

SEARCH MOP - Section 5
Training of SEARCH Personnel
Table of Contents

5. TRAINING OF SEARCH PERSONNEL	5-1
5.1. TRAINING	5-1
5.2. CERTIFICATION	5-1
5.2.1. <i>Physical Examination</i>	5-5
5.2.1.1. Anthropometry	5-5
5.2.1.2. Blood pressure	5-6
5.2.1.3. Acanthosis nigricans	5-7
5.2.1.4. Laboratory Specimen	5-8
5.2.2. <i>Interviewing</i>	5-8
5.2.2.1. Questionnaire Administration	5-8
5.2.2.2. Food Frequency Questionnaire Administration	5-10
5.2.3. <i>Primary Certification for Retinopathy</i>	5-11
5.2.4. <i>Primary Certification for SphygmoCor</i>	5-11
5.2.5. <i>MNSI Examination Training Competency and Certification Instructions</i>	5-12
5.2.6. <i>Recertification</i>	5-12
<i>Appendix A: Acanthosis References</i>	5-15
<i>Appendix B: MNSI Competency and Certification Checklist</i>	5-16

5. Training of SEARCH Personnel

5.1. TRAINING

Key clinic staff from each clinical site will be trained at the initial SEARCH study central training session. A train-the-trainer model will be used, i.e., key staff trained at the central training session will be responsible for training and re-training other staff members at their local sites. Certification and re-certification are required in order to assure that SEARCH personnel have a clear understanding of the SEARCH study Protocol and Manual of Procedures (MOP) and for standardization of procedures at all centers. This chapter will describe both general and specific procedures. Procedures for visit data collection and laboratory measurements are carefully outlined in Sections 12-15.

5.2. CERTIFICATION

Certification is required of SEARCH personnel performing activities listed in Table 5-1. SEARCH personnel are required to complete certification prior to obtaining SEARCH study measurements in a specific area. The Project Manager (or designee) is responsible for documenting that each of the certification tasks has been completed. A list of certified center personnel and their associated identification numbers are to be sent to the Coordinating Center. The Coordinating Center will have a continually updated list of certified personnel on the SEARCH website to assist sites.

Based on the train-the-trainer model, certified personnel will train new individuals at their centers. Training slides and web-based information will be provided to each center to use for training purposes. Each trainer must certify that SEARCH study personnel meet the same requirements as listed in each following section of the MOP. All certification measures are based on each SEARCH study personnel's data being compared to the 'standard' for agreement.

Table 5-1. Certification Requirements

Certification Components	Initial Certification Requirements	
	Number	Parameters
<i>Physical examination procedures</i>		
Height	2 volunteers	<p><i>Note: If a site utilizes the RoadRod™ or Mobile Mount™ for this measurement, SEARCH personnel are to be certified using this instrument. If the site does not utilize the RoadRod™ or Mobile Mount™ SEARCH personnel are to be certified using a wall mounted stadiometer.</i></p> <ul style="list-style-type: none"> ▪ Each volunteer will be measured twice ▪ If measurements are not within 0.5 cm of each other, a third measurement will be taken ▪ The mean of the two closest measurements will be used to determine the agreement with the mean of two measures taken by the 'gold standard' or the trainer ▪ Trainee and trainer measurement variance must be equal to or less than 1.0 cm
Weight	2 volunteers	<ul style="list-style-type: none"> ▪ Each volunteer will be measured twice. ▪ If measurements are not within 0.2 kg of each other, a third measurement will be taken ▪ The mean of the two closest measurements will be used to determine the agreement with the mean of two measures taken by the 'gold standard' or the trainer. ▪ Trainee and trainer measurement variance must be equal to or less than 0.2 kg
Waist circumference	3 volunteers	<ul style="list-style-type: none"> ▪ Each volunteer will be measured four times – twice using the NHANES protocol and twice using the natural waist. ▪ If measurements are not within 1.0 cm of each other, a third measurement will be taken ▪ The mean of the two closest measurements in each protocol will be used to determine the agreement with the mean of two measures taken by the 'gold standard' or the trainer. ▪ The mean of trainee and trainer measurement must be within 2.0 cm

Certification Components	Initial Certification Requirements	
	Number	Parameters
Blood Pressure	2 volunteers PLUS Video-tape	<ul style="list-style-type: none"> ▪ Each trainee is to watch the DVD prior to conducting blood pressure measurements. Since the video demonstrates blood pressure measured using a mercury manometer, it is not necessary to take the test. The purpose of watching the video is to learn about the difference between K-4 (muffling of sound) and K-5 (disappearance of sound). Each trainee is to evaluate the blood pressure of two volunteers. Trainees are required to be within ± 6 mm/Hg of readings obtained by the trainer using a dual-headed stethoscope.
Acanthosis nigricans		<ul style="list-style-type: none"> ▪ Read reference articles (see Appendix A) ▪ Review set of 61 acanthosis nigricans slides on website ▪ Classify a minimum of 57 slides correctly on web-based certification test
Laboratory procedures		
Blood draw, urine collection, processing and shipping	1 complete set (fresh and frozen) for both registry and cohort laboratory measures	<ul style="list-style-type: none"> ▪ Review laboratory MOP (Section 13) and complete local training on laboratory procedures (by previously certified SEARCH staff) ▪ Submit one complete set of blood and urine samples (fresh and frozen) for registry visit measures and one complete set of blood and urine (fresh and frozen) for cohort visit measures. These can be drawn on two different volunteer subjects (not SEARCH participants). Note: If urine collection is not available, water can be sent in its place and should be noted on the shipment form so the lab does not analyze it.
Interviewing Procedures		
Interviewing	1 set of interview forms and 1 audio-tape 2 sets of self-administered forms	<ul style="list-style-type: none"> ▪ Primary Survey Administrator (PSA) at each center is to practice conducting interviews on children and adults. ▪ Interview volunteers are <u>not</u> to be SEARCH participants. It is preferable to have children of the same age range if available; if not, adults can be used for certification purposes. ▪ The PSA is to submit to the Coordinating Center three sets of edited form packets. Two of these should be self-administered forms with the SEARCH personnel providing instructions; and one set should be completed by interview. Forms to be completed are the Medication Inventory and Family Medical History. ▪ This form packet is to include an associated audio-tape of the interview session.

Certification Components	Initial Certification Requirements	
	Number	Parameters
Diet Interview	1 interview form 2 self-administered forms and 1 audiotape	<ul style="list-style-type: none"> ▪ Primary Diet Interviewers (PDI) at each center are to practice conducting interviews on children and adults. ▪ Interview volunteers are not to be SEARCH participants. It is preferable to have children of the same age range if available; if not, adults can be used for certification purposes. ▪ The PDI is to submit to the Diet Assessment Center three completed food frequency questionnaires. Two of these should be self-administered forms with the SEARCH personnel providing instructions; and one form should be completed by interview. ▪ This form packet is to include an associated audiotape of the SEARCH personnel providing instructions for one of the forms.
Data Entry		
Data entry See MOP Section 6 for more details	2 forms	<ul style="list-style-type: none"> ▪ Data entry certification will be done via web-based entry. The forms will consist of one Registry IPS form - parent version, and one physical exam form. ▪ Each person is required to complete the designated on line forms. ▪ 100% accuracy is the acceptable threshold.
DM Complications Testing		
Retinal photographs	Photographs of 10 eyes (5 right and 5 left eyes) (F1 and F2 of each)	<ul style="list-style-type: none"> ▪ Complete and submit Photographer Certification Request Form (in lieu of SEARCH Image Inventory Batch Form) (See Section 14, page 29) ▪ Submit images of 10 eyes (5 right eyes and 5 left eyes, F1 and F2 of each) imaged following the study protocol. ▪ A photographer is fully certified after submitting satisfactory quality images of 10 eyes taken on non-study volunteers and the form is signed and sent to the Coordinating Center by the OERC. ▪ Small pupil aperture (SPA) should not be used for certification photos

Certification Components	Initial Certification Requirements	
	Number	Parameters
SphygmoCor measurements	3 volunteers with repeat measures on two separate days	<ul style="list-style-type: none"> ▪ Review MOP (Section 15) and training slides ▪ Complete SphygmoCor measures on three volunteers repeated on two separate days ▪ Transmit readings to the CoC, along with the certification worksheet. ▪ If measures are consistent, CoC will notify you that you are certified. ▪ If one or more measures are not consistent, the CoC will ask the site to send screen shots of the tracings for the volunteers with inconsistent readings to Elaine Urbina, elaine.urbina@cchmc.org ▪ After reviewing screen shots, Dr. Urbina will send individualized feedback about how to adjust technique to get more consistent readings ▪ Repeat certification measures and submit to the CoC for evaluation
Michigan Neuropathy Screening Instrument (MNSI)	3 volunteers	<ul style="list-style-type: none"> ▪ Review MOP and training slides ▪ Complete MNSI on 3 volunteers in accordance with the detailed competency checklist (Section 5, Appendix B)

Note: for all components, the following tasks must be completed:

- Attendance at the SEARCH study centralized training session; training by someone who attended the centralized training session; or alternative training approved by the SEARCH Steering Committee. If the primary trainer leaves the study site, the PI or his/her designee should contact the CoC to arrange for training a primary trainer.
- Required reading: Manual of Procedures and Protocol.

Attendance at central training is not sufficient for certification. Site personnel who attend the central training session must also complete all bulleted items above.

5.2.1. Physical Examination

5.2.1.1. Anthropometry

Anthropometry is the study of the measurement of the human body in terms of the dimensions of bone, muscle and adipose (fat) tissue. This measure can help in providing critical information regarding the presence of obesity and its relationship to diabetes. SEARCH personnel will be instructed on the use of anthropometric equipment pertinent to the study (see Section 12 for more complete information) and compliant with minimum specifications. The *minimum* equipment required for these measures are:

Table 5-2. Equipment Guidelines

Height	RoadRod™ or Mobile Mount™ stadiometer or wall-mounted stadiometer
Weight	Recommended scale is the SECA 770 or 876. Minimum standard is digital scale measuring weight in 0.1 kg for weights up to 150 kg and to 0.2 kg for weights > 150 kg. It is suggested the scale be capable of measuring up to at least 220 kg.
Waist circumference	The fiberglass tape measure required for measuring waists up to 150 cm is model BMS-8 (Creative Health Products). The flexible steel tape measure required for measuring waists >150 cm is the Anthropometric tape from Roscraft.

SEARCH study personnel will be trained on the principles and concepts of measurement as well as the location of measurement sites/landmarks and be requested to provide evidence of understanding by correctly completing multiple measurements under the guidance of a trained person who is knowledgeable of SEARCH procedures. Certification criteria are as follow:

Table 5-3. Anthropometry Measurement Criteria

<ul style="list-style-type: none"> ▪ Read and become familiar with SEARCH Protocol and Manual of Procedures. ▪ Height <ul style="list-style-type: none"> ○ Properly assemble portable stadiometer (if applicable) ○ Accurately measure the height of two volunteers (within 1.0 cm) ▪ Weight <ul style="list-style-type: none"> ○ Demonstrate proper digital scale zeroing technique ○ Accurately measure the weight of two volunteers (within 0.2 kg) ▪ Waist Circumference (Both NHANES and natural waist protocols) <ul style="list-style-type: none"> ○ Identify appropriate physical landmarks for waist measurement ○ Measure waist circumference using both measurement methods, of three volunteers (within 2.0 cm)
--

5.2.1.2. Blood pressure

Each data collector will be trained and certified to perform all data collection tasks. Blood pressure measurements will be made using an aneroid manometer and appropriately sized cuffs for the person being measured. Blood pressure cuffs are to be available in the following sizes:

- Infant

- Child/Small Adult
- Adult
- Large adult or Large arm
- Thigh

The certification procedure includes training the research staff at each center in the techniques and process of performing the actual measurements. During this training the actual methodology, recording of results, equipment calibration, and potential sources of error will be demonstrated.

Each site will identify a trainer. Designated trainers will be responsible for training and certifying new staff members. Certification will involve training related to Korotkoff sounds 1 and 5. Instructions will be provided regarding cuff selection and application, measurement sites, and terminal digit bias.

Certification criteria for blood pressure measurements are as follow:

Table 5-4. Blood Pressure Measurement Criteria

- | |
|---|
| <ul style="list-style-type: none">▪ Watch DVD (on website or local copy of DVD)▪ Demonstrate proper selection of cuff size and application▪ Determine POP and MIL▪ Demonstrate proper deflation rate (2-4 mm Hg/sec.)▪ Accurately identify K1 and K5 reading within +/- 6 mm Hg |
|---|

5.2.1.3. Acanthosis nigricans

Acanthosis nigricans is an eruption of the skin characterized by hyperpigmentation and velvety cutaneous thickening that can occur on any part of the body but characteristically affects the axillae, the posterior portion of the neck, the groin, the antecubital and popliteal surfaces and the umbilicus. Acanthosis nigricans is now recognized as a sign of insulin resistance. Insulin resistance, however, can occur in the absence of acanthosis nigricans. A higher prevalence of acanthosis nigricans is found in ethnic populations with darker skin than lighter skin. Studies in children and adolescents demonstrated that the neck was most significantly affected and always involved when other areas of the body have acanthosis nigricans. In a field study, the anatomical area that proved to be the most reproducible was the neck. Changes in texture must be present to identify acanthosis nigricans.

Acanthosis nigricans can be a difficult sign for the untrained person to detect. Training will provide in-depth presentation of cases of acanthosis nigricans in children. Slides will be provided to centers for use in training and retraining center personnel. Based on an education program previously conducted by Burke and

colleagues (1999), personnel will be provided with literature to review as background information, slides depicting acanthosis nigricans in children, and will be expected to pass a visual examination determining the presence or absences of acanthosis in 61 cases.

Table 5-5. Acanthosis Nigricans Certification Criteria

- Read reference articles; references can be found in Appendix A.
- Review set of 61 acanthosis nigricans slides
- Classify a minimum of 57 slides correctly on web based certification test

5.2.1.4. Laboratory Specimen

Instructions for obtaining and processing laboratory specimen will be provided by SEARCH Laboratory personnel from Northwest Lipid Laboratories (see Section 13 for details). Certification specimens are sent to the SEARCH Lab in the same manner as those specimens obtained from SEARCH participants.

Table 5-6. Laboratory Specimen Certification Criteria

- Read and become familiar with SEARCH Laboratory Manual of Procedures
- Collect, process and ship 1 set of fresh and 1 set of frozen registry samples
- Collect, process and ship 1 set of fresh and 1 set of frozen cohort samples
- Label all certification specimen with "Certification" label
- Submit correctly completed specimen shipment forms

5.2.2. Interviewing

5.2.2.1. Questionnaire Administration

- Each center must designate a Primary Survey Administrator (PSA), who will have responsibility for the training and supervision of their center's data collectors. This person must be certified by the SEARCH Coordinating Center before he/she can begin training other data collectors at their respective sites. If a PSA leaves a site, the site will designate a new PSA, who will need to complete the certification process before training and supervising other data collectors.

Table 5-7. Certification Criteria for Primary Survey Administrator (PSA)

- Become thoroughly familiar with the MOP and know which measures are to be administered to study participants at which visits, either via telephone, via mail, or in-person.
- Practice the administration of the study forms in both interview-administered and self-administered modes. This practice should be with youth of the age targeted in SEARCH, if possible.

- Submit three completed and edited form packets to the Coordinating Center for review. Form packets must consist of the following instruments:
 - Family Medical History Form
 - Medication Inventory
- One of the three form packets must be accompanied by an audiotape of the interview-administered forms. This audio taped interview must include the instructions given to the participant prior to the beginning of the interviews, as well as the “closing” of the interview.

The forms should be mailed to:

Dr. Michelle Naughton
Department of Social Science and Health Policy
Division of Public Health Science
Medical Center Boulevard
Winston-Salem, NC 27157
- Feedback will be provided as needed and certification will be given upon successful review. *PSAs should not do interviews with participants until certification has been completed, in case certification is denied. (05/12)*

These forms are NOT to be collected from potential participants unless absolutely necessary. All forms relating to children should be completed by youth in the age range targeted in SEARCH whenever possible.

- The Coordinating Center will review the forms and audiotape and provide feedback and certification upon successful review. *PSAs should not complete data collection on participants, or train other staff, until certification has been completed, in case certification is denied.*
- Once certification is obtained, the PSA is authorized to certify other secondary interviewers/data collectors at their site.

Table 5-8. Certification Criteria for Secondary Interviewer/Data Collector

- Read and review MOP.
- Practice self-administration and interviewer administered modes of data collection with youth in the targeted age range of SEARCH.
- Have the PSA observe, with the participant’s permission, at least one interviewer administered session and provide feedback as needed.
- Have the PSA review at least *three* completed and edited form packets (similar to those required for PSA certification) for completeness and accuracy. If an interview was unable to be observed, one of the interviewer-administered sessions must be audio taped and provided to the Primary Survey Administrator for simultaneous review.

- A Secondary Interviewer/Data Collector may be requested to complete and submit to the PSA additional interviewers/form packets if the submitted forms and/or audiotape are judged to be deficient by the PSA.
- The PSA must inform the Coordinating Center of successful certification of all Secondary Interviewers/Data Collectors.
- All new employees who will be collecting participant data must be certified by the PSA, using the procedures outlined above, before they are permitted to interview/collect data from study participants.

5.2.2.2. Food Frequency Questionnaire Administration

- Each center must designate a Primary Diet Interviewer (PDI). This person is expected to read and review the MOP carefully and to practice delivery of the form several times, until he/she is comfortable with the flow and with the likely situations that may arise.

Table 5-9. Certification Criteria for Primary Diet Interviewer

- Practice sessions. Personnel administering the FFQ should perform:
 - 2 self-administered forms with the SEARCH personnel providing instructions to the Participant (audio tape one of these sessions), and
 - 1 interviewer-administered form
 - The PDI will submit to Beth Mayer-Davis
 - *Three completed and edited forms. These forms are NOT to be collected from SEARCH participants. It is preferable to have children of the study's age range but if that is not possible, certification can be conducted in adults.*

The forms should be mailed to:

Dr. Beth Mayer-Davis

UNC Chapel Hill

2211 McGavran-Greenberg Hall, CB 7461

Chapel Hill, NC 27599

- Feedback will be provided as needed and certification will be given upon successful review. *PDI's should not do interviews with participants until certification has been completed, in case certification is denied.*

The PDI is then empowered to certify other secondary diet interviewers (SDI) at their site.

Table 5-10. Certification Criteria for Secondary Dietary Assessment measures

- Read and review MOP.
- Practice delivery of the form.

- Have the PDI observe at least one session (either in person or by audio tape) and provide feedback as needed.
- Have the PDI review at least three completed and edited forms (including quality control questions) for completeness and accuracy. These forms are not to be collected on SEARCH participants.

(The PDI must inform the Coordinating Center of successful certification of SDIs. The PDI can contact Beth Mayer-Davis if any questions or concerns arise.)

5.2.3. Primary Certification for Retinopathy

Each photographer taking fundus images will need to become certified before taking images for the study. The initial group of photographers will receive didactic and hands-on training at a centralized training. Each site will receive assistance from Synemed to install and configure their camera system after which time site photographers should practice taking images and prepare image sets for submission to the OERC for certification. Certification begins with the completion of the Photographer Certification Request Form (Section 14, page 29). This form will be used in lieu of the SEARCH Image Inventory Batch Form and will be submitted along with images of 10 eyes (5 right eyes and 5 left eyes, F1 and F2 of each) imaged following the study protocol. A photographer is fully certified after submitting satisfactory quality images of 10 eyes taken on non-study volunteers and the form is signed and sent to the Coordinating Center by the OERC. These images must show proper field definition (Fields 1 and 2 of each eye, 20 images total), proper exposure, alignment and focus. Photography certification subjects will be given a unique 8-digit subject ID number. It will begin with CERT and the next number will be a number one through 5. The last 3 digits will be the photographer's 3 digit initials (i.e., CERT1ABC is the first person imaged for this photographer and CERT2ABC is the second person etc). The OERC will confirm certification to the Coordinating Center who will notify the photographers at each site or will provide helpful feedback requesting the submission of additional images to resolve a problem and complete certification.

Small pupil aperture (SPA) feature usage -- should not be used for certification photos, as it should be the photographer's best images. We will not accept certification images using the SPA feature. You may practice using this feature, in the event that for a subject it is necessary, but it should not become routine. Remember, it is in the study's best interest to NOT use this feature.

5.2.4. Primary Certification for SphygmoCor

Each staff member responsible for SphygmoCor measures will need to be certified before completing measurements on study participants. Certification includes attending in-person training (or equivalent), detailed review of the MOP, and completion of SphygmoCor measures on three volunteers repeated on two separate days. Measures will

be sent to the Coordinating Center for evaluation. If the readings are consistent, the Coordinating Center will notify the site that certification is complete. If one or more readings are inconsistent, the Coordinating Center will ask the site to send screen shots of the tracings to Elaine Urbina (elaine.urbina@cchmc.org). Dr. Urbina will review the screen shots and send individualized feedback to the site about how to adjust the technique to get more consistent readings. The certifier must repeat certification measures and transmit new readings to the Coordinating Center for evaluation.

5.2.5. MNSI Examination Training Competency and Certification Instructions

The MNSI is a brief physical examination involving 1) inspection of the feet for deformities, dry skin, hair or nail abnormalities, callous or infection, 2) semi-quantitative assessment of vibration sensation at the dorsum of the great toe, 3) grading of ankle reflexes and 4) monofilament testing. All components of the MNSI are done on each foot.

All SEARCH staff performing the MNSI must be trained, and then certified. Previously trained and certified SEARCH staff must be observed correctly performing and scoring the MNSI twice by an already certified SEARCH staff member, or other approved MNSI trainer to be re-certified. SEARCH staff who have not been previously trained and certified must be observed correctly performing and scoring the MNSI three times by an approved trainer (or other MNSI certified SEARCH staff) to obtain initial certification. (See certification checklist in Appendix B).

5.2.6. Recertification

The recertification processes will be consistent with procedures required for initial certification - that is, all criteria listed in Table 5-1 are to be repeated except for laboratory sample collection, diet interview, data entry, retinal photographs, and SphygmoCor measurements. These procedures will be monitored via other methods of quality control. The MNSI will require recertification on two individuals according to the MNSI certification checklist. Recertification for physical measurements, acanthosis, and interviewing will be completed as indicated in Table 5-10 below. *Note: Any SEARCH study personnel currently conducting study measurements that fails to recertify, will be suspended from taking measurements until recertification requirements are met.*

Physical Measurement and Interview Recertification

- Recertification of secondary personnel will be required 6 months and one year after initial certification, and then every two years thereafter. This will be carried out at each clinical center by the designated primary trainer.
- Because designated primary trainers are responsible for re-certifying local personnel, primary trainers are considered re-certified whenever they conduct re-certification of secondary personnel.

Table 5-11 provides an overview of recertification requirements.

Table 5-11. Recertification Requirements

Recertification Components	Recertification Requirements for Secondary Personnel		
	N	Freq	Parameters
<i>Physical Examination Procedures</i>			
Height	2 volunteers	6 months 1 year then every 2 years	<ul style="list-style-type: none"> ▪ Each volunteer will be measured twice. ▪ If measurements are not within 0.5 cm of each other, a third measurement will be taken ▪ The mean of the two closest measurements will be used to determine the agreement with the mean of two measures taken by the 'gold standard' or the trainer. ▪ Trainee and trainer measurement variance must be equal to or less than 1.0 cm
Weight	2 volunteers	6 months 1 year then every 2 years	<ul style="list-style-type: none"> ▪ Each volunteer will be measured twice. ▪ If measurements are not within 0.2 kg of each other, a third measurement will be taken ▪ The mean of the two closest measurements will be used to determine the agreement with the mean of two measures taken by the 'gold standard' or the trainer. ▪ Trainee and trainer measurement variance must be equal to or less than 0.2 kg
Waist circumference	2 volunteers	6 months 1 year then every 2 years	<ul style="list-style-type: none"> ▪ Each volunteer will be measured four times – twice using the NHANES protocol and twice using the natural waist. ▪ If measurements are not within 1.0 cm of each other, a third measurement will be taken ▪ The mean of the two closest measurements in each protocol will be used to determine the agreement with the mean of two measures taken by the 'gold standard' or the trainer. ▪ Trainee and trainer measurement variance must be equal to or less than 2.0 cm
Blood Pressure	2 volunteers	6 months 1 year then every 2 years	<ul style="list-style-type: none"> ▪ Each trainee is to evaluate the blood pressure (single measurement) of two volunteers. Trainees are required to be within ± 6 mm/Hg of readings obtained by the trainer using a dual-headed stethoscope.

Recertification Components	Recertification Requirements for Secondary Personnel		
	N	Freq	Parameters
Acanthosis nigricans		6 months 1 year then every 2 years	<ul style="list-style-type: none"> ▪ Review set of 61 acanthosis nigricans slides ▪ Classify a minimum of 57 slides correctly on web based certification test
<i>Interviewing Procedures</i>			
Interviewing	1 observed interview or audio-tape	6 months 1 year then every 2 years	<ul style="list-style-type: none"> ▪ The PSA must monitor the on-going performance of the secondary interviewers/data collectors. The PSA is to observe the Secondary Interviewers/Data Collectors complete one set of interviews or submit one audio taped interview and forms. Forms to be completed are the Medication Inventory and Family Medical History.
<i>DM Complications Measures</i>			
Michigan Neuropathy Screening Instrument (MNSI)	2 volunteers	6 months 1 year then every 2 years	<ul style="list-style-type: none"> ▪ Review MOP and training slides ▪ Complete MNSI on 2 volunteers in accordance with the detailed competency checklist

Appendix A: Acanthosis References

[Acanthosis nigricans in obese patients: Presentations and implications for prevention of atherosclerotic vascular disease](#)

<http://care.diabetesjournals.org/cgi/gca?gca=22%2F10%2F1655&sendit=Get+All+Checked+Abstract%28s%29><http://care.diabetesjournals.org/cgi/gca?gca=22%2F10%2F1655&sendit=Get+All+Checked+Abstract%28s%29>

<http://www.dshs.state.tx.us/diabetes/PDF/dpn62n02.pdf>

<http://www.minoritynurse.com/features/health/03-01-05e.html>

Appendix B: MNSI Competency and Certification Checklist

Name of person to be certified: _____

SEARCH ID Number (if applicable): _____

Previously SEARCH MNSI Certified (circle)? Yes No

If yes, must be observed correctly performing MNSI on 2 people to be re-certified.

If no, must be observed correctly performing MNSI on 3 people to be certified.

Certification Examination # (circle): 1 2 3

Certification Examination Date: _____

Name and SEARCH ID Number of Observer: _____

<i>Competency/Required Behaviors:</i>	<i>Met</i>	<i>Not Met</i>	<i>Initials</i>
<i>Explains procedure to patient</i>			
<ol style="list-style-type: none"> 1. Examination of foot will be done 2. Not painful or invasive 3. Will use tuning fork on big toe (describes that will feel a "buzzing sensation") 4. Will measure reflexes by tapping on the back of the ankle 5. Will measure ability to feel light touch by touching the big toes with a filament, ("like a piece of fishing line") 6. Will take less than 10 minutes 			
<i>Positions patient</i>			
<ol style="list-style-type: none"> 1. On exam table or chair that is high enough for foot to be off the floor 2. Legs dangle freely from over the edge of the table or off the chair and are not crossed 3. Patient is relaxed 			
<i>Prepares foot for examination</i>			
<ol style="list-style-type: none"> 1. Gathers required equipment (Tromner or Queen's square reflex hammer, 10 gram calibrated monofilament, C128Hz tuning fork), examination recording form 2. Instructs participant to remove footwear and socks 3. Begins examination within 5 minutes of removing footwear 			
<i>Examiner washes hands</i>			
<ol style="list-style-type: none"> 1. Soap and water for at least 15 seconds 			

<ol style="list-style-type: none"> 2. Thoroughly dries hands 3. Apply gloves (optional) 			
<p>Examines feet (visual and tactile) for deformities, infection, callus, dry skin, fissures, ulcers</p>			
<ol style="list-style-type: none"> 1. Top and bottom 2. Between toes 3. Records findings for left and right foot. <p>EXAMPLES of COMMON REPORTABLE DEFORMITIES: Hallux Valgus (bunion at great toe), Tailor’s bunion (fifth toe bunion), overlapping toes, hammer toe, claw foot, Charcot joint (“rocker bottom foot”).</p> <p>EXAMPLES OF REPORTABLE INFECTIONS: toenail infection (redness, drainage from around the nail bed), wound or other skin infections, cellulitis, gangrene, athlete’s foot infection.</p> <p><i>Note: Onychomycosis, a common toenail fungal infection, should be captured as “other”. Feel free to make note of actual findings, e.g., “Red macerated skin between toes with flaking and scaling c/w athlete’s foot infection”, or “second toe crosses third toe”.</i></p> <p>DISTINGUISHING ULCERATION FROM OTHER TYPE OF WOUND: True neuropathic ulcers tend to occur over pressure points (e.g., over bony prominences, beneath calluses, on the plantar surface of the heel, or metatarsal heads – the “ball of the foot”), are quite often painless, are generally well demarcated and are usually more or less circular in shape. They penetrate through more than the epidermis, so that the dermis and often deeper sub-cutaneous tissue is visible. Ulcer margins often “thick” or whitish and there may be a whitish film or eschar that covers the central ulcerated area. The central area may also appear red and “beefy” (indication granulating tissue is filling in the ulcer as healing occurs). Ulcers generally persist for at least two weeks and are slow to heal. True neuropathic ulcers are not generally associated with a known traumatic injury (a cut from a sharp object, stepping on a piece of glass, these are common traumatic injuries that generally result in simple lacerations, epidermal abrasions or punctures to the skin. While an injury of this sort can develop into an ulcer, it should not be graded as such unless it clearly meets the description of a neuropathic ulcer outlined above. Simple lacerations, abrasions, thermal injuries, punctures and other traumatically injured feet are not graded on the MNSI, unless the wound is infected (mark infection on the form).</p>			

<p><i>Performs reflex assessment</i></p>			
<ol style="list-style-type: none"> 1. <i>Has subject seated with leg/foot hanging relaxed and freely</i> 2. <i>Encourages subject to relax foot</i> 3. <i>Explains that examiner will lightly stretch foot upward, but participant should try to stay as relaxed as possible</i> 4. <i>Examiner slightly dorsiflexes foot, either with hand, or by placing foot on examiner thigh</i> 5. <i>Examiner identifies Achilles tendon on posterior ankle</i> 6. <i>Taps firmly/briskly on Achilles tendon while watching/feeling for foot response (brisk plantar flexion)</i> 7. <i>If no response, repositions foot and repeat</i> 8. <i>If no response, asks subject to perform Jendrassic Maneuver (grasps hands, pulls, grits teeth) while examiner elicits the response</i> 9. <i>Reminds subject to relax between attempts</i> 10. <i>If no response after at least two attempts, examiner stops and repeats procedure on the second foot</i> 11. <i>Records findings for each foot; Present, Present with Reinforcement (if response elicited with Jendrassic Maneuver) or Absent (no response)</i> 			
<p><i>Determines Vibration Perception</i></p>			
<ol style="list-style-type: none"> 1. <i>Explains procedure to patient – will apply a tuning fork to the top of the big toe. Participant will be asked to say “stop” when they no longer feel any vibration or “buzzing”</i> 2. <i>Demonstrates the feeling of the buzzing tuning fork on the hand of the participant</i> 3. <i>Positions the participant with the foot hanging freely (not supported by floor or examiner hand)</i> 4. <i>Identifies the DIP joint on the great toe by bending the toe</i> 5. <i>Asks the participant to close his or her eyes</i> 6. <i>Applies the tuning fork (non-vibration) to the joint and tells the participant “that is the feeling of the tuning fork without any vibration”</i> 7. <i>Strikes the tuning fork against a solid object or examiner’s hand to start vibration</i> 8. <i>Holds the vibrating fork by the stem</i> 9. <i>Re-applies the tuning fork to the DIP joint and asks the participant to confirm that they feel the “buzzing” or vibration. If they do not feel the</i> 			

<p>vibration, examiner verifies with his or her own hand whether or not fork is vibrating, then re-strike the hammer and re-apply</p> <p>10. Uses only a finger or two against the tip of the big toe to stabilize the foot during vibration assessment</p> <p>11. Confirms that the participant feels the vibration and then ask them to say “stop” when they no longer feel any vibration or “buzzing”</p> <p>12. As soon as the participant says “stop” moves the tuning fork (still held by the stem) to his/her own finger (DIP of the thumb or first finger)</p> <p>13. Times with a watch or clock with a second hand, the number of seconds that the examiner feels vibration</p> <p>14. Scores the vibration correctly</p> <p>A. If examiner feels the vibration on his/her finger for less than 10 seconds after patient says “stop”, then records score as “present”</p> <p>B. If examiner feels the vibration on his/her finger for longer than 10 seconds, scores as “reduced”</p> <p>C. If participant is not able to detect any vibration from the tuning fork, and examiner confirms that positioning was correct and vibration was present, the score marked is “absent”</p> <p>15. Repeats assessment for other foot</p>			
<p><i>Determines Monofilament Perception</i></p>			
<p>1. Explains procedure to subject; “I am going to lightly touch your big toe with this filament- it’s a thin piece of nylon, sort of like fishing line”</p> <p>2. Pre-stresses the filament on the participant’s hand to demonstrate the feeling of the filament</p> <p>3. With each application, the filament bends to a “c” shape and each application lasts about 1 second</p> <p>4. Positions the participant with the foot hanging freely</p> <p>5. Supports the foot to be tested with the examiner’s hand (sole of foot in palm of hand (or, can have sole of foot resting on a firm surface, e.g., carpeted floor , or stool, as long as the surface is not overly cool or warm)</p> <p>6. Instructs the subject to close his or her eyes and to say “yes” if they feel the filament touching the toe</p> <p>7. Applies the monofilament to the dorsum of the great toe, on the skin between the DIP and base of the nail</p>			

<p>8. <i>Applies sufficient pressure to create a “c” shaped bend in the filament and the duration of application is about 1 second</i></p> <p>9. <i>Removes the filament and waits for the subject response</i></p> <p>10. <i>After the subject responds, waits a couple of seconds and reapply</i></p> <p>11. <i>Repeats the application process for a total of 10 applications. The duration of the pause between applications is staggered, and the examiner periodically checks to make sure that the subject still has his or her eyes shut.</i></p> <p>12. <i>Records the number of correctly identified filament touches. If 8 or more are correctly identified, the response is “present”, if 1 to 7 are correctly identified, the score is “reduced” and if none of the applications are correctly identified, “absent” is marked.</i></p> <p>13. <i>Repeats the process for the second foot.</i></p> <p>14. <i>If the subject does not respond to the first or second touch, the examiner has the patient open his or her eyes, and reviews the instructions again, while testing on the hand. Then, resume testing on the foot.</i></p>			
--	--	--	--