching or lifestyle program. Follow-up questions and outcome evaluation contact form must be complete and entered in MBCIS.
- Once for Positive Change based on a positive participant response to questions 6 and 8 on outcome evaluation contact form.

Responsibilities of Provider

Provider of Medical Evaluation

- Complete the bottom half of the Referral for Medical Evaluation Form including the date of the medical evaluation and the plan of care.
- On the bottom of the Referral for Medical Evaluation Form, check the box of the Office Visit CPT Code for which you plan to bill.
- Submit the completed Referral for Medical Evaluation Form to the referring agency.
- Bill the Cancer Section Billing Service for the Office Visit CPT Code at the **Usual And Customary Rate** on a CMS 1500 or UB-04 claim form. (See the current fiscal year WISEWOMAN Unit Cost Reimbursement Rate Schedule for a list of allowable CPT codes.) Billing should follow the same procedures as for BCCCP. (See BCCCP website for most current billing manual: http://www.michigancancer.org/bcccp/)
    - It is important that the service date and CPT code on the claim match the date of medical evaluation and Office Visit CPT code checked on the Referral for Medical Evaluation Form.

Provider of Laboratory Services

- Submit the results of the Lipid Panel, Fasting Plasma Glucose, or Hemoglobin A1c to the referring agency.
- Bill the Cancer Section Billing Service for all reimbursable lab services provided at the **Usual and Customary Rate** on a CMS 1500 or UB-04 claim form**.** (See the current fiscal year WISEWOMAN Unit Cost Reimbursement Rate Schedule for a list of allowable CPT codes.) Billing should follow the same procedures as for BCCCP. (See BCCCP website for most current billing manual: http://www.michigancancer.org/bcccp/)
    - It is important that the service date on the claim matches the service date on the Laboratory Results submitted to MDCH.
    - MDCH will use the “date collected” as the authorization date for all laboratory procedures.

Responsibilities of Local WISEWOMAN Program Agency

- Enter WISEWOMAN data into the WISEWOMAN module of the Michigan Breast and Cervical Cancer Information System (MBCIS).
    - Failure to enter data in a timely manner will delay payment to the agency or service provider.
- Bill the Cancer Section Billing Service for all WISEWOMAN services at the **Usual And Customary Rate** on a CMS 1500 claim form. Billing should follow the same procedures as for BCCCP. (See BCCCP website for most current billing manual: http://www.michigancancer.org/bcccp/)
    - See the current fiscal year WISEWOMAN Unit Cost Reimbursement Rate Schedule for a list of allowable CPT Codes and reimbursement rates for the WISEWOMAN program.
    - When billing for Case Management, CPT Code 99429 or 93799, the service date on the claim must match the Screening Date.

Note: The adjudication process matches claims to authorizations based on the participant MBCIS number, service date and CPT code. In order to avoid delays in payment, it is important that the participant information, service date and CPT code on the claim match the data entered into the WISEWOMAN module of MBCIS.

WISEWOMAN Reimbursement

Code	Rate	When to bill	Billing Date of Service	Conditions	ICD-10
T1023	$35	New WISEWOMAN recruited	Enrollment Date	New to WISEWOMAN since 2008	Z00.00; Z00.01; Z13.6
99211 99212	$15.79	When WISEWOMAN screening not done with BCCCP	Enrollment Date	Not possible to do WISEWOMAN with BCCCP; May only bill partial office visit	Z00.00; Z00.01; Z13.6
99201 99202	$34.40				
93799	$20	Hypertension Case Management	Enrollment Date	Case management form received at MDCH (Cannot be billed with 99429)	I10; R03.0
99429	$75	Alert Value Case Management	Enrollment Date	Case management form received at MDCH (Cannot be billed with 93799)	I10; R03.0; E11.9; E11.8; R73.01; R73.09
S5190	$30	Client is not ready to change: Make F/U Call in 1 – 2 months	Date of call	Detailed contact data in MBCIS (Cannot be billed with S0315 and/or S0340)	Z71.9
S0315	$30	Client initiates Medication Adherence	Date goal is set	Medication adherence goal set; Medication Adherence Questionnaire complete (Cannot be billed with S5190 and/or S0340)	I10
S0340	$30	Client participated in 1st health coaching session or LSP encounter	Date of contact	Contact date greater than screening date (Cannot be billed with S5190 and/or S0315)	Z71.9 TOPS – E66.3;E66.8 DPP – R73.01; R73.09
S0342	$65	Client completes health coaching or LSP	Date marked complete	Health Coaching - minimum of 3 contacts; TOPS - 12 sessions; DPP - 9 core sessions All health coaching contacts occur after screening Detailed contact data in MBCIS	Z71.9 TOPS – E66.3;E66.8 DPP – R73.01; R73.09
S0316	$75	Outcome Evaluation contact	Date of contact	Follow-up questions complete Outcome evaluation contact form complete Both entered in MBCIS	Z71.9
S9445	$125	Client exhibits positive changes on Outcome Evaluation contact	Date of contact	Based on questions 6 and 8 on outcome evaluation contact form	Z71.9

WISEWOMAN Program
Records Retention Policy

This policy pertains **ONLY** to WISEWOMAN local coordinating agencies, **NOT** subcontracted providers. Agencies that have clinical data retention policies should continue to follow those policies unless the time frames stated in those policies are **LESS** than this policy.

For agencies using Electronic Medical Records

- Data must be verified for accuracy and completeness prior to being entered in MBCIS/ WISEWOMAN and authorized for reimbursement
- Agencies that document WISEWOMAN participant care in Electronic Medical Records **DO NOT** need to print paper copies of records as long as these records can be accessed to verify data for WISEWOMAN participants

Time Frame for Retention of WISEWOMAN Paper Data Forms

The following paper data forms must be retained at the WISEWOMAN agency for the time period specified below.

- Informed Consent: All signed consent forms for the client, for each year enrolled in the program
- WISEWOMAN Questions and Readiness/Confidence Ruler: Keep **current** year's copy
- Screening Form, Case Management Form, and Referral for Medical Evaluation:
  - Participants with alert values: Keep for **3** years from date of screening
  - Participants with uncontrolled hypertension: Keep for **2** years from date of screening
  - Participants with no alert values or uncontrolled hypertension: Keep **current** year's copy
- Participant Agreement: Keep for **2** years
- Medication Adherence Questionnaire or Self-Efficacy for Appropriate Medication Use Scale: Keep for **2** years from date of screening
- Individual Navigation Form: Keep for **2** years
- TOPS Request and DPP Request: Keep for **3** years
- Contact Form: Keep for **2** years