Data Support Document
cIMT Measurement

1.0 PURPOSE AND SCOPE

Carotid ultrasound has been routinely used for the evaluation of ischemic cerebrovascular signs and symptoms. In the utilization of carotid ultrasound in the context of risk stratification, the carotid intima-media thickness (cIMT) is measured for the objective of detecting preclinical or subclinical cardiovascular disease. Measurement of the cIMT is considered to be a surrogate marker for the measurement of carotid artery atherosclerosis, which correlates with the presence of coronary atherosclerosis. This procedure measures the thickness of the carotid artery wall (between the innermost layer of the artery, the intima, and the middle layer of the artery, the media)[1].

The cIMT and plaque scans were collected in the Canadian Longitudinal Study on Aging (CLSA) Comprehensive cohort, comprised of more than 30,000 participants from across Canada, who were 45-85 years old at recruitment [2,3]. Image files and raw data from the carotid ultrasound scanners may be available on special request. For more information on the CLSA, data previews, and on how to request data through the CLSA, refer to the CLSA website, at www.clsa-elcv.ca.

2.0 INSTRUMENTS AND METHODOLOGY

2.1. Data Collection

To ensure consistency across all Data Collection Sites (DCS) the CLSA developed the standard operating procedure: *SOP_DCS-0011 – Carotid Intima-Media Thickness*[4].

The cIMT measurement was performed at the DCS on participants who were able to stand without the assistance of another person. The measurement was completed using the GE VIVIDi machine (model number 905521), 3 Meditrace Foam 230 electrodes, and Aquasonic Ultrasound gel. (*Note: CLSA was provided 20 cases (600/case) of IVY ECG Electrodes (Item number E8007RG) in kind from our VIVIDi equipment supplier; these electrodes were used to complete approximately the first 4000 participant measurements.*)
The participant was required to lie on the exam bed for at least 5 minutes before the measurement was taken.

All contraindications for a participant not being eligible to take a cIMT ultrasound measurement were detailed in *SOP_DCS-0011 – Carotid Intima-Media Thickness* [4] and the CLSA Interpretation and Contraindications Questionnaire (Comprehensive) document [5].

All changes to the collection of the measurement were detailed in *SOP_DCS-0011 – Carotid Intima-Media Thickness* revision history [4].

2.2. Available Data Overview

The following images and data were captured [6]:

- Right & left cIMT – 5 images for each side
  - Cineloop (3 consecutive cardiac cycles)

  - One still image
  - One (SR) Structured Report file
- Right & left plaque sweep

The alphanumeric data from Baseline data collection were available as of Fall 2017, as part of the CLSA Data and Bio-specimen Request Application. Image files and raw data from the carotid ultrasound scanners are available by special request. Please contact the CLSA via access@clsa-elcv.ca for more information on how to access these data.

The following baseline data are available to researchers:

- Exam time, date and side.
- The cIMT image(s)
- The CLSA Quality Control (QC) rating of the cIMT image(s) (see below for overview of this QC rating).
- Plaque sweep(s)
- Measurement(s):
  - IMT posterior nmeas: the number of discrete intima media thickness measurements
  - IMT posterior sd: standard deviation of the measurements (mm)
  - IMT posterior min: minimum measurement value (mm)
  - IMT posterior max: maximum measurement value (mm)
  - IMT posterior average: average measurement value (mm);

An overview and summary of alphanumeric variables for the cIMT measurement can be located on the Data Preview Portal at https://datapreview.clsa-elcv.ca/.

The Data Preview Portal also contains information on the total number of participants who completed, skipped or were contraindicated for the measurement.

3.0 DATA PREPARATION

Alphanumeric data were reviewed for completeness and compatibility and formatted into a .csv file format. An indicator variable was added indicating whether the extraction of alphanumeric data attached to the still image was possible for each identifier. Impossible 0 values of measurements were replaced by missing value codes.

4.0 QUALITY

4.1. Quality Assurance

The CLSA Data Curator along with members of the Quality Assurance Committee performed a monthly review of the sizes of all cIMT image files collected. The purpose of the review was to identify anomalies such as unusually small or exceedingly large image files, which could suggest problems with image quality. The reviewer notified the NCC Comprehensive Research Coordinator of any file size anomalies and they discussed these issues with the DCS Coordinators, the IT specialists and the expert reviewers to identify the source(s) of the anomalies and implemented corrective actions.

As part of the CLSA quality assurance (QA) process, a team of experts reviewed approximately 10 images per DCS, randomly selected, on a monthly basis. These images were rated for

quality as described in the *Quality Check for cIMT Rating Information Document*. DCSs were provided feedback regarding the quality of the scans reviewed and further individual staff training was provided, when required.

Some of the errors identified by the QA process include:

- Good image, with analysis box(es) in the wrong spot(s).
- Clear image of the artery but no IMT present.
- Interviewers were not analyzing the best frame; the
  - Frozen single frame (not analyzed) was different than the single frame analyzed.
  - Unanalyzed frame should have been analyzed.
- The focus point needed to be moved to the far wall of the cIMT in the image.
- Contrast needed to be adjusted to ensure that the cIMT was clearly visible.

NOTE: Requests for a copy of the *Quality Check for cIMT – rating* algorithm can be sent to access@clsa-elcv.ca if required upon receipt of data.

Please note that only the cIMT images were reviewed by the QC team. The plaque images were not reviewed. Furthermore, plaque images and measurements will not be collected beyond the baseline visit.

4.2. Quality Control

All images had a quality assurance rating completed using the *Quality Check for cIMT – rating information*, completed prior to releasing the data to researchers. The rating determined if an image is good, re-analyzable or not usable. This Quality Check rating was provided to approved users along with the image data.

NOTE: Requests for a copy of the *Quality Check for cIMT – rating* algorithm can be sent to access@clsa-elcv.ca if required upon receipt of data.

5.0 CONDITIONS OF USE

Conditions of use for alphanumeric data are described in the CLSA data access agreement.

6.0 REFERENCES

1. Global. Cigna Medical Coverage Policy Subject Carotid Intima-Media Thickness Measurement. Available at: https://cignaforhcp.cigna.com/public/content/pdf/coveragePolicies/medical/mm_0475_coveragepositioncriteria_carotid_intima_media_thickness.pdf. (Accessed: 21st July 2017)

2. Wolfson, R. & Kirkland. CANADIAN LONGITUDINAL STUDY ON AGING (CLSA) PROTOCOL: Canadian Longitudinal Study on Aging Protocol. *Canadian Longitudinal Study on Aging Protocol* Available at: https://clsa-elcv.ca/doc/511. (Accessed: 21st July 2017)

3. CLSA Follow-Up 1 Renewal Protocol. Available at: https://www.clsa-elcv.ca/doc/519. (Accessed: 21st July 2017)

4. SOP_DCS_0011 Carotid Intima Media Thickness. Available at: https://www.clsa-elcv.ca/doc/522. (Accessed: 21st July 2017)

5. Data Collection Site Questionnaires (Comprehensive). Available at: https://clsa-elcv.ca/doc/1122. (Accessed: 21st July 2017)

6. Physical assessments collected in the Canadian Longitudinal Study on Aging (CLSA). Available at: https://www.clsa-elcv.ca/doc/1309. (Accessed: 21st July 2017)