

*The Commission for the Accreditation of
Medical Screening Services (CAMS)*

**2010 STANDARDS FOR
ACCREDITATION IN VASCULAR
SCREENING EXAMINATIONS**

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SECTION 1: Supervision and Personnel

Introduction: A screening service performs non-invasive vascular screening examinations under the overall direction of a Medical Director and one or more Technical Directors.

A screening unit is defined as the group performing vascular screening under the supervision of a Technical Director. A screening service may be made up of one or more units. Each screening unit is separately accredited.

A screening unit may be made up of one or more teams. A screening team is the group performing vascular screening at a specific event.

STANDARD – Medical Director

1.1 A qualified Medical Director must be designated for the facility.

1.1.1 Responsibilities include but are not limited to:

- 1.1.1.1 All clinical services provided and the quality and appropriateness of the screening services provided.
- 1.1.1.2 Supervises the entire clinical operation of the screening service; may delegate specific duties to appropriate staff.
- 1.1.1.3 Appoints the medical staff, grants privileges and supervises their work.
- 1.1.1.4 Maintains and assures compliance to the standards as outlined in this document.

Comment: If the Medical Director is off site, he/she must have a physical presence in the lab to participate in regular QA meetings, case study review conferences, personnel interviews and other laboratory operations.

1.1.2 Medical Director qualifications:

- 1.1.2.1 Must be a licensed physician
- 1.1.2.2 Licensed in the state or jurisdiction of the screening service
- 1.1.2.3 Must be qualified to interpret noninvasive vascular examinations

1.1.3 Training and experience requirements

The Medical Director must demonstrate an appropriate level of training and experience by meeting one or more of the following:

1.1.3.1 Formal training

Completion of a residency or fellowship that includes appropriate didactic and clinical vascular laboratory experience as an integral part of the program. For those examination areas in which training is provided, the physician must have experience in interpreting the following minimum number of diagnostic studies while under supervision:

- Carotid duplex ultrasound - 100 cases
- Peripheral arterial physiologic - 100 cases
- Abdominal aorta ultrasound - 100 cases
- Carotid intima-media thickness - 25 cases

1.1.3.2 Informal training

Appropriate training and experience for proper qualifications to interpret noninvasive vascular screening examinations can be achieved through formal accredited post graduate education.

1.1.3.2.1 A minimum of 40 hours of relevant Category 1 CME credits must be acquired within the three year period prior to the initial application.

- Twenty (20) hours must be courses specifically designed to provide knowledge of the techniques, limitations, accuracies and methods of interpretations of noninvasive vascular screening examinations the physician will interpret.
- Twenty (20) hours may be dedicated to appropriate clinical topics relevant to vascular examinations.
- Eight (8) of the 40 hours must be specific to each examination area the physician will interpret.

Comment: Documentation of the CME courses with a listing of the content must be submitted.

1.1.3.2.2 The physician must acquire a minimum of 8 hours supervised practical experience for each examination area to be interpreted; observing or participating in diagnostic noninvasive vascular examination procedures in an accredited laboratory.

Comment: Experience must be documented with a letter from the Medical Director of the lab where the experience was obtained.

1.1.3.2.3 For those examinations the physician will interpret, there must documentation of interpretation for the following minimum number of diagnostic noninvasive vascular examinations while under the supervision of a physician who has already met the ICAVL criteria.

- Carotid duplex ultrasound - 100 cases
- Peripheral arterial physiologic - 100 cases
- Abdominal aorta ultrasound - 100 cases
- Carotid intima-media thickness - 25 cases

1.1.3.3 Established practice

Current training and current experience will be considered appropriate for a physician who has met the qualifications of and has worked for an accredited vascular laboratory for the past three years and has interpreted the following minimum number of diagnostic studies in the specific areas that will be interpreted.

- Carotid duplex ultrasound - 300 cases
- Peripheral arterial physiologic - 300 cases
- Abdominal aorta ultrasound - 300 cases
- Carotid intima-media thickness - 25 cases

1.1.3.4 Physician credential for vascular interpretation

1.1.3.4.1 Registered Physician in Vascular Interpretation (RPVI)

1.1.3.4.2 Neurosonology credential (ASN) from the American Society of Neuroimaging (For physicians who interpret extracranial)

1.1.4 Continuing experience

1.1.4.1 The monthly volume must be sufficient to maintain proficiency in examination interpretation.

Comment: In general, the Medical Director should interpret a minimum of 5 noninvasive diagnostic or screening vascular examinations per month.

1.1.4.2 The total volume of interpretations may be combined from sources other than the applicant screening service.

Comment: Lower volumes than those recommended here should not dissuade a laboratory that is otherwise compliant from applying for accreditation.

1.1.5 Continuing medical education (CME)

The Medical Director must show evidence for maintaining current knowledge by participating in CME courses that are relevant to the areas of screening in which the screening service is applying in. To be relevant the course content must address principles, instrumentation, techniques or interpretation of noninvasive vascular ultrasound or physiologic examinations.

1.1.5.1 A minimum of 15 hours of CME is required every three years, of which 10 hours must be Category 1.

Comment: Laboratory internal quality assurance meetings are not eligible as part of this CME requirement.

1.1.5.2 The CME requirement will be waived if, in the previous three years prior to the application submission, the Medical Director has:

- Completed formal training
- Acquired an appropriate vascular credential
- Been employed in the laboratory less than one year

STANDARD – Technical Director

1.2 A qualified Technical Director(s) must be designated for the screening unit.

1.2.1 The Technical Director is generally a full-time position.

1.2.1.1 If the Technical Director is not a full-time employee, he/she must work a minimum of 20% of normal business hours each month AND

1.2.1.2 An appropriately credentialed lead sonographer must be appointed in the Technical Director's absence and report to the Technical Director.

Comment: The Medical Director or a member of the medical staff must satisfy the qualifications of the Technical Director to serve in that capacity.

1.2.2 Technical Director responsibilities include but are not limited to:

1.2.2.1 Must report directly to the Medical Director

1.2.2.2 All screening unit duties as delegated by the Medical Director

1.2.2.3 Supervision of the technical and ancillary staff (may be delegated)

1.2.2.4 Provides direct supervision of each screening team two full working days per month.

1.2.2.5 Provides direct supervision of each technical staff member at a minimum of once a month; may be delegated to the lead technologist.

Comment: There must be a written protocol for documentation of regular direct supervision of all technical staff.

1.2.2.6 Compliance of the technical staff to the protocols

1.2.2.7 Daily technical operation of the laboratory: staffing, scheduling, record keeping

1.2.2.8 Quality patient care

1.2.2.9 Operation and maintenance of the equipment

1.2.2.10 Compliance to the standards as outlined in this document

1.2.2.11 Technical training

1.2.3 Technical Director qualifications

1.2.3.1 The Technical Director must have an appropriate credential in vascular testing

1.2.3.1.1 Registered Vascular Technologist (RVT)

1.2.3.1.2 Registered Vascular Specialist (RVS)

1.2.3.1.3 Registered Technologist Vascular Sonography [(RT)(VS)]

1.2.3.1.4 Abdominal aorta examinations only: Registered Diagnostic Medical Sonographer in Abdomen [RDMS (AB)]

1.2.3.1.5 Physician technical directors for extracranial examinations only: Neurosonology credential (ASN) from the American Society of Neuroimaging

1.2.3.2 For each examination area applying for, the Technical Director must have performed the following minimum number of diagnostic studies:

- Carotid duplex ultrasound - 100 cases
- Peripheral arterial physiologic - 100 cases
- Abdominal aorta ultrasound - 100 cases
- Carotid intima-media thickness - 25 cases

Comment: If the Technical Director does not meet the examination volume requirements for any examination section, a qualified co-technical director must be appointed for those examination sections.

1.2.4 Continuing experience

1.2.4.1 The monthly volume must be sufficient to maintain proficiency in examination performance.

Comment: In general, the Technical Director should perform a minimum of 5 noninvasive vascular screening or diagnostic examinations per month.

1.2.4.2 The total volume of cases may be combined from sources other than the applicant laboratory.

Comment: Lower volumes than those recommended here should not dissuade a laboratory that is otherwise compliant from applying for accreditation.

1.2.5 Continuing medical education

The Technical Director must show evidence of maintaining current knowledge by participating in CME courses that are relevant to the areas of screening examinations the service is applying in. To be relevant the course content must address principles, instrumentation, techniques or interpretation of noninvasive vascular ultrasound or physiologic examination.

1.2.5.1 A minimum of 15 hours of CME is required every three years.

1.2.5.2 At least one of the 15 CME should be relative to work related musculoskeletal disorders (MSD)

Comment: Laboratory internal quality assurance meetings are not eligible as part of this CME requirement.

1.2.5.3 The CME requirement will be waived if, in the previous three years prior to the application submission, the Technical Director has:

- Acquired an appropriate vascular credential
- Been employed in the laboratory less than one year

STANDARD – Lead Technologist

1.3 A qualified lead technologist must be designated for each screening team and present for each screening event.

1.3.1 Lead technologist responsibilities include but are not limited to:

1.3.1.1 Reports directly to the Technical Director and communicates at least weekly with the Technical Director regarding clinical matters and to assure compliance with the screening standards.

1.3.1.2 All laboratory duties as delegated by the Technical Director

1.3.1.3 Supervises, performs and assists others in performing screening examinations

1.3.1.4 Oversees day to day activities of the screening team

Comment: The Technical Director may serve as the lead technologist.

1.3.2 Lead technologist qualifications

1.3.2.1 The lead technologist must have an appropriate credential in vascular testing.

1.3.2.1.1 Registered Vascular Technologist (RVT)

1.3.2.1.2 Registered Vascular Specialist (RVS)

1.3.2.1.3 Registered Technologist Vascular Sonography [RT(VS)]

1.3.2.1.4 Abdominal aorta examination only: Registered Diagnostic Medical Sonographer in Abdomen [RDMS (AB)]

1.3.2.1.5 Physician lead technologist for extracranial examination only: Neurosonology credential (ASN) from the American Society of Neuroimaging

1.3.2.2 For each screening area provided, the lead technologist must have performed the following minimum number of diagnostic studies:

- Carotid duplex ultrasound - 100 cases
- Peripheral arterial physiologic - 100 cases
- Abdominal aorta ultrasound - 100 cases
- Carotid intima-media thickness - 25 cases

1.3.3 Continuing experience

1.3.3.1 The monthly volume must be sufficient to maintain proficiency in examination performance.

Comment: In general, the lead technologist should perform a minimum of 5 noninvasive vascular screening and/or diagnostic examinations per month.

1.3.3.2 The total volume of cases may be combined from sources other than the applicant laboratory.

Comment: Lower volumes than those recommended here should not dissuade a laboratory that is otherwise compliant from applying for accreditation.

1.3.4 Continuing medical education

The lead technologist must show evidence of maintaining current knowledge by participating in CME courses that are relevant to the areas of screening examination the service is applying in. To be relevant the course content must address principles, instrumentation, techniques or interpretation of noninvasive vascular examination.

1.3.4.1 A minimum of 15 hours of CME is required every three years.

Comment: Laboratory internal quality assurance meetings are not eligible as part of this CME requirement.

1.3.4.2 The CME requirement will be waived if, in the previous three years prior to the application submission, the lead technologist has:

- Acquired an appropriate vascular credential
- Been employed in the laboratory less than one year

STANDARD – Medical staff

1.4 A qualified Medical Staff must be designated for the facility.

1.4.1 Medical Staff responsibilities include but are not limited to:

1.4.1.1 The medical staff interprets and/or performs noninvasive vascular screening examinations in accordance with privileges approved by the Medical Director and in compliance with the standards outlined in this document.

1.4.2 Medical Staff qualifications

1.4.2.1 Must be a licensed physician

1.4.2.2 Licensed in the state or jurisdiction of the screening service

1.4.2.3 Must be qualified to interpret noninvasive vascular examinations

1.4.3 Training and experience requirements:

Must demonstrate an appropriate level of training and experience by meeting one or more of the following:

1.4.3.1 Formal training

Completion of a residency or fellowship that includes appropriate didactic and clinical vascular laboratory experience as an integral part of the program. For those examination areas in which training is provided, the physician must have experience in interpreting the following minimum number of diagnostic examinations under supervision:

- Carotid duplex ultrasound - 100 cases
- Peripheral arterial physiologic - 100 cases
- Abdominal aorta ultrasound - 100 cases
- Carotid intima-media thickness - 25 cases

1.4.3.2 Informal training

Appropriate training and experience for proper qualifications to interpret noninvasive vascular screening examinations can be achieved through formal accredited post graduate education.

1.4.3.2.1 A minimum of 40 hours of relevant Category 1 CME credits must be acquired within the three year period prior to the initial application.

- Twenty (20) hours must be courses specifically designed to provide knowledge of the techniques, limitations, accuracies and methods of interpretations of noninvasive vascular screening examinations the physician will interpret.
- Twenty (20) hours may be dedicated to appropriate clinical topics relevant to vascular examination.
- Eight (8) of the 40 hours must be specific to each examination area the physician will interpret.

Comment: Documentation of the CME courses with a listing of the content must be submitted.

- 1.4.3.2.2 The physician must acquire a minimum of 8 hours supervised practical experience for each examination area to be interpreted; observing or participating in diagnostic noninvasive vascular examination procedures in an accredited laboratory.

Comment: Experience must be documented with a letter from the Medical Director of the lab where the practical experience was obtained.

- 1.4.3.2.3 For those examinations the physician will interpret, there must documentation of interpretation for the following minimum number of diagnostic examinations while under the supervision of a physician who has already met the ICAVL criteria.

- Carotid duplex ultrasound - 100 cases
- Peripheral arterial physiologic - 100 cases
- Abdominal aorta ultrasound - 100 cases
- Carotid intima-media thickness - 25 cases

1.4.3.3 Established practice

Current training and current experience will be considered appropriate for a physician who has met the qualifications of and has worked for an accredited vascular laboratory the past three years and has interpreted the following minimum number of diagnostic studies in the specific screening testing areas that will be interpreted.

- Carotid duplex ultrasound - 300 cases
- Peripheral arterial physiologic - 300 cases
- Abdominal aorta ultrasound - 300 cases
- Carotid intima-media thickness - 25 cases

1.4.3.4 Physician credential for vascular interpretation

1.4.3.4.1 Registered Physician in Vascular Interpretation (RPVI)

1.4.3.4.2 Neurosonology credential (ASN) from the American Society of Neuroimaging (For physicians who interpret extracranial)

1.4.4 Continuing experience

- 1.4.4.1 The monthly volume must be sufficient to maintain proficiency in examination interpretation.

Comment: In general, all medical staff members should interpret a minimum of 5 noninvasive vascular screening and/or diagnostic examinations per month.

- 1.4.4.2 The total volume of interpretations may be combined from sources other than the applicant laboratory.

Comment: Lower volumes than those recommended here should not dissuade a laboratory that is otherwise compliant from applying for accreditation.

1.4.5 Continuing medical education

Each medical staff member must show evidence of maintaining current knowledge by participating in CME courses that are relevant to the areas of screening examination the service is applying in. To be relevant the course content must address principles, instrumentation, techniques or interpretation of noninvasive vascular examination.

- 1.4.5.1 A minimum of 15 hours of CME is required every three years, of which 10 hours must be Category 1.

Comment: Laboratory internal quality assurance meetings are not eligible as part of this CME requirement.

- 1.4.5.2 The CME requirement will be waived if, in the previous three years prior to the application submission, the medical staff member has:

- Completed formal training
- Acquired an appropriate vascular credential
- Been employed in the laboratory less than one year

STANDARD – Technical Staff

1.5 A qualified Technical Staff must be designated for the facility.

- 1.5.1 Technical Staff responsibilities include but are not limited to:

1.5.1.1 Reports to the Technical Director and/or lead sonographer

1.5.1.2 Performance of screening examinations and other assigned tasks

- 1.5.2 Technical Staff qualifications:

The technical staff must have an appropriate level of training, technical certification or documented experience by meeting one or more of the following criteria:

- 1.5.2.1 Credential: An appropriate credential in vascular testing.

1.5.2.1.1 Registered Vascular Technologist (RVT)

1.5.2.1.2 Registered Vascular Specialist (RVS)

1.5.2.1.3 Registered Technologist Vascular Sonography [RT(VS)]

1.5.2.1.4 Abdominal aorta examination only: Registered Diagnostic Medical Sonographer in Abdomen [RDMS (AB)]

- 1.5.2.2 Formal ultrasound training: Successful completion of a diagnostic ultrasound, vascular technology or cardiovascular technology program that includes verified didactic and supervised clinical experience in noninvasive vascular testing.

1.5.2.2.1 The program should be accredited by the Commission for Accreditation of Allied Health Education Programs (CAAHEP) in collaboration with the Joint Review Committee on Education in Diagnostic Medical Sonography (JRC-DMS) and/or the Joint Review Committee on Education in Cardiovascular Technology (JRC-CVT) or the Canadian Medical Association (CMA).

- 1.5.2.3 Post secondary education plus 6 months full time (at least 35 hours/week) vascular screening examination experience plus one of the following:
 - 1.5.2.3.1 Completion of a formal two-year program or equivalent in another allied health profession
 - 1.5.2.3.2 Completion of a bachelor's degree unrelated to vascular technology
 - 1.5.2.3.3 An MD or DO degree
- 1.5.2.4 Experience only
 - 1.5.2.4.1 For physiologic arterial examination: a minimum of 12 months of vascular screening experience under the direct supervision of an appropriately qualified medical or technical staff member OR the performance of at least 300 physiologic arterial screening examinations under the direct supervision of an appropriately qualified medical or technical staff member (as defined by these Standards).
 - 1.5.2.4.2 For duplex ultrasound examination: a minimum of 12 months full time vascular screening experience AND the performance of at least 500 vascular screening examinations in each of the examination areas requiring duplex ultrasound provided by the screening service while under the direct supervision of an appropriately qualified medical or technical staff member (as defined by these Standards).

Comment: An individual who does not meet one of the above is considered a trainee.

1.5.3 Continuing experience

- 1.5.3.1 The monthly volume must be sufficient to maintain proficiency in examination performance.

Comment: In general, all technical staff members should perform a minimum of 5 noninvasive screening and/or diagnostic vascular examinations per month.

- 1.5.3.2 The total volume of cases may be combined from sources other than the applicant laboratory.

Comment: Lower volumes than those recommended here should not dissuade a laboratory that is otherwise compliant from applying for accreditation.

1.5.4 Continuing medical education

The Technical Staff must show evidence of maintaining current knowledge by participating in CME courses that are relevant to the areas of screening examinations the service performs. To be relevant the course content must address principles, instrumentation, techniques or interpretation of noninvasive vascular ultrasound or physiologic examination.

- 1.5.4.1 A minimum of 15 hours of CME is required every three years.

Comment: Laboratory internal quality assurance meetings are not eligible as part of this CME requirement.

- 1.5.4.2 The CME requirement will be waived if, in the previous three years prior to the application submission, the technical staff member has:
- Acquired an appropriate vascular credential
 - Been employed in the laboratory less than one year

STANDARD – Trainees

1.6 Training if conducted must not compromise patient care and must benefit the trainee.

1.6.1 Trainee requirements

- 1.6.1.1 Supervision: The Medical Director and/or Technical Director must ensure that the responsibilities assumed by the trainee are appropriate.
- 1.6.1.2 Trainees must perform screening examinations only with direct qualified medical and/or technical staff supervision.

SECTION 2: Physical Facilities

STANDARD – Examination areas

- 2.1 Examinations must be performed in a setting providing participant safety, comfort and privacy.**
- 2.1.1 Examinations must be performed in a setting providing technical staff safety and comfort.
- 2.1.2 A policy must be in place to address technical staff safety, comfort and avoidance of work related musculoskeletal disorders (MSD).
- Comment: For additional information regarding MSD, please visit:
- [http://www.cdc.gov/niosh/docs/wp-solutions/2006-148/;](http://www.cdc.gov/niosh/docs/wp-solutions/2006-148/)
 - [http://www.sdms.org/OSHA/etool.asp;](http://www.sdms.org/OSHA/etool.asp)
 - <http://www.sdms.org/pdf/wrmsd2003.pdf>

STANDARD – Interpretation Space

- 2.2 Adequate designated space must be provided for the interpretation of examination results and preparation of reports.**

STANDARD – Storage Space

- 2.3 Adequate designated space must be provided for the convenient storage of supplies, records and reports.**

SECTION 3: Examination Interpretation, Reports and Records

STANDARD – Examination Interpretation and Reports

3.1 Vascular screening examinations are interpreted and reported by the Medical Director or a member of the medical staff of the screening service.

Comment: A final screening report or document that describes the results of the examination findings and recommended follow-up must be provided to the participant and/or participant's physician.

3.1.1 Requirements

- 3.1.1.1 All reporting must be standardized.
- 3.1.1.2 All physicians interpreting vascular screening examinations must agree on and utilize uniform diagnostic criteria and a standardized report format.
- 3.1.1.3 The report must accurately reflect the content and results of the examination.
- 3.1.1.4 The report must be verified and signed by the Medical Director or a member of the medical staff of the screening service.
- 3.1.1.5 The report must be typed and must include but is not limited to:
 - 3.1.1.5.1 The date of the screening examination.
 - 3.1.1.5.2 An adequate description of the test performed including the name of the examination and its integral parts.
 - 3.1.1.5.3 Pertinent positive and negative findings
 - 3.1.1.5.4 Incidental findings
 - 3.1.1.5.5 Reasons for a technically limited, suboptimal or incomplete examination.
 - 3.1.1.5.6 Interpreting physician typed name and signature and/or electronic verification.

Comment: The use of a signature stamp is strongly discouraged. The use of the signature stamp provides the potential for inappropriate use by personnel other than the physician whose signature appears on the stamp.
 - 3.1.1.5.7 Date of interpreting physician signature or verification.
 - 3.1.1.5.8 Identification of the technologist performing the screening examination must appear as part of the permanent record.
 - 3.1.1.5.9 If preliminary findings are provided, the preliminary nature must be clearly indicated to the participant.
 - 3.1.1.5.10 A mechanism must be defined whereby the results of the screening examination demonstrate urgent or life threatening findings are communicated to the appropriate health-care professionals in a timely fashion.
 - 3.1.1.5.11 The physician interpretation must be available within 14 calendar days of the examination.

STANDARD – Records

3.2 Provisions exist for the generation and retention of examination records of all examinations performed.

3.2.1 Requirements

3.2.1.1 Essential portions of all examinations must be documented on media appropriate for long term storage.

Comment: Final submission of representative case studies to the IAC must be in a digital format (e.g. CD, DVD or flash drive; no videotape recordings will be accepted).

3.2.2 All records of the examination, including a signed dated report, patient demographics including age, presence or absence of symptoms and pertinent cardiovascular history must be retained in accordance with applicable state or federal guidelines for medical records, generally five to seven years for adult patients.

SECTION 4: Safety and Confidentiality

STANDARD – Safety

4.1 Participant and staff safety must be ensured by written policies and procedures.

- 4.1.1 A written procedure must be in place for identification of participants who suffer untoward effects or complications of studies performed and a permanent record of such is maintained.
- 4.1.2 A written procedure must be in place with respect to:
 - 4.1.2.1 Control of infectious disease
 - 4.1.2.2 Transducer cleaning
 - 4.1.2.3 Protection of screening service personnel from the transmission of infectious disease and blood borne pathogens.
 - 4.1.2.4 Handling acute medical emergencies
 - 4.1.2.5 Routine inspection and testing for electrical safety on all equipment.
 - 4.1.2.6 The screening service must meet the standards as set forth by the Occupational Safety and Health Administration (OSHA) and the Joint Commission (JC), where applicable.

STANDARD – Patient confidentiality

4.2 All screening service personnel must ascribe to professional principles of patient physician confidentiality as legally required by federal, state, local or institutional policy or regulation.

SECTION 5: Participant Recruitment and Education

STANDARD – Participant Recruitment and Education

- 5.1 Marketing and promotional materials shall accurately reflect the nature, benefits and limitations of screening examinations.**
- 5.1.1 Educational materials describing the nature of vascular screening and the significance of normal and abnormal results must be provided to the participant.
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SECTION 6: Indications

STANDARD – Indications

- 6.1 Risk factors for symptoms of vascular disease must be assessed and documented.**
- 6.1.1 Screening examinations are performed to determine the presence or absence of peripheral vascular or cerebrovascular disease or to evaluate risk for cardiovascular or cerebrovascular events, in participants without specific signs or symptoms.
- 6.1.2 Screening guidelines for the appropriate selection of participants should be based upon contemporary scientific publications.
- 6.1.3 Screening cannot replace diagnostic examinations for symptomatic individuals.

SECTION 7: Equipment

STANDARD – Equipment

7.1 Equipment must provide accurate data.

- 7.1.1 Imaging equipment – Duplex ultrasound with color flow Doppler, if used for screening examination, must be provided with:
 - 7.1.1.1 Imaging frequencies appropriate for the structures evaluated.
 - 7.1.1.2 Doppler frequencies appropriate for the vessels evaluated.
 - 7.1.1.3 Range-gated spectral Doppler with the ability to adjust the depth and position of the range gate within the area of interest.
 - 7.1.1.4 A Doppler angle which is measureable and adjustable.
 - 7.1.1.5 A visual display, an audible output and a permanent recording of the Doppler waveform and corresponding image which includes the Doppler angle.
- 7.1.2 Continuous Wave (CW) and Pulsed Wave (PW) Doppler, if used for screening examination, must be provided with:
 - 7.1.2.1 A direction sensitive Doppler blood flow meter.
 - 7.1.2.2 Doppler transducer frequencies appropriate for the vessels evaluated, which must be at least 3 MHz or greater.
 - 7.1.2.3 Doppler waveform display demonstrating bidirectional flow.
 - 7.1.2.4 An audible output and a permanent recording of the waveform.
- 7.1.3 Cuffs of varying widths appropriate to the limb segment to be evaluated.
- 7.1.4 An appropriate instrument for blood pressure measurement; must be expressed in mmHg.
- 7.1.5 Computerized assisted electronic calipers or semiautomatic edge detection software must be utilized for CIMT.

STANDARD – Equipment quality control

7.2 Equipment used for screening examinations must be maintained in good operating condition.

- 7.2.1 Equipment maintenance must include, but is not necessarily limited to:
 - 7.2.1.1 Recording of the method and frequency of maintenance of all imaging equipment and non-imaging equipment.

7.2.1.2 Establishment of and adherence to a policy regarding routine safety inspections and testing of all laboratory electrical equipment.

7.2.1.3 Establishment of and adherence to an equipment cleaning schedule that includes routine cleaning of equipment parts, including filters and transducers, according to specifications of the manufacturer.

Comment: The cleaning schedule for each system will depend on the degree of use and should be frequent enough to allow for accurate collection of data.

SECTION 8: Protocol

STANDARD – Protocol

8.1 Each screening examination must have a written protocol. The protocol must include:

- 8.1.1 The equipment to be used for screening examination.
- 8.1.2 The elements of proper technique (also see STANDARD – Techniques).
- 8.1.3 The anatomic extent that constitutes a screening examination.
 - 8.1.3.1 Bilateral examination is considered an integral part of a screening examination.
- 8.1.4 The documentation that must be acquired for normal screening examinations and the additional documentation that must be acquired to describe abnormalities, if present (also see STANDARD – Documentation).
- 8.1.5 A description of how color Doppler or other flow imaging modes (e.g. power Doppler) are used to supplement gray scale imaging, spectral Doppler and velocity measurements.

SECTION 9: Techniques

STANDARD – Techniques

9.1 Appropriate techniques must be used for screening examinations to assess for the presence of any abnormalities.

9.1.1 Elements of proper technique include, but are not limited to:

9.1.1.1 Performance of an examination according to the written, laboratory specific protocol.

9.1.1.2 Proper patient positioning.

9.1.1.3 Appropriate equipment selection and placement

9.1.1.4 Optimization of equipment gain and display settings.

9.1.1.5 Appropriate transducer selection.

9.1.1.6 Proper sample volume size and positioning.

9.1.2 For imaging equipment, elements of proper technique include, but are not limited to:

9.1.2.1 A spectral Doppler angle of 60 degrees or less with respect to the vessel wall and/or direction of blood flow when measuring velocities.

9.1.2.2 Proper measurement of spectral velocities as required by the protocol.

9.1.2.3 Identification of vessels by imaging and Doppler.

9.1.2.4 The use of computerized assisted electronic calipers or semiautomatic edge detection software for CIMT measurements.

9.1.3 Ankle brachial index (ABI)

9.1.3.1 Extremity (brachial artery) systolic pressures must be obtained from both arms and the higher of the two pressures used to calculate the ABI.

9.1.3.2 Measurement of ankle systolic pressures must be obtained bilaterally from the distal posterior tibial (PT) artery and distal anterior tibial (AT)/dorsalis pedis (DP) artery and the higher of the two pressures on each side used to calculate the ABI.

SECTION 10: Documentation

STANDARD – Documentation

10.1 All vascular screening examinations must include standard components as required by the protocol and provide sufficient documentation to allow proper interpretation including but not limited to:

- Gray scale images
- Spectral Doppler waveforms
- Velocity measurements
- Other measurements as indicated by the protocol

10.1.1 Extracranial cerebrovascular screening

- 10.1.1.1 Required techniques must include bilateral permanent recordings of spectral Doppler waveforms.
- 10.1.1.2 Normal examination: One site in the proximal internal carotid artery with peak systolic and end diastolic velocity measurements.
- 10.1.1.3 Abnormal examinations: Peak systolic and end diastolic velocity measurements documenting area(s) of significant findings in accordance with screening diagnostic criteria.

10.1.2 Carotid Intima-Media Thickness (CIMT) Screening (see Appendix)

Comment: CIMT has been effectively used as a marker of atherosclerosis in many patient populations, and has also been used as a primary endpoint demonstrating therapeutic efficacy with different pharmacologic therapies. Studies using CIMT to make treatment decisions based on a single IMT measurement, with documentation of the outcome for specific interventions, for individual patients, are lacking. The ICAVL does not advocate use of carotid IMT as a screening method for atherosclerotic risk until further peer-reviewed literature is available. If providers choose to perform CIMT testing, rigorous methodological protocols should be strictly followed.

10.1.2.1 Required techniques must include but are not limited to:

- 10.1.2.1.1 Bilateral measurements obtained during end diastole.
- 10.1.2.1.2 Measurements from at least three longitudinal imaging planes (optimal and two complementary imaging planes – anterior, lateral or posterior to the optimal angle).
- 10.1.2.1.3 Measurements obtained from the far wall of the distal 1-2 cm of the CCA. Measurements may also be obtained from the near wall of the CCA segment, as well as the near and far wall of the bifurcation and the proximal 1 cm of the ICA.
- 10.1.2.1.4 When plaque is present, plaque characterization and/or dimensions should be documented separately.

10.1.3 Peripheral arterial screening:

10.1.3.1 Ankle Brachial Index (ABI)

- 10.1.3.1.1 Bilateral brachial artery systolic pressures
- 10.1.3.1.2 Bilateral ankle systolic pressures

- 10.1.4 Abdominal aorta aneurysm screening:
 - 10.1.4.1 Gray scale images must be permanently recorded of the abdominal aorta.
 - 10.1.4.2 Normal examination: One transverse image at the level of maximum width perpendicular to the long axis of the aorta with documentation of the outer wall to outer wall diameter measurement.
 - 10.1.4.3 Abnormal examination: Transverse view(s) with diameter measurements of the abdominal aorta segment(s) documenting the maximum outer wall to outer wall diameter measurement.
 - 10.1.4.4 One transverse view documenting the outer wall to outer wall diameter measurement of a non-dilated abdominal aorta segment for comparison.

SECTION 11: Diagnostic Criteria

STANDARD – Diagnostic Criteria

11.1 Each vascular screening examination must have a single set of written, validated diagnostic criteria to interpret the presence of disease.

11.1.1 Diagnostic criteria must be screening service specific.

Comment: These criteria can be based on published reports or internally generated and internally validated as outlined in STANDARD – Quality Assurance.

11.1.2 For imaging equipment, for each examination performed there must be diagnostic criteria for the interpretation of:

11.1.2.1 Gray scale images

11.1.2.2 Spectral Doppler waveforms

11.1.2.3 Spectral Doppler velocities

11.1.2.4 Color Doppler images (if used)

11.1.3 For non-imaging equipment, there must be diagnostic criteria for the interpretation of each examination performed.

11.1.4 Each screening examination must have examination specific diagnostic criteria.

11.1.4.1 Extracranial cerebrovascular

11.1.4.1.1 Absence of disease; normal

11.1.4.1.2 Presence of disease with no overall significance; in adherence to the laboratory specific diagnostic criteria.

11.1.4.1.3 Presence of disease with overall significance; in adherence to the laboratory specific diagnostic criteria.

11.1.4.1.4 Occlusion

11.1.4.2 Carotid intima-media thickness screening: CIMT

11.1.4.2.1 Age, gender and race associated risk according to a standardized table of CIMT measurements should be used to generate a cardiovascular risk assessment report.

11.1.4.2.2 The report should include standard deviations or prediction ranges for the measurements based on age and gender.

11.1.4.2.3 Specific measurement values (i.e. mean, maximum, mean maximum) used for the risk prediction report should be the same as those used in the study(s) providing the basis for the risk prediction reporting.

11.1.4.2.4 Plaque characteristics and dimensions should be reported separately.

- 11.1.4.3 Ankle brachial index
 - 11.1.4.3.1 Absence of disease; in adherence to the screening service specific criteria
 - 11.1.4.3.2 Presence of disease; in adherence to screening service specific criteria
 - 11.1.4.3.3 Non-diagnostic ABI
- 11.1.4.4 Abdominal aorta aneurysm
 - 11.1.4.4.1 Absence of aneurysmal disease; in adherence to the screening service specific criteria
 - 11.1.4.4.2 Presence of aneurysmal disease; in adherence to the screening service specific criteria
 - 11.1.4.4.3 Aneurysmal status not defined due to non-visualization

SECTION 12: Interpretation

STANDARD – Interpretation

- 12.1 Interpretation using the documented findings and the diagnostic criteria must be performed by the Medical Director or a member of the medical staff to indicate the absence or presence of abnormalities in the sites and vessels that were examined.
- 12.1.1 A report or documentation that describes the results of the screening examination findings and recommended follow up must be provided to the participant and/or the participant's physician.
- 12.1.2 Educational materials describing the nature of vascular screening and the significance of normal and abnormal results must be provided to the participant.
- 12.1.3 Documentation of all screening results both negative and positive must be maintained in the laboratory.

SECTION 13: Quality Assurance

STANDARD – Quality Assurance

13.1 Quality assurance must be performed.

- 13.1.1 There must be a written policy regarding quality assurance for all screening examinations performed.
- 13.1.2 Results of screening examinations must be regularly correlated with other imaging modalities, complete diagnostic noninvasive vascular examination, angiographic and/or surgical findings as described below.
 - 13.1.2.1 The correlation must be reported using the comparison of the results of the screening examination and the results of the validating study with regard to the presence or absence of disease as defined by the diagnostic criteria utilized by the screening service.
 - 13.1.2.2 A minimum of 50 screening examinations per each type of screening performed must be correlated.

There must be a minimum of five (5) correlations from each screening team within the unit. (Example: A unit with only four teams would be required to submit 50 correlations for each type of screening examinations performed, with at least five from each team. A unit with 12 teams would be required to submit 60 correlations for each type of screening examination performed with at least five from each team).

Comment: The time interval between the vascular laboratory examination and the correlative study for quality assurance purposes should be appropriate for the disease being correlated. For diseases which may change rapidly (e.g. vasospasm), a short time interval is appropriate. For diseases which generally change more slowly (e.g. atherosclerosis) and where there has been no change in signs or symptoms, a longer interval is acceptable. Many current clinical trials of atherosclerotic disease accept a 90-120 day interval between an imaging study and enrollment. Confirmation of a normal vessel also may have a longer interval before correlation is performed. If the patient's signs or symptoms change in the interval between the vascular laboratory examination and the correlative study, comparison of these studies is not an acceptable quality assurance mechanism.

13.1.2.3 For CIMT: Acceptable methods for mandatory correlation include:

- 13.1.2.3.1 Repeat examination
 - 13.1.2.3.2 Over-reading including recalculation of the IMT
- 13.1.3 The correlation log must demonstrate greater than 70% accuracy agreement.
 - 13.1.4 Documentation of correlation must be maintained.
 - 13.1.5 Correlation data for each type of screening examination must include participants with normal and abnormal findings.

Comment: The correlations submitted must have been completed within the three years preceding submission of the application. If the screening service is unable to obtain the minimum number of correlations, alternative methods for QA may be considered on an individual basis. The screening service must submit the written plan of action for documentation of ongoing quality measures to assess the accuracy of examinations.

- 13.1.6 Procedures must be in place for ongoing dissemination of correlation findings and other relevant information to both medical and technical staff members.

STANDARD – Quality Assurance Meetings

13.2 A minimum of two vascular laboratory quality assurance meetings per year must be held to:

- 13.2.1 Review the results of comparative studies
- 13.2.2 Address discrepancies
- 13.2.3 Discuss difficult cases
- 13.2.4 Address laboratory quality assurance issues
- 13.2.5 Minutes of the quality assurance meetings must be maintained

SECTION 14: Procedure Volumes

STANDARD – Procedure Volumes

14.1 The annual procedure volume must be sufficient to maintain proficiency in examination technique and interpretation.

Comment: In general, a screening unit should perform a minimum of 300 screening examinations per examination section annually.

14.1.1 Records must be maintained that permit evaluation of annual screening volumes.
The records must include information on:

14.1.1.1 Examinations(s) performed

14.1.1.2 Findings

APPENDIX

Carotid Intima-Media Thickness (IMT) ICAVL Executive Summary

A. IMT: Common Carotid Artery vs. Other Segments

Carotid IMT measurements are commonly obtained from the common carotid artery (CCA), as this vessel offers the easiest standardization due to its location, tubular shape, and parallel walls in most patients. In the Atherosclerosis Risk in Communities (ARIC) study involving carotid ultrasound examinations in 13,824 individuals, IMT measurements were obtainable from the CCA in 91.4%, from the bifurcation in 77.3%, and from the internal carotid artery (ICA) in 48.6% of participants¹.

In addition, use of the CCA IMT has correlated well with prevalent cardiovascular disease and/or outcome. In the Cardiovascular Health Study (CHS), the combination of CCA and ICA IMT resulted in similar relative risks for subsequent myocardial infarction or stroke than did CCA or ICA IMT alone (1.36 vs. 1.27 and 1.30, respectively, for 1 SD increase)². Based on the ease of imaging and the general correlation with cardiovascular disease and clinical events, use of the CCA is generally advised to measure the IMT.

Some advocate evaluation of a broader/more widespread selection of arterial segments to provide a more stable and robust prediction of risk. Therefore IMT measurements must be obtained from the far wall of the distal 1-2 cm of the CCA, and may also be obtained from the near wall of the CCA segment, as well as the near and far wall of the bifurcation, and the proximal 1 cm of the ICA.

B. IMT: Far Wall vs. Near Wall

The IMT may be measured from the near (closest to the transducer) and/or the far wall. Although measurement reproducibility of the near and far walls has been reported to be comparable³, measurement yield of the near wall is lower⁴ and accuracy may be less than that of the far wall due to technical considerations. Therefore, measurement is best obtained from the far wall of the CCA, and is commonly taken from the distal 1-2 cm of the distal CCA, proximal to the flow divider⁵.

C. IMT: B-mode vs. M-mode Measurement

IMT has most commonly been measured from B-mode images. Alternatively, B-mode guided M-mode images of the distal CCA may be obtained. Whatever the method, because of the very small diameter of the intima-media layer, wall thicknesses should be measured using computer assistance with electronic calipers or semi-automated edge-detection algorithms⁶.

D. IMT: Timing of Measurement

Variations in IMT and lumen diameter must be anticipated, and therefore, electrocardiographic-gating and/or determination of minimal (end-diastolic) and maximal (peak-systolic) diameters are important components of IMT measurements. With systolic expansion of lumen diameter, obligatory thinning of IMT will occur through conservation of mass (although some degree of longitudinal stretch will occur)⁷. Therefore, measurements must be obtained at the identical timing of the cardiac cycle (preferably at end-diastole) within a particular lab so as to avoid these physiologic changes.

E. Definition of Abnormal IMT

IMT increases with age and, on average, is larger in men than women⁸. In addition, modest racial differences in IMT have been reported⁹. Thus, a single threshold value for abnormality, e.g., 1 mm, may result in systematic under-detection of abnormality in younger individuals and over-detection in older individuals. Therefore, a standardized table of IMT measurements accounting for age, gender, and race must be used to determine the true value of single IMT measurements. The extent to which carotid intimal-medial thickening is a manifestation of early or diffuse atherosclerosis, as opposed to smooth muscle hypertrophy and/or hyperplasia induced by pressure overload and/or age-related sclerosis, remains uncertain.

Internal diameter of the vessel lumen (usually the CCA) can be measured at a single point in time from B-mode images, and determination of minimum and maximum lumen diameters is mandatory for assessment of vascular mechanics¹⁰.

F. Non-Obstructive Plaque

Plaque characterization or dimensions should not be incorporated into IMT measurements, and must be reported separately in those cases where plaque is present¹¹. Plaque is defined as:

- i. Focal structure encroaching in the lumen >0.5 mm OR
- ii. 50% of the surrounding intima-media thickness OR
- iii. Plaque thickness >1.5 mm.¹²

Process

Carotid IMT measurements should be performed by technologists with training and experience in vascular ultrasound testing. IMT measurements are obtained with the patient in the supine position with the neck slightly hyperextended and the head rotated to the opposite side. High frequency ultrasound probes are used, with a frequency of >7 MHz. Measurements are obtained in the distal CCA, 1-2 cm from the flow divider, in the far wall, using automated edge detection software, commonly available from ultrasound manufacturers. Measurements should be obtained from both vessels. Plaque should be reported separately from the IMT measurements. IMT measurements should ideally be reported using tables that account for age, race, and gender. Laboratories must submit internally validated diagnostic criteria based on their experience and published literature. In addition, laboratories must develop patient education tools that will assist in educating patients on the meaning of the carotid IMT and the importance of risk factor intervention to modify cardiovascular risk.

Finally, all laboratories must provide details of their internal quality assurance programs to support the performance of carotid IMT measurements.

Summary

CIMT has been effectively used as a marker of atherosclerosis in many patient populations, and has also been used as a primary endpoint demonstrating therapeutic efficacy with different pharmacologic therapies. Studies using CIMT to make treatment decisions based on a single IMT measurement, with documentation of the outcome for specific interventions, for individual patients, are lacking. The ICAVL does not advocate use of carotid IMT as a screening method for atherosclerotic risk until further peer-reviewed literature is available. If providers choose to perform CIMT testing, rigorous methodological protocols should be strictly followed.

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