

IV. Medical Examination Manuals

G. Neurology

1. Introduction

- a. This manual is written for neurologists performing examinations for the Veterans' Health Study. It is an adjunct for the data entry process to be completed during the examination period. The examination represents a portion of a specialized protocol. It is intended for a particular purpose, is designed to be highly reproducible, and is not meant to be exhaustive. This manual was developed to increase reproducibility and decrease interobserver variability. The examiner is expected to adhere to these general Guidelines and Directions.
- b. For additional information related to data entry see Section 3. Data Management. Comments of findings which otherwise would go unnoted should be handwritten on the "Comments to Diagnosticians" form. This will allow not only the appropriate medical findings to be conveyed to the Diagnosticians, but also allow the CDC to revise the questions to reflect recurring, but non-codable findings.
- c. Much of the manual is based on testing procedures described in standard references. Of particular importance in compiling the instructions incorporated in this Manual were:
 - (1) Members of the Department of Neurology and the Department of Physiology and Biophysics, Mayo Clinic and Mayo Foundation, University of Minnesota, Rochester, eds. Clinical examinations in neurology. 5th ed. Philadelphia: WB Saunders, 1981.
 - (2) DeJong RN. The neurologic examination. 4th ed. Hagerstown, MD: Harper and Row, 1979.
- d. Under most circumstances, the examination is to be initiated and conducted with participant in a sitting position, relaxed, and with legs dangling from the examining table. Abdominal and Babinski reflexes are to be tested in the supine position. Romberg and gait testing are to be done at the end of the test. All items are to be entered onto the data collection form before the participant leaves the examining room.
- e. Some determinations (e.g., weakness, stretch reflexes) are based on the examiner's best assessment, recognizing differences such as general habits, specific muscle mass, handedness and degree of relaxation. In this examination, the method of testing strength is that of the participant resisting pressure initiated by the examiner. Decreased strength is defined as that which is less than expected in an individual participant, taking into

account the differences mentioned above, and also comparison with the power in the contralateral muscle groups.

2. The Neurology Examination

a. Cranial Nerves

(1) Smell

Olfaction is tested using a small vial of coffee, easily smelled by the examiner. Participant alternately closes one nostril and sniffs the vial, held about one-half inch from the open nostril. He is asked to identify the odor; if this is not possible, simple appreciation of "a definite smell" is considered sufficient to exclude anosmia.

1. Normal 2. Abnormal 8. Don't know

Right [] Left []

(2) Visual fields

(a) Only peripheral confrontation visual field testing and ophthalmoscopy of the optic disc region is to be done. The examiner closes his/her own eye, the participant places a card over the ipsilateral eye and is instructed to fix his gaze on the open eye of the examiner. The participant is instructed to say "now" when he first sees the moving finger of the examiner, who slowly introduces his moving forefinger into the four fields of vision of each eye. The examiner utilizes his own field of vision as a control. He/She stands approximately 1.0 meter away with his open eye directly in front of the contralateral open eye of the participant, and moves his finger equidistant from the eye of the examiner and the participant.

(b) For purposes of recording, the visual fields are divided into quadrants as though the participant were looking at the examiner:

Right Eye 1= upper, outer quadrant
 2= upper, inner quadrant
 3= lower, outer quadrant
 4= lower, inner quadrant

Left Eye 5= upper, inner quadrant
 6= upper, outer quadrant
 7= lower, inner quadrant
 8= lower, outer quadrant

More than one numeral is possible, e.g., a homonymous hemianopsia would be recorded (1,3,5,7).

Right defect	[]	$\frac{1}{3}$	$\frac{2}{4}$
Left defect	[]	$\frac{5}{7}$	$\frac{6}{8}$

(3) Optic disc

Examination of the fundus is done with an electric ophthalmoscope and without the participant wearing correcting lenses. Participant is instructed to focus his gaze on the opposite wall. The optic disc is examined for evidence of either papilledema or atrophy. Criteria for papilledema include: blurring and elevation of disc margins, absence of physiologic cup, venous dilation and absence of pulsation and hemorrhages at disc margin. "Primary" optic atrophy (resulting from involvement of optic nerve per se) produces a white disc with sharply outlined borders, a visible lamina cribosa, and may involve only a portion of the disc. "Secondary" optic atrophy (a sequel to papilledema) is manifested by a grayish-white disc with blurred margins, invisible lamina cribosa and always involves the entire disc.

OPTIC DISC: 1. Normal 2. Atrophy 3. Papilledema 4. Other (Specify)

Right [] Left []

(4) Pupil size Right [] Left []
(in millimeters)

(5) Light reaction

Pupillary reaction to light is tested by instructing the participant to focus his gaze on a point on the opposite wall and abruptly shining a light from the side into the participant's eye. The light source is the special examination arm of an electric ophthalmoscope-otoscope. If pupillary constriction occurs in one second or less, it is to be recorded as NORMAL; within 10 seconds as SLUGGISH; and after 10 seconds as NONE.

Pupillary Reaction to Light: 1. Normal 2. Sluggish 3. None

Right [] Left []

- (6) Ptosis 1. Absent 2. Partial 3. Complete

Ptosis is narrowing of the palpebral fissure secondary to drooping of the upper eyelid. Asymmetry is noted by differences between the margins of the upper eyelid and iris. Significant incomplete ptosis is considered due to a Horner's Syndrome or a palsy of cranial nerve III. In Horner's Syndrome there is also an ipsilateral constriction, while a defect of cranial nerve III may be associated with dilation.

- (7) Ocular mobility 1. Normal 2. Strabismus 3. Dysmetria
4. Nerve/Muscle/Gaze Paresis 5. Other (Specify)

Right [] Left []

- (8) Nystagmus

Nystagmus is here defined as involuntary to and fro movement of the eyes which has a quick and slow phase, is sustained for more than two seconds, and is present when gazing within the limits of binocular vision.

NYSTAGMUS 1. None 2. Horizontal 3. Vertical
4. Rotary 5. Other (Specify)

Right [] Left []

- (9) Jaw strength

The motor portion of cranial nerve V is tested by clenching the jaws tightly and palpating the masseter muscles and by asking the participant to deviate his jaw to the right or left. It is recorded as follows:

JAW STRENGTH [] 1. Normal 2. Weak Right 3. Weak Left
4. Weak bilaterally 5. Other (specify)

- (10) Jaw jerk

The participant's jaw should be relaxed and half-opened. The Examiner's finger is pressed downward on the chin and the finger percussed. The reflex is normally difficult to obtain.

JAW JERK [] 1. Normal 2. Increased

(11) Facial pain perception

The sensory portion of cranial nerve V is tested in all three portions for pain and by testing the corneal reflex. Pain sensation is tested in all three portions of cranial nerve V by asking the patient to differentiate between the sharp and dull end of a sharp safety pin.

FACIAL PAIN (pinprick) perception 1. Normal 2. Increased
3. Decreased 4. Absent 5. Other (Specify)

Right []	Left []	Ophthalmic
Right []	Left []	Maxillary
Right []	Left []	Mandibular

(12) Corneal reflex

The corneal reflex is tested with a wisp of cotton drawn out onto a fine point. The participant is requested to look up and out with the outer portion of the cornea touched from the direction opposite to the direction of gaze. All of the above tests are to be repeated until the examiner is able to make a judgment and record appropriately.

CORNEAL REFLEX 1. Normal 2. Decrease 3. Absent
4. Other (Specify)

Right [] Left []

(13) Facial muscles

Strength is tested by asking the participant to smile, close his eyes tightly, wrinkle his forehead and attempt to whistle. He is instructed to blow out his cheeks fully while the examiner presses against them for an escape of air from either side. Supranuclear (upper motor neuron) and lower motor neuron weakness is differentiated by the inability to wrinkle the forehead normally on the involved side in lower motor neuron weakness (Bell's palsy).

FACIAL MUSCLE STRENGTH 1. Normal 2. Upper motor neuron weakness
3. Lower motor neuron weakness 4. Tics
5. Chorea 6. Other (Specify)

Right [] Left []

(14) Palate motion with phonation

The participant is instructed to say "Ahhhhh" while the tongue is gently depressed with a tongue blade and the

examiner notes the movement of the soft palate. Normally, the median raphe rises in the midline; in unilateral weakness, there is lowering and flattening of the palatal arch deviation to the intact side. The participant is asked to swallow since, with bilateral dysfunction, there may be difficulty in swallowing. The presence or absence of palatal myoclonus (60 plus/minute lateral or up and down movement of palate and/or pharyngeal muscles) is noted.

PALATE MOTION WITH PHONATION [] 1. Normal
2. Absent 3. Deviates right 4. Deviates left 5. Palatal myoclonus 6. Other (Specify)

(15) Gag reflex

The examiner depresses the tongue with a tongue blade and gently touches one, and then the other side of the posterior pharyngeal wall with a cotton swab. A normal response is prompt contraction of the pharyngeal muscles, with or without an actual gagging response.

GAG REFLEX [] 1. Normal 2. Depressed right
3. Depressed left 4. Depressed bilaterally

(16) Accessory nerves

The sternocleidomastoid muscle is tested by instructing the participant to turn his head forcibly against the examiner's hand (away from the muscle being tested) while the SCM is palpated. Trapezius function is tested by asking the participant to shrug his shoulders while the examiner attempts to depress them. The participant then elevates his anteriorly positioned and outstretched arms against resistance.

ACCESSORY NERVE FUNCTION 1. Normal 2. Weak SCM
3. Weak trapezius 4. Weak SCM and trapezius 5. Other (Specify)

(17) Tongue motion

The participant is asked to protrude the tongue and also to push laterally against a tongue depressor placed against the side of the tongue. In unilateral dysfunction there is deviation of the tongue to the side of the lesion and weakness in pushing to the opposite side. Myoclonus or unilateral atrophy are to be recorded.

TONGUE MOTION [] 1. Normal 2. Weakness
3. Other (Specify)

Right [] Left []

b. Motor Systems

(1) Amputation/losses

AMPUTATION/LOSSES 1. Hand 2. Arm 3. Fingers
4. Leg 5. Foot 6. Other (Specify)

Right [] Left []

Self explanatory

(2) Gait

(a) Gait is examined with the participant barefoot. He is asked to walk across the examining room in his "normal fashion", making at least two 180 degree turns. He is then to walk heel to toe, or "in tandem", across the room. Walking is tested repeatedly until the examiner is satisfied.

(b) Abnormalities of gait are herein defined as follows:

(i) Hemiparetic

Dragging, abduction and circumduction of the weak leg, with lack of freedom of movement in all joints.

(ii) Spastic

Abnormal flexion and stiffness of lower extremities with bilateral circumduction, sometimes resulting in "scissoring"; there may be compensatory movements of the upper extremities.

(iii) Ataxic

Wide base, with clumsiness and uncertainty, uneven spacing of steps and a tendency to sway, lurch, stagger or totter; may be a tendency to guide the steps by watching the floor, especially with loss of position sense; with cerebellar disease, the extremities may appear "loose", with uncoordinated, then overcompensated movement.

(iv) Parkinsonian

Difficulty in initiating movement, short and shuffling steps, flexion of body and extremities, and sometimes anteropulsion. Frequent diminution in associated arm movements, often other clinical features of Parkinsonism. Abnormality may be unilateral.

(v) Foot drop

Asymmetrical lifting of the foot on the affected side resulting from increased flexion at the hip and knee, sometimes producing a "slapping" gait. Features of spasticity are absent.

GAIT [] 1. Normal 2. Abnormal (If normal, skip to "arm swing".)

RIGHT: 1. Absent 2. Present

Hemiparetic []
Spastic []
Ataxic []
Parkinsonian []
Foot Drop []
Other [] (Specify)

LEFT: 1. Absent 2. Present

Hemiparetic []
Spastic []
Ataxic []
Parkinsonian []
Foot Drop []
Other [] (Specify)

(3) Arm swing

The arm swing is noted as part of gait testing when the patient is walking "normally." It may be reduced as part of a hemiparetic or parkinsonian gait. "Other" is checked when arm swing is not normal, secondary abnormality, unusual movements or posturing, amputation, etc.

ARM SWING 1. Normal 2. Reduced 3. Other (Specify)

Right [] Left []

(4) Tandem gait (See "GAIT" above.)

TANDEM GAIT [] 1. Normal 2. Abnormal

(5) Station

Participant is asked to stand with his feet close together, head erect, and eyes open and then closed. Unusually marked swaying or tendency to fall with eyes closed is so noted.

STATION [] 1. Normal 2. Abnormal

Eyes open [] Eyes closed []

(6) Muscle consistency

Muscle consistency is here defined as an abnormality detected either with palpation or with passive movement. Palpation may reveal significant focal or diffuse flabbiness, doughiness, or firmness.

CONSISTENCY [] 1. Normal 2. Abnormal (If normal, skip to "atrophy".)

1. Absent 2. Present

right hand	[]	left hand	[]
right arm	[]	left arm	[]
right leg	[]	left leg	[]
trunk	[]	neck	[]

(7) Muscle "tone"

Passive movement of the participant's extremities is used to detect the increased tone of spasticity (a characteristic "catch") or rigidity ("lead pipe" or "cogwheel").

MUSCLE "TONE" [] 1. Normal 2. Abnormal

If abnormal, then [] 1. Rigid 2. Spastic
3. Chorea 4. Athetosis

right hand	[]	left hand	[]
right arm	[]	left arm	[]
right leg	[]	left leg	[]
right trunk	[]	left trunk	[]

(8) Atrophy

Atrophy is defined as abnormally decreased bulk and for purposes of this exam DOES include congenital absence of muscle or failure of muscle development. Palpation and inspection of muscle are used with contralateral comparison.

ATROPHY	[]	1. Absent	2. Present
Right hand	[]	Left hand	[]
Right arm	[]	Left arm	[]
Right leg	[]	Left leg	[]
Trunk	[]	Neck	[]

(9) Strength

Strength is tested with the participant sitting upright. He is instructed to resist maximally, the pressure initiated by the examiner. Individual muscles or muscle groups are tested as follows:

(a) Deltoids

The arm is abducted almost to the horizontal with the participant resisting the examiner's effort to depress the limb at the elbow.

(b) Triceps and Biceps

The forearm is placed in half flexion and the participant is instructed to resist the examiner's effort to further flex and extend, respectively, the extremity.

(c) Wrist Extensors

The participant extends (dorsiflexes) his wrist maximally and then resists the examiner's efforts to flex the wrist ventrally.

(d) Grip

The participant is asked to grip two or three of the examiner's fingers.

(e) Finger Abductors

The participant partially extends his arms and fully abducts the fingers, resisting the examiner's effort to adduct them by pressing on thumb and 5th finger.

(f) Hip Flexors

The participant is instructed to flex the hip maximally and resist the examiner's efforts to depress the leg by pushing at the knee.

(g) Knee Extensors

The participant fully extends the leg at the knee and resists the examiner's efforts to flex the limb.

(h) Foot Dorsiflexors

The participant dorsiflexes the foot, resisting the examiner's efforts to plantar flex and invert the foot.

(i) Foot Plantar Flexors

The participant plantar flexes the foot, resisting the examiner's efforts to dorsiflex the foot.

(j) Toe Extensors

The participant stabilizes his foot in a neutral position and resists the examiner's efforts to flex the toes.

STRENGTH 1. Normal 2. Decreased right
3. Decreased left 4. Decreased bilaterally

Deltoids	[]	Biceps	[]
Triceps	[]	Wrist extensors	[]
Grip	[]	Finger abductors	[]
Hip flexors	[]	Knee extensors	[]
Knee flexors	[]	Foot dorsiflexors	[]
Foot plantar flexors	[]	Toe extensors	[]

(10) Tremors

Tremors are defined as relatively rhythmic, oscillatory movements involving alternate contractions of opposing muscle groups. The following definitions are to be used:

(a) Parkinsonian Tremor

Occurs particularly in an attitude of repose (at rest) and is diminished with movement. The tremor frequency is ordinarily at 3-8 cps, is greater distally and often associated with increased tone.

(b) Essential (Familial) Tremor

Is ordinarily absent at rest, occurring with movement and, unlike parkinsonian tremor, is intensified rather than suppressed by voluntary motion, and may be increased toward the termination of a movement.

(c) Cerebellar

Tremor is initiated with movement and is accentuated near the termination of the movement (intention or action tremor).

(d) Anxiety

Is rapid and often of low amplitude in participants who are nervous and tense, or are reacting to the stress of the examination.

(e) "Other"

For purposes of this examination, this should be checked if there is rubral tremor (proximal and rhythmic); irregular flapping movement of liver disease; the "wing--beating" of Wilson's disease; or dystonia, chorea or athetosis.

TREMORS 1. Absent 2. Parkinsonian 3. Essential
4. Cerebellar 5. Other (Specify)

Right arm [] Left arm []
Right leg [] Left leg []

(11) Finger-nose ataxia

Finger-nose ataxia is tested by instructing the participant to keep his eyes OPEN and begin from a position of full extension at the elbow with the upper arm in the horizontal plane. He is then asked to bring his index finger slowly to his nose, return to the starting position and repeat the sequence as necessary.

FINGER-NOSE ATAXIA [] 1. None 2. Right
3. Left 4. Right and Left

(12) Hand pronation/supination

The participant is instructed to pronate and supinate his hands rapidly on his own thighs.

HAND PRONATION/SUPINATION [] 1. None 2. Right
3. Left 4. Right and Left

(13) Heel-shin ataxia

Heel-shin ataxia is tested in the SUPINE position by instructing the participant to stabilize his foot in the

dorsiflexed position, place his heel precisely on the opposite knee and slide the heel smoothly down the shin toward the great toe and then back to the knee.

HEEL-SHIN ATAXIA [] 1. None 2. Right 3. Left
4. Right and Left

(14) Arm drift

Arm drift is tested by instructing the participant to hold his arms forward and at a 90 degree position with his palms facing upward and his eyes closed for 20 seconds.

ARM DRIFT [] 1. None 2. Right 3. Left
4. Right and Left

(15) Finger tap

The participant is asked to tap the interphalangeal joint of the thumb with the tip of the index finger of the same hand as rapidly and smoothly as possible.

FINGER TAP [] 1. Normal 2. Right Abnormal
3. Left Abnormal 4. Both Abnormal

(16) Excess rebound

Excess rebound is considered partly related to hypotonia and partly to dyssynergia of opposing muscle groups. For this examination, the participant is asked to flex his arm against resistance offered by the examiner. The examiner protects the participant's face and neck with his opposite arm, and then suddenly releases his own efforts to extend the arm.

EXCESS REBOUND [] 1. None 2. Right 3. Left
4. Right and Left

(17) Speech

Speech abnormalities will ordinarily be evident with contextual speech. Dysarthria is defined as a deficit in articulation. This may become more obvious with test phrases. The participant is asked to repeat: "around the rugged rock the ragged rascal ran, third riding artillery brigade, methodistepiscopal"; and "la-la-la-la". Aphasia may be primarily sensory, motor, or mixed. It is recorded when the participant fails to comprehend simple instruction without other neurosensory deficit, or converses in jargon; understands, but is unable to reply, or only with slow hesitant, or substitutive speech. Anomia is considered a

manifestation of aphasia and is tested by asking the participant to name different parts of a watch (i.e., face, stem, band) and pen (i.e., point, cap, clip). Stuttering is herein defined as faltering or interrupted speech with difficulty in enunciating syllables, and joining them together. There may be habitual and spasmodic repetitions of consonants or syllables, alternating with pauses. Stammering is very similar, but with involuntary hesitations during which the participant would be unable to utter the expected sound. Stammering also may indicate embarrassment, while stuttering is considered more severe.

SPEECH [] 1. Normal 2. Dysarthric 3. Aphasic
4. Stammer/Stutter 5. Other (Specify)

(18) Other motor condition

Under "other motor conditions" can be recorded diverse information related to the participant's motor activity, i.e., sprained ankle, fractured wrist, disabling arthritis, etc.

OTHER MOTOR CONDITIONS [] 1. Absent 2. Present
(Specify)

c. Reflexes

Accurate elicitation of the stretch reflexes depends on several factors, of which the most important are: participant relaxation, proper positioning of the extremity to achieve the optimal degree of muscle tension by passive stretching and application of a proper stretch stimulus. Reinforcement maneuvers are not to be done. Participant is to be in the sitting position with legs dangling from the examining table.

(1) Clonus is defined as repetitive reflex activity when the muscle is kept under tension. It is to be sought when the participant has grade 4 activity in the ankle or knee jerks, when tested in the usual fashion. Ankle clonus is tested in the sitting position with the participant instructed to relax the extremity and the examiner then sharply dorsiflexing the foot, maintaining upward pressure for a few seconds. Clonus of the knee is elicited by placing the patient in a supine position and sharply moving the patella downward toward the great toe, maintaining pressure for a few seconds. Unsustained clonus is herein defined as fewer than 5 beats.

(2) Biceps Reflex

The participant's arms are to be slightly flexed with forearms and hands resting on the thighs. The biceps tendon

is palpated in the antecubital fossa with the examiner's thumb, and the thumbnail then struck briskly with a reflex hammer.

(3) Triceps Reflex

Participant's arms are to be partially flexed and then held akimbo on the hips. The tendon of insertion above the elbow is tapped and the muscle belly palpated for contraction.

(4) Knee Reflex

The participant sits with legs dangling and feet not touching the floor. Patellar tendon is directly tapped with a reflex hammer.

(5) Ankle Reflex

The participant is asked to relax while the examiner grasps and dorsiflexes the foot to obtain the proper degree of stretch. The Achilles tendon is then struck directly with the reflex hammer.

REFLEXES 1. Absent 2. Hypoactive 3. Normal
4. Hyperactive 5. Unsustained clonus 6. Sustained clonus

RIGHT

Biceps []
Triceps []
Knee []
Ankle []

LEFT

Biceps []
Triceps []
Knee []
Ankle []

(6) Plantar Response

The plantar response is best tested when the participant is as relaxed as possible. The examiner may distract him with conversation. The point of a key is applied to the lateral aspect of the sole, near the heel. The sole is then gently stroked toward the little toe and, the ball of the foot is reached, the stimulus is carried across to the base of the great toe. The stimulus may need to be repeated and/or increased. The response is said to be REVERSED (positive) if there is extension of the great toe, usually with fanning; (abduction and some flexion) of the other toes.

- (a) "Normal" indicates plantar flexion;
- (b) "Reversed" is a positive Babinski response;
- (c) "Absent" indicates failure to obtain any response, either extensor or flexor;
- (d) "other" is to be used to record responses.

PLANTAR RESPONSE 1. Normal 2. Reversed 3. Absent
4. Other (Specify)

Right [] Left []

(7) Other Reflex Condition (Specify)

d. Peripheral Sensory Testing

(1) Pinprick

(a) Pain is tested by asking the participant to distinguish between the sharp and dull end of a safety pin after the examiner demonstrates the difference and then applies single stimuli. The upper extremity proximal stimuli are to be applied over the middle of the biceps (ventral) and triceps (dorsal); the distal stimuli over the dorsal and ventral surface of the proximal phalanx of the index finger.

(b) The lower extremity proximal stimuli are to be applied over the middle of the quadriceps and the hamstrings, and the distal stimuli over the anteromesial portion of the foot (dorsal) and anterolateral portion of the foot (ventral).

PINPRICK [] 1. Normal 2. Absent 3. Not Applicable
Due to Missing Limbs 4. Not Done

ARMS

Right Left

Proximal

[] [] Dorsal
[] [] Ventral

Distal

[] [] Dorsal
[] [] Ventral

LEGS

Right Legs

Proximal

[] [] Dorsal
[] [] Ventral

Distal

[] [] Dorsal
[] [] Ventral

(2) Vibratory Sensation

This is tested using a tuning fork with a frequency of 128 Hz. The Examiner first demonstrates the vibrating and non-vibrating tuning fork by application to the sternum of the participant. The lower extremities are tested by application of the tuning fork on the lateral malleoli. The participant's perception of the tuning fork "buzzing" or not "buzzing" should approximate that of the Examiner.

VIBRATORY SENSATION [] 1. Normal 2. Decreased
3. Absent 4. Not Applicable Due to Missing Limb 5. Not Done

Lateral Malleolus Right [] Left []

Patella Right [] Left []

e. Sensory Extinction

The somatic part of this test utilizes double simultaneous stimulation with two safety pins. The participant is instructed that he may feel the pin on one or both sides. He then closes his eyes and, after symmetrical stimuli with the pin, he is asked to localize the pinprick. Correct responses to two stimulations in each extremity (single and double) are sufficient to consider the test normal. For the visual field part of the examination, the participant is asked to fix his eyes on the eyes of the examiner and is told to point to left, right or both sides where he sees a moving finger. Each quadrant is tested with single and double stimulation. Failure to detect the moving finger in one or more quadrants in three attempts is considered abnormal.

SENSORY EXTINCTION 1. None 2. Right (is not perceived)
3. Left (is not perceived) 4. Right and Left (are not consistently perceived)

Face [] Arms [] Legs [] Visual Field []

Completion: [] 1. Completed 2. Incomplete (terminated)
3. Interrupted 4. Sick 5. Other (Specify) 9. Refused

3. Data Management

A data collection form has been designed that will provide for input of all relevant data. Through the use of this structured form complete examinations are assured. At the conclusion of the entry process, the data form will be reviewed by the physician for errors and subsequently will become part of the hardcopy medical record.

a. Data Collection

After the neurology examination is completed, the results will be entered onto the data collection form. All responses, both free text and coded, will be entered by the physician. This procedure will provide the most accurate and immediate capture of the needed information.

b. General Data Flow

The following procedures will be followed for the collection and reporting of medical data:

- (1) At the beginning of the day, the day's scheduling report will be distributed to the staff. This report will list each participant that is to have a physical examination for the day. The report does not list the participants in the order to be examined, however, it does show the schedule number (1-23) that the participants have been assigned.
- (2) The scheduled participant will arrive.
- (3) The physician will check off the participant on the daily schedule. This will provide an ongoing record of participants that have or have not been examined.
- (4) The physician will perform the neurological examination.
- (5) After the physician has completed the examination, he/she will enter the exam results onto the data collection form. Initially, he/she will enter his or her ID# and the status of the exam and then the results. With only a few exceptions, the results have all been coded. Coding appears on the form to facilitate a quick entry process. For those entries requiring free text, the physician will enter the text. For responses too large to fit in the allocated space, the physician will be required to abbreviate the participant's response in order to make the text fit.
- (6) After the physician completes entry of the results, he/she will enter the exam completion time.
- (7) The physician will review the results. If errors are found, the physician will go to the appropriate incorrect answer and correct it.
- (8) The physician may have comments or impressions regarding the examination that he/she wishes to highlight. In these cases, the physician will handscribe on the bottom of the final narrative any such remarks.

- (9) Once the physician is satisfied with the accuracy of the exam, he/she will verify the narrative by signing it.
- (10) The physician will take the narrative to the nursing station and place it in the appropriate exam slot.
- (11) The physician is now ready for the next participant and will continue with steps (3)-(10) until all participants for the day have been examined.
- (12) After all participants have been examined, the daily schedule should be taken to the Clinic Manager and filed.

4. Quality Control

Quality control of the neurological examination occurs through 1) requirement for examiners who are board-certified or board-eligible in neurology, 2) certification of the ability of the examiners to perform the neurology exam in the standard manner, 3) performance of blind, repeat examinations (one per day) on participants randomly selected according to the procedure described in the Data Management Manual, and 4) assessment of inter-examiner variability in findings.

5. Backup

Backup examiners will be provided from the group of board-certified neurologists participating in the study.

6. Supervision

All examinations will be conducted under the supervision of the Medical Director.

7. Subject Problems

If, during the course of testing, a participant decides to terminate or refuse the neurology examination, the Clinic Manager will be notified. The participant will then be reminded of the importance of completing the test, recognizing that the individual has the right to refuse. If the participant, at that time, still decides not to continue the test, a refusal with the signatures of the participant and the Clinic Manager will be entered into his record.

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IV. Medical Examination Manuals

H. Peripheral Vascular

1. Introduction

The results of the Air Force Ranch Hand Project included significant differences in the clinical findings for two peripheral leg pulses when the Ranch Hand group was compared to the control group. Therefore, a Doppler examination of the peripheral vascular system will be used to provide objective data on the characteristics of the peripheral vascular systems of participants in the Veterans' Health Study. Three waveform indices will be used to distinguish between normal and abnormal velocity waveforms. They are:

- a. Wave morphology of the radial, dorsalis pedis, and the posterior tibial arteries
- b. Resting ankle/brachial pressure indices
- c. Hyperemic ankle/brachial pressure indices

2. Testing Equipment and Supplies

- a. Model 1010-LA Dual Frequency BiDirectional Doppler
- b. Baumometer Blood Pressure Bag and Cuff
- c. Stethoscope (Littman Cardiology)
- d. Ultrasound transmission gel

3. Doppler Calibration

A "Cal A-Cal B" toggle switch on the Parks Dual Frequency BiDirectional Doppler enables velocity calibration. The velocity calibration used is determined by the setting on the back panel marked calibration. The "Cal A" position puts a calibration signal into the signal processor, causing the flow toward the meter and the recorder to be indicated on the front panel. The "Cal B" position does the same for flow away from the transducer. The calibration knob selects the velocity reference signal displayed on the chart paper and meters. Various calibration settings are tested each morning to make sure that the instrument is in working order before participants are tested. A notebook of daily calibrations is maintained by the Doppler technician.

4. Operation of the Model 1010-LA Dual Frequency BiDirectional Doppler

Operator may refer to Operations Manual (Parks Medical Electronics, Inc., Beaverton, OR 97075).

5. Subject Preparation

- a. The participant is asked to assume a supine position on a standard examination table.
- b. Participants should not smoke, drink coffee or caffeine containing drinks, or exercise for one hour prior to testing.

6. Peripheral Vascular Examination Procedure

- a. Name, identification number, date and time will be recorded on the individual data sheets.
- b. Waveform morphology of the radial artery, dorsalis pedis artery, and the posterior tibial artery is used to examine pulsatility. Pulsatility is described as multiphasic, monophasic, or absent. A multiphasic pattern is characteristic of a normal artery with unobstructed flow. A waveform exhibits multiphasic pulsatility if there is a clear distinction between systole and diastole and the diastolic portion is oscillatory.
- c. Systolic pulse is easily recognizable in a monophasic waveform, but oscillatory activity during diastole is not present. Monophasic patterns demonstrate reduced arterial compliance and they may indicate a stenosis proximal to the examination site and/or low resistance in distal vessels. Pulsatility is described as absent when the systolic peak is obliterated. The resultant tracing is indicative of continuous forward flow. The absence of pulsatility may reflect the existence of one or more significant obstructions in the major proximal arteries. The pattern seen at the site of the examination may represent collateral flow.
- d. Right and left brachial blood pressures will be taken using the Doppler technique. An occluding cuff is placed around the arm. The brachial artery is palpated in the antecubital fossa and acoustic gel is applied to the skin over the artery. An arterial signal is found using the Doppler probe and the cuff is then inflated until the arterial signal disappears. The cuff is slowly deflated while the operator listens to the Doppler for systolic breakthrough. It is crucial that the transducer remain directly over the artery during inflation and deflation of the cuff.
- e. After brachial pressures are recorded, the right and left supine ankle pressures will be measured. The cuff is placed around the ankle with the lower edge just above the malleolus. The Doppler transducer is placed over the posterior tibial and/or the dorsalis pedis artery. The posterior tibial artery is located posterior to the medial malleolus, and the dorsalis pedis artery is present on the dorsum of the foot. The vessel

with the strongest Doppler signal is chosen. The cuff is inflated and the operator listens for systolic breakthrough as the cuff bleeds down.

f. If the pulse cannot be palpated, the instrument output power is increased and the search continued. Before declaring the pulse absent, several attempts will be made both to palpate and to locate by using the probe. In the event that the arteries cannot be located by palpation or by instrumentation, the proximal artery (eg. ulnar or femoral) will be palpated in order to assess whether a segmental obstruction is present. These findings will be clearly documented by the technician on the data collection form.

g. A resting pressure index will be calculated from the resting ankle systolic pressure and brachial systolic pressure using the following equation:

$$(1) \text{ Resting Pressure Index} = \frac{\text{Ankle Systolic Pressure}}{\text{Brachial Systolic Pressure}}$$

h. In normal subjects, the ankle systolic pressure is higher than the brachial pressure. Therefore, a normal pressure index is greater than 1.0. Severe arterial occlusive disease results in abnormally low ankle pressures. Thus, a complete occlusion in a main arterial pathway will result in an abnormal pressure index evidenced as a pressure index less than 1.0.

i. After the resting index has been completed, a reactive hyperemia index will be calculated. Thigh cuffs are placed at mid-thigh level bilaterally. Both legs are tested simultaneously. The participant elevates his legs at a 45-degree angle (with knees bent and feet on the table) to empty the venous capacitance vessels. When the legs are up, the thigh cuffs are inflated to a pressure approximately 50 mmHg higher than the brachial systolic pressure recorded earlier. After inflation of the cuffs is completed, the legs are brought down on the table. The pressure is maintained for five minutes. At the end of five minutes, both cuffs are deflated simultaneously. Ankle pressures are measured immediately post-occlusion and at one minute postocclusion.

j. A hyperemic pressure index will be calculated from the arm pressure and the hyperemic ankle pressure.

$$(1) \text{ Hyperemic Pressure Index} = \frac{\text{Hyperemic Ankle Systolic Pressure}}{\text{Brachial Systolic Pressure}}$$

k. A normal test is defined as:

(1) The lowest ankle index is greater than 0.80 AND

(2) The ankle index returns to 90% of the baseline value within one minute following release of the cuffs.

1. Subjects with mild claudication may have an ankle index which reaches 80-90% recovery in the first minute. A slower recovery is indicative of significant arterial disease.

7. Data Management

The following procedures will be followed for the collection and reporting of Doppler exam data:

- a. At the beginning of the day, the day's scheduling report will be distributed to the staff. This report will list each participant that is to have a Doppler exam for the day. The report does not list the participants in the order to be examined; however it does show the schedule number (1-23) that the participants have been assigned.
- b. The scheduled participant will arrive.
- c. The technician will check off the participant on the daily schedule. This will provide an ongoing record of participants that have or have not been examined.
- d. The technician will enter the medical record number assigned to the participant, the participant's name, the date, the technician's ID #, and the exam start time onto the data collection form.
- e. After participant identification is recorded, the peripheral vascular exam will be performed as described in this manual.
- f. As results are obtained, they will be entered onto the data collection form. All results will be entered by the technician. This procedure will provide accurate and immediate capture of the needed information. After the technician has completed entry of the results, he/she will enter the exam completion time.
- g. The technician will review the printed results. If errors are found, the technician will go to the incorrect answer and correct it.
- h. Once the technician is satisfied with the accuracy of the exam, he/she will verify the narrative by signing it.
- i. The technician will take the data collection form to the nursing station and place it in the appropriate exam slot.

- j. The technician is now ready for the next participant and will continue with steps 2-9 until all participants for the day have been examined.
- k. After all participants have been examined, the daily schedule will be taken to the Clinic Manager and filed.

8. Supervision

Supervision of Doppler technicians will be by the Director of the LMF Vascular Laboratory, or his/her designee, in conjunction with the Veterans' Health Study Clinic Manager. For technical questions or problems related to performance of the peripheral vascular examination or operation of the equipment, the technician should contact the Director of the LMF Vascular Laboratory. For questions related to problems with participants, scheduling, supplies, etc., the technician should contact the Clinic Manager.

9. Quality Control

The Clinic Manager and Peripheral Doppler Supervisor are responsible for coordination of the quality control program, in conjunction with the Special Assistant for Quality Control and Scientific Affairs. Personnel are taught a standardized system of data collection to assure consistency in data collection and accuracy in reporting. The accuracy and reliability of examination data are monitored through a retesting procedure designed to validate the test findings. A physician or research vascular specialist repeats the technician's exam once per day on a randomly selected participant. The proportion of tests and retests agreeing is analyzed by the Special Assistant for Quality Control and Scientific Affairs. Acceptable reproducibility is defined as:

- a. Total agreement on waveform morphology AND
- b. Less than 10% variation in all pressure measurements.

10. Backup

- a. Backup Doppler equipment will be provided by the Lovelace Medical Center, Inc., (LMCI) Vascular Lab.
- b. The audiology technician has been cross-trained to perform as backup Doppler technician. Additional backup personnel are provided by the LMCI Vascular Laboratory.

11. Subject Problems

If, during the course of testing, a participant decides to terminate or refuse the peripheral vascular tests, the Clinic Manager will be notified. The participant then will be reminded of the importance of completing the test, recognizing that the

individual has the right to refuse. If the participant, at that time, still decides not to continue the test, a refusal with the signatures of the Clinic Manager and the participant will be entered into his record.

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IV. Medical Examination Manuals

I. Physical Examination

1. Introduction

- a. This manual describes the physical examination for the Veterans' Health Study. The first part of the examination is performed by the nurse. The second part is performed by the physician. The examination has been standardized, in sequence of steps and in content. The examination is not exhaustive. Steps of a usual physical exam which are not required by the CDC for this study have been omitted. The second part of the examination is divided into steps according to the positions of the examiner and the participant. In sections where active range of motion of joints or the spine is assessed, movements are best demonstrated by the examiner. The results of the examination will be entered into the data collection forms from which the CDC will collate their information. The physician is not to ask questions regarding the participant's history. The data collection forms generally ask for specific answers. In some places, space is offered for free text to describe findings not covered by specific questions. Where no free text space is offered, additional descriptive data are recorded in the free-text space at the end of the data collection form.
- b. After these forms have been filled out, additional or more detailed findings relevant to special concerns expressed by the participant will be recorded on a separate sheet that will not be part of the CDC data base.
- c. Medical information for this manual was excerpted from:
 - (1) DeGowan EL, DeGowan RL. Bedside diagnostic examination. New York: MacMillan, 1981.
 - (2) Bates B. The guide to physical examination. Philadelphia: JB Lippincott, 1984.
 - (3) Judge RD, Zuidema GD, Fitzgerald FT. Clinical diagnosis, a physiological approach. Boston: Little Brown, 1982.

2. Examination, Performed by the Nurse

a. Vital Signs

(1) Height (cm)

All measurements will be done with shoes off. All heights will be recorded in centimeters, rounding off to the nearest cm. For 0 to 0.5 round off to the next lowest cm. For 0.6 to 0.9 round off to the next highest cm.

(2) Weight (kg)

All weights will be done with clothing on and shoes off. All weights will be recorded in kilograms, rounding off to the nearest kg. For 0 to 0.5 round off to the next lowest kg. For 0.6 to 0.9 round off to the next highest kg.

(3) Pulse rate (min)

To be taken with the subject sitting by palpation of the radial artery. Calculated from a count taken over 30 seconds.

(4) Pulse regularity

To be taken over a 30-second period at the radial artery. Any rhythm other than a completely regular rhythm is to be considered irregular.

(5) Respiration

To be taken over 30 seconds in the sitting position after the subject has been sitting for a minimum of two minutes.

(6) Blood pressure

(a) Equipment:

- (i) Stethoscope.
- (ii) Sphygmomanometer (mercury-type) cuff 9.5 and 13 cm.

(b) The cuff size will be measured in the following manner:

- (i) The width of the bag will be 40% of the circumference of the limb.
- (ii) The length of the bag will be about 80% of the circumference of the limb.

(c) Procedure:

- (i) Assure that participant is relaxed and comfortable
- (ii) Free arm of clothing.
- (iii) Center the inflatable bag over the brachial artery on the inside of the arm. The lower border should be 2.5 cm above the antecubital crease.
- (iv) Secure the cuff snugly.
- (v) Position the participant's arm so that it is slightly flexed at the elbow. Support it yourself

or rest it on a pillow, table, or other steady surface making sure that the cuff lies at the heart level.

- (vi) Find the brachial artery by palpating just medial to the biceps tendon.
- (vii) With the thumb or fingers of one hand resting on the brachial artery, rapidly inflate the cuff to about 30 mm Hg above the level at which the pulsations disappear. The operator should be at eye level with the manometer.
- (viii) Deflate the cuff slowly until you again feel the pulse. This is the palpatory systolic pressure and helps you avoid being misled by an auscultatory gap.
- (ix) Deflate the cuff completely.
- (x) Place the bell of the stethoscope lightly over the brachial artery.
- (xi) Inflate the cuff again to about 30 mm Hg above the palpatory systolic pressure. Then deflate the cuff slowly, allowing the pressure to drop at a rate of 3 mm Hg per second. Note the level at which you hear the sounds of at least two consecutive beats. This is the systolic pressure.
- (xii) Continue to lower the pressure slowly until the sounds become muffled and then disappear. Then deflate the cuff rapidly to zero. The disappearance point marks the generally accepted diastolic pressure.
- (xiii) Reading will be recorded in the following manner:
 - BP sitting, right arm
 - BP sitting, left arm
 - BP sitting, right arm
 - BP sitting, left arm

(d) Special Problems:

- (i) The apprehensive participant
Anxiety is a frequent cause of high blood pressure. The registered nurse will make every attempt to get the participant relaxed.
- (ii) The obese arm
If there is difficulty fitting the cuff to an obese arm, you may apply a standard cuff to the forearm and listen to the radial artery.

- (iii) Inaudible blood pressure
Erroneous placement of stethoscope; search again for the brachial artery. Venous engorgement of the arm from repeated inflation of the cuff; elevate the participant's arm above his head for one or two minutes, then reapply the cuff and try again.

3. Examination, Performed by the Physician

- a. The examiner should note that the order of examination if based on a sequence of positions will permit maximum efficiency for the examiner while minimizing position changes for the participant. Thus, the order of examination and the order in which data are recorded differ. Consequently, the paragraph letters/numbers in the examination manual and on the recording form do not correspond.
- b. The order of examination is posted in each physical examination room so that the examiner does not have to rely on memory alone in following the standard examination sequence.
- c. The examiner introduces himself to the participant before beginning the physical examination. The examiner briefly describes to the participant each step of the physical exam before or while he/she is performing it.
 - (1) Participant Seated on a Stool and the Examiner in Front of Participant
 - (a) Palpation of the submental, parotid and sublingual (salivary) glands for any abnormalities, which may include enlargement, tenderness, or the presence of a mass.
 - (b) Palpation of cervical and occipital lymph nodes. Assess these lymph nodes for abnormality. If abnormal, record their size and whether they are tender, firm, fixed, or confluent.
 - (c) Inspection and palpation of the trachea. Assess for tracheal deviation and for audible stridor and hoarseness of the voice.
 - (d) Palpation of carotid pulses. Gentle carotid palpation is performed on first one side of the neck and then on the other side.
 - (e) Palpation of the skull and scalp. Abnormalities are individually described in free text.

- (2) Participant Seated on a Stool and the Examiner Behind the Participant
- (a) Palpation of the thyroid gland. Include palpation of the thyroid while the subject is swallowing. The thyroid will be coded as normal or abnormal, and, if abnormal, questions will follow on size, tenderness, and the presence of nodules. The normal adult thyroid gland is said to be 5 cm. long; the greatest diameter is 3 cm.; the thickness is about 2 cm.; and the right lobe is usually larger than the left.
 - (b) Palpation of supraclavicular nodes. This includes palpation when the participant is relaxed and also during coughing, which sometimes makes the contents of the supraclavicular fossae more prominent.
 - (c) Palpation of neck masses other than enlarged lymph nodes and thyroid gland.
 - (d) Assessment of passive range of motion of the cervical spine. Test passive flexion and extension at the neck, flexion to the right and left, and rotation to the right and left.
- (3) Participant Seated on Examination Table
- (a) Frontal maxillary sinuses are palpated and lightly percussed for evidence of tenderness.
 - (b) Inspection of the eyes. Observe for the presence or absence of one or both eyes. Assess for conjunctival discharge. Assess for abnormalities of the cornea and media, to include corneal irregularity and scarring, cataracts, and scleral icterus. Funduscopic exam includes assessment for arterio-venous crossing defects or "nicking," arteriolar spasm, increased light reflex, papilledema, abnormal cupping of the optic disk, disk pallor, retinal exudates and hemorrhages. Assess for proptosis and lid lag.
 - (c) Inspection of the ears. External ear canals are assessed for cerumen impaction. The tympanic membrane, designated in the physical exam forms as the "middle ear", is assessed as normal or abnormal, and abnormalities include drum perforation, retraction, scarring, bulging, and inflammation.
 - (d) Inspection of the nose. Both nostrils are inspected with a light, looking for abnormalities of the septum, including perforation and deviation, nasal polyps, and

ulceration and bleeding. Patency of each nasal passage is then tested by having the participant occlude one nostril and snort through the other.

- (e) Inspection of the throat, mouth, teeth, gums, and tongue. This examination must be performed thoroughly with a light and a tongue blade. It includes inspection of the posterior pharynx, tonsils, tongue, upper and lower labial and buccal alveolar margins, buccal mucosa, and the sublingual mucosa (participant lifts tongue from floor of mouth). The throat is examined for pharyngitis, and the tonsils are assessed as normal or abnormal, enlarged and/or abscessed. Examine the hard and soft palate and describe any abnormalities in the section for communication to the diagnostician.
- (i) Dental status is described as good, fair, poor, or edentulous. Good dental status implies the absence of caries and gingivitis, fair dental status indicates some abnormalities of the teeth and gums, and poor dental status includes the presence of severe gingival and dental disease. The edentulous state is self-explanatory. Remove dentures, if worn. Note whether the edentulous subject routinely wears dentures. Look carefully at all mucosal surfaces for ulcers, plaques, and masses. Note that question F4 in the physical exam questionnaire refers to the presence or absence of mucosal plaques, not dental plaque.
- (ii) Examine the tongue carefully, noting whether it is smooth, ulcerated, fissured, coated, stained, pigmented, a "geographic" tongue, or is inflamed and painful. The question related to the tongue includes only the opportunity to mention glossitis, so other abnormalities will need to be noted in the free text at the end of the questionnaire.
- (iii) Carefully examine the gums for any abnormalities, including gingivitis, hypertrophy, hyperplasia, and abnormal pigmentation. Abnormal pigmentation will need to be described in free text at the end of the questionnaire.
- (f) Assessment of chest shape and movement. Specified abnormalities of chest shape are pectus excavatum and pectus carinatum, but an opportunity is also given to comment on other deformities which will include barrel chest kyphosis, scoliosis, etc. Chest expansion is

assessed by standing to the side of the participant, placing one hand on the anterior chest and one hand on the posterior chest, and asking him to take maximal inspiration. Excursion is assessed by splaying the hands over the posterior chest and noticing the movement of the splayed fingers, and/or the adjoining thumbs, as the participant takes a deep breath.

- (g) Assessment for spinal tenderness by both palpation and percussion.
- (h) Percussion for costovertebral angle tenderness. Self-explanatory.
- (i) Chest percussion. Resonance is assessed by percussion anteriorly and posteriorly over the upper, middle, and lower zones of both lung fields. The questionnaire requires documentation of hyperresonance, localized to one or both lungs, and of dullness, which is to be more precisely localized.
- (j) Chest auscultation. Auscultation is performed in the same zones for which resonance is assessed (described above) while the subject is breathing quietly, with normal tidal volumes, through the mouth. Listen for, and localize, diminished breath sounds, crackles (further characterized as fine, medium, or coarse), and wheezes. Listen for and localize any pleural friction rub.
- (k) Auscultation for aortic insufficiency. Have the subject lean forward, listen in the aortic area during expiration.
- (l) Auscultation of the carotid arteries. This is performed with subject holding his breath. If sounds are detected over the carotid arteries, attempt to distinguish between carotid bruits and radiating cardiac sounds which can be traced to the base of the heart.
- (m) Palpation of the precordium to detect any thrills. Palpate over the apex, xiphisternum, and aortic and pulmonic areas.
- (n) Examination of the breasts. Assess for gynecomastia. Record the amount of palpable breast tissue in the section for free text, classify as fatty tissue, true glandular enlargement, hard mass, etc. For abnormalities of the nipples, include nodules, swelling, ulcerations, or discharge. It is recommended that the breast tissue and nipples be gently squeezed to assess for discharge.

(4) Participant Supine on the Examination Table

- (a) Inspection and palpation to determine the point of maximum cardiac impulse, and to assess whether it is increased.
- (b) Auscultation of the heart. Listen to the heart with the diaphragm of the stethoscope at the base, lower left sternal border, mid left sternal border, pulmonic and aortic areas. Assess for murmurs, clicks, gallops, and pericardial friction rubs. Systolic murmurs will be described in terms of intensity (grades 1-6), pitch (low, medium, or high), configuration (crescendo, decrescendo, crescendo/decrescendo, plateau), timing (midsystolic, holosystolic, early systolic or late systolic), site of maximal intensity, (specified on forms), and radiation, with direction if pertinent. Diastolic murmurs are described in the same manner. Continuous murmurs are described in terms of intensity, site of maximum intensity, and radiation. Systolic clicks are assessed as single or multiple, and are timed (early, mid, or late systole). Gallops are assessed according to their timing (presystolic/atrial/S4, or diastolic/ventricular/S3, or summation gallop). Variation of gallops with phases of respiration are also described. Pericardial friction rubs are described only as absent or present, and any further description needs to be put into the free text section. During cardiac auscultation it is required that subjects also lie on the right lateral decubitus position so that auscultation for mitral murmurs can be performed with the bell at the apex.
- (c) Auscultation of the abdomen. Without excessive pressure, listen for bruits in the epigastrium just below the xiphisternum, and in right and left upper and lower quadrants.
- (d) Auscultation of the femoral arteries.
- (e) Palpation of inguinal lymph nodes. Assess as normal or abnormal, and if abnormal, as tender, firm, fixed, confluent, or other. If the nodes are enlarged, their size should be recorded.
- (f) Inspection and palpation of the abdomen. The abdomen is inspected for ascites, visible mass, or spider angiomas. If other abnormalities are visible, they need to be described in the free text section. Palpation is performed while the subject is breathing normally in all sections of the abdomen, including the epigastrium, right upper and lower quadrants, left upper

and lower quadrants, and the suprapubic area. Assess for and localize any abdominal tenderness, and characterize as diffuse, rebound, or percussion tenderness. Localize and describe any abdominal masses. Record the position of the liver edge below the right costal margin in the right midclavicular line, describe the edge (sharp or blunt, other descriptions in the free text), and describe its consistency as hard or nodular. Percuss for and measure liver dullness in the right midclavicular line. Feel for a palpable spleen with the subject supine, and again in the lateral decubitus position. If palpable, describe in the free text the distance of the spleen tip below the left costal margin. A sketch might be helpful here. It may be necessary to ask the subject to take deep breaths to define the liver edge or spleen tip.

(g) Assessment for abdominal hernias. While the subject is supine, have him raise his head and palpate for epigastric, ventral, incisional, and other hernias.

(5) Participant Supine on the Examination Table

- (a) Assessment of active range of motion on straight leg raising. Describe whether this motion is normal, limited by back pain, limited by thigh pain, or limited by muscle stiffness.
- (b) Palpation of the leg. Palpate the thigh and the calf assessing for muscle bulk, soft tissue masses, and pedal, ankle, and pretibial edema.
- (c) Assessment of passive range of motion of both hips and both knees. These include flexion of the hip and knee, abduction of the hip with the knee flexed, external and internal rotation of both hips with the knee flexed, and extension of the knees.
- (d) Palpation for knee abnormalities and swelling.
- (e) Assessment of passive range of motion of the ankle, to include flexion, extension, inversion and eversion.
- (f) Assessment for clubbing of the toes. An early diagnosis of clubbing is based on obliteration of the unguophalangeal angle and abnormal springiness of the nail on the nail bed. Changes of advanced clubbing include increased longitudinal and horizontal curvatures of the nail and increased volume of the distal phalanx.

- (g) Palpation of axillary lymph nodes. These are assessed as normal or abnormal. If they are enlarged, the size is recorded and they are described as tender, firm, fixed, or confluent.

(6) Participant Standing

- (a) Examination of genitalia. Assess whether pubic hair is normal or decreased. Examine the shaft and the glans of the penis, and retract the foreskin if the participant is not circumcised. Note the presence or absence of urethral discharge. Any abnormalities of the penis not described above, such as blisters, ulcers, condylomata, chancres, varicosities, tumors or deformities will have to be described in free text. Scrotal contents are examined. Length is measured by calipers along the long axis of both testes. (After January 1, 1986, orchidometers, wooden models, were used to estimate the volume of the testis.) Assess whether the epididymis is thick or tender. Check for varicoceles. If other scrotal abnormalities or masses are found, the questionnaire offers the opportunity to describe them (hydrocele, hernia, spermatocele, etc.).
- (b) Check for inguinal hernia by palpation and by insertion of the index finger into the external inguinal ring. Have the participant cough during this maneuver.
- (c) Examination for presacral edema.

(7) Participant on Elbows and Knees on Examining Table

- (a) Rectal examination. Check for hemorrhoids, anal fissure, rectal mass, and make an assessment of anal sphincter tone.
- (b) Digital examination of the prostate. Describe as normal or abnormal, and if abnormal, whether diffusely enlarged, atrophic, with single or multiple nodules, of soft consistency, or tender. Other abnormalities are noted in the free text.
- (c) Smear a sample of stool, if any, on the hemocult card for subsequent testing for occult blood.

(8) Participant Standing and Physician Moving From Back to Front as Specific Examination Dictates

- (a) Inspection of the spine. The spine is examined with the subject both upright and again leaning forward (ask the subject to touch his toes). The spine is described as normal or abnormal, with opportunities to document

scoliosis, kyphosis, tenderness (previously assessed with subject sitting), and pelvic tilt. Assess active range of motion with flexion forward, and to each side, and rotation to both sides.

- (b) Inspection of the backs of thighs and calves for varicose veins.
 - (c) Assessment of active range of motion of the shoulder, including flexion extension (normally to 50°), abduction (normally to 180°) external rotation, and internal rotation.
 - (d) Assessment of active range of motion of the elbow, to include flexion (normally to 160°), and extension (normally 0°).
 - (e) Palpation of epitrochlear nodes. Describe as normal or abnormal. The size of enlarged nodes is quantified, and they are further described according to whether they are firm, fixed, tender, or confluent.
 - (f) Palpation of the arm for soft tissue masses.
 - (g) Assessment of active range of motion of the wrist including flexion extension, and ulnar and radial deviation.
 - (h) Palpation of the finger joints.
 - (i) Inspection of the fingers for clubbing (previously described under clubbing of the toes), and for cyanosis.
- d. This concludes the formalized part of the physical examination required for data gathering for the CDC. When this examination is complete, the physical examination form, including the section for free text, if needed, will be filled out. However, the physician requests that the participant remain undressed and in the examining room during this procedure. After completion of the forms, the physician asks the participant if he has any special health concerns or abnormal finding he would like the examiner to review. Any extra findings are then entered on an additional page for communication between examiner and interviewer. The opportunity for this communication will enhance the quality of the overall clinical assessment while not biasing the findings of the CDC.

4. Data Management

- a. A series of data collection forms has been designed that provide for input of all relevant data. Through the use of these structured forms complete examinations are assured. A one-page

worksheet will be utilized by the physician during the examination for recording abnormalities. After the exam is complete, the physician will enter all of the results onto the formal data collection form. This form will be reviewed by the physician for errors and subsequently will become part of the hardcopy medical record.

b. The following procedures will be followed for the collection and reporting of medical data:

- (1) At the beginning of the day, the day's scheduling report will be distributed to the staff. This report will list each participant that is to have a physical examination for the day. The report does not list the participants in order to be examined, however, it does show the schedule number (1-23) that the participants have been assigned.
- (2) The scheduled participant will arrive.
- (3) The nurse will check off the participants on the daily schedule. This will provide an ongoing record of participants that have or have not been examined.
- (4) The nurse will record the medical record number assigned to the participant, the participant's name, the date, the nurse's ID# and the exam start time.
- (5) The nurse will take the participant's vital signs. He/she will enter these vitals onto the data collection form as they are taken. Once this information is entered, the participant will be ready for the physician.
- (6) The physician will perform the physical examination. During the exam, he/she will notate abnormalities on the exam worksheet. This worksheet is simply a sheet of paper with the major categories of the exam listed on it.
- (7) After the physician has completed the examination, he/she will enter the exam results onto the formal data collection form. Initially, he/she will enter his or her ID# and the status of the exam and then the results. With only a few exceptions, the results have all been coded. Coding appears on the form to facilitate a quick entry process. For those entries requiring free text, the physician will enter the text.
- (8) After the physician completes entry of the results, he/she will enter the exam completion time and review the results. If errors are found, the physician will go to the appropriate incorrect answer and correct it.

- (9) The physician may have comments or impressions regarding the examination that he/she wishes to highlight. In these cases, the physician will handwrite on the bottom of the final narrative any such remarks.
- (10) Once the physician is satisfied with the accuracy of the exam, he/she will verify the narrative by signing it.
- (11) At this point the physician may ask the participant if he has any health concerns he wishes to mention, or any physical abnormality that he would like the physician to assess. The physician will then repeat or enlarge on pertinent aspects of the exam to clarify these issues. Findings will be entered on a separate form specifically designed to record results of any examination taking place after the standard study exam has been completed.
- (12) The physician will take all results forms to the nursing station and place them in the appropriate exam slot.
- (13) The physician is now ready for the next participant and will continue with steps (2)-(14) until all participants for the day have been examined.
- (14) After all participants have been examined, the daily schedule should be taken to the Clinic Manager and filed.

5. Quality Control

Quality control of the physical examination occurs through requirement for examiners who are board-certified or board-eligible in internal medicine; certification of the ability of the examiners to perform the physical exam in the standard manner; performance of blind, repeat examinations (one per day) on participants randomly selected according to the procedure described in the Data Management Manual; and assessment of inter-examiner variability in findings.

6. Backup

Backup examiners will be provided from the group of board-certified or eligible examiners and diagnosticians participating in the study. Note, however, that a given physician may not serve as both examiner and diagnostician for the same study participant.

7. Supervision

All examinations will be conducted under the supervision of the Medical Director.

8. Subject Problems

If, during the course of testing, a participant decides to terminate or refuse the physical examination, the Clinic Manager will be notified. The participant will then be reminded of the importance of completing the test, recognizing that the individual has the right to refuse. If the participant, at that time, still decides not to continue the test, a refusal will be entered into his record.

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J. Pulmonary Functions

1. Introduction

- a. Pulmonary function tests will be provided using state-of-the-art techniques for recording the flow-volume loop. Lovelace has in place a system for collection of high quality flow-volume loops at sites remote to the main pulmonary function laboratory. As is the case for ECG testing, a pulmonary function system will be placed in the Project Examination Center and digital data will be transmitted via telephone to the pulmonary function computer in the main pulmonary function lab for analysis.
- b. The pulmonary function system utilizes the MedScience Wedge spirometer which records the flow-volume loop. Analog data is converted to digital output for transmission to the central computer. The vital capacity (VC), which can be calculated from either a forced (FVC) or slow (SVC) expiratory maneuver, the forced expiratory volume in 1.0 seconds ($FEV_{1.0}$), mid maximal expiratory and mid maximal inspiratory flow (MMEF, MMIF) are calculated and compared to predicted values.
- c. Flow volume loop nomenclature:
 - (1) SVC
Slow Vital Capacity: Vital capacity performed with a moderate rate, maximal expiratory effort.
 - (2) FVC
Forced Vital Capacity: Vital capacity performed with a rapid maximal expiratory effort.
 - (3) FEV_t
Forced Expiratory Volume (timed): Maximal volume of air expelled in a specified time during performance of forced vital capacity (e.g., FEV_1 - volume of air expelled in first second of FVC).
 - (4) FEV_t/FVC
Forced Expiratory Volume (timed) to Forced Vital Capacity ratio: Expressed as a percentage.
 - (5) PEF
Peak Expiratory Flow: Peak flow during a forced vital capacity maneuver.
 - (6) MMEF
Maximal Mid Expiratory Flow: L/min measured at the middle half of the forced expiratory vital capacity.

(7) MMIF

Maximal Mid Inspiratory Flow: L/min measured at the middle of the forced inspiratory vital capacity.

- d. Contraindications: Prior to testing, spirometer tubing will be changed for each participant. There are no infectious disease contraindications for proceeding with pulmonary function testing on any participant.

2. Equipment

- a. MedScience 570 Wedge Spirometer
- b. Digital DEC Writer III
- c. Pulmonary Function Computer

3. Supplies

- a. Vacuumed clean bore tubing
- b. Vacuumed cardboard mouthpieces
- c. Computer paper

4. Maintenance

a. Wedge Spirometer

Provided by LMC, Inc., Pulmonary Function Lab. Supervised with MedScience 570 Wedge Spirometer manual. Further information concerning maintenance or troubleshooting: MedScience, 1455 Page Industrial Blvd, St. Louis, MO 63132; MedScience stat service 314-427-1000, Telex 710-347-7588.

- b. Digital Dec Writer III
Digital Equipment Corp.
Field Service
5600 Kircher Blvd NE
Albuquerque, NM (505-345-4471).

- c. Pulmonary Function Computer
 - (1) LMC Pulmonary Function Lab
 - (2) LMF Biomedical Engineering Department

- d. Manuals for all of the equipment listed above may be found in the Pulmonary Function Testing room and in the Clinic Manager's office.

5. Calibration of Wedge Spirometer

The Wedge Spirometer will be calibrated weekly using a 3-liter calibrated syringe. No other routine maintenance is needed. Consult the Equipment Manual for further details on the calibration procedure.

6. Procedure

- a. At the beginning of the day, the day's scheduling report will be distributed to the staff. This report will list each participant that is to have a Pulmonary Function test for the day. The report does not list the participants in the order to be examined, however it does show the schedule number that the participants have been assigned.
- b. The scheduled participant will arrive.
- c. The technician will check off the participant on the daily schedule. This will provide an ongoing record of participants that have or have not been examined.
- d. The technician will perform the Pulmonary Function test as described below.
 - (1) Turn the PF computer system on.
 - (2) Check the paper in the terminal.
 - (3) Check that the "Caps Lock" key is down and locked. The computer recognizes only capital letters.
 - (4) Press the "reset" switch and the "local start" switch on the computer console.
 - (5) Each morning, obtain the barometric pressure from the LMC Pulmonary Function Lab. Enter this reading into the computer on all PFTs done that day.
 - (6) Take the room temperature reading from the thermometer attached to the PFT computer and enter it into the computer just before the start of each test.
 - (7) Follow instructions as given by the terminal, remembering to always press "return" key after completion of any instruction.
 - (8) The participant will be asked to perform one slow vital capacity test (a maximal slow inhalation followed by a maximal exhalation).
 - (9) After the participant's breathing has returned to normal, he will perform a minimum of three forced expiratory maneuvers. He should be instructed to inhale maximally and then exhale as fast and completely as possible. Completion of the latter part of the exhalation with maximal effort is particularly critical for accurate measurement of vital capacity and assessment of small airway function.
 - (10) The need for additional trials will be based on technician evaluation of participant effort.
 - (11) During testing of the participant, the technician should observe the red L.E.D. ladder lights. Using these lights, the technician can then make a judgment on the acceptability of a test.
 - (12) When giving the participant instructions prior to commencement of tests, the technician should stress the importance of the participant exhaling and inhaling maximally.

- (13) The technician will stress that speed and volume are important when doing the forced vital capacity (inspiration as well as expiration).
 - (14) While the participant is blowing, the technician should constantly encourage the participant, even to the point of being excessively loud.
 - (15) If the participant has not obtained adequate effort after 8 tries then the testing will be temporarily postponed, and the participant will be retested at a later time.
 - (16) The retest will be scheduled at the participant's convenience by the Clinic Manager or clinic nurse.
- e. After the technician has completed the test, the computer will select the best effort based on the largest ($FEV_1 + VC$). The flow volume loop for the best effort will be printed. This result's printout will be reviewed by the technician. If an adequate effort was not obtained, the test will be readministered and another printout generated. Once satisfied with the test, the technician will note the completion time on the printout and sign it. If more than one printout was generated, the invalid copies will be marked as such.
 - f. The technician will take the data collection form and computer printout to the nursing station and place them in the appropriate exam slot. If more than one copy of the results was printed, all copies will be taken to the nursing station.
 - g. The technician is now ready for the next participant and will continue with steps (3)-(6) until all participants for the day have been tested.
 - h. After all participants have been tested, the daily schedule will be taken to the Clinic Manager for review and filing.
 - i. Medical Records staff will collect the Pulmonary Function Test results from the nursing station. The results will then be taken to the Pulmonary Medicine department for interpretation (as described in the Medical Records manual). Once interpreted, the results will be taken to Data Processing for input.
 - j. Data Processing will log and input the test results. Each test will be input according to the procedures outlined in the Data Management manual.
 - k. After the test results have been input, Medical Records personnel will collect the printouts and file them in the participants' records.
 - l. Test results will be compared to standard values obtained from the "Clinical Pulmonary Function Testing Manual" which is published by the Intermountain Thoracic Society.

Interpretation of each test will be provided by a board-certified pulmonologist and recorded in handwriting on the bottom of the hard-copy tracing printed by the computer. This interpretation will be provided to the diagnostician but will not be coded for research purposes.

7. Data Management

Data collection for the Pulmonary Function testing will be a traditional data entry process. The test will be administered by a technician using the MedScience Spirometer. The spirometer will produce a printout of the test results. After interpretation by a Pulmonary Medicine physician, the printout will be forwarded to Data Processing where the results will be input following the protocol described in the Data Management manual. Once completed, the results will be forwarded to Medical Records for filing in the participant's chart.

8. Supervision

Supervision of pulmonary function technicians will be provided by the LMCI Pulmonary Function Department in conjunction with the Veterans' Health Study Clinic Manager. For technical questions or problems related to performance of the pulmonary function test or operation of the equipment, the technician should contact the Director of the Pulmonary Function Department. For questions related to problems with participants, scheduling, supplies, etc. the technician should contact the Clinic Manager.

9. Quality Control

For pulmonary function, consistency of effort in multiple expiratory efforts is identified in the original recording. Another trained technician will perform one independent, repeat test per day on a randomly selected participant. The Clinic Manager periodically observes the performance of all PF technicians, looking especially at the manner in which they encourage good effort by the participant, and the adequacy of the test as reflected by the ladder lights on the spirometer.

10. Backup

- a.) Backup equipment is provided by LMC, Inc., Pulmonary Function Lab.
- b.) Backup technicians are provided by LMCI Pulmonary Function Lab. All technicians are trained by the Director of the Pulmonary Function Laboratory and are required to meet the requirements of that laboratory.

11. Subject Problems

If, during the course of testing, a participant decides to terminate or refuse the pulmonary function tests, the Clinic Manager will be notified. The participant then will be reminded of the importance of completing the test, recognizing that the individual has the right to refuse. If the participant, at that time, still decides not to continue the test, a refusal with the signatures of the participant and the Clinic Manager will be entered into his record.

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IV. Medical Examination Manuals

K. Quantitative Peripheral Sensory (QPSI) - Vibration Threshold

1. Introduction

The procedures outlined in this manual are designed to be used in concert with a clinical neurological exam to detect the presence of peripheral neuropathy. Vibration threshold is a measure of the integrity of the distal portion of the long and large diameter axons that innervate the pacinian and Meissner corpuscles in both hands and feet. This measure has proven a particularly sensitive index of toxic distal axonopathy.

2. Testing Equipment

- a. Foam pad
- b. Alcohol pads
- c. Two complete vibration machines

(1) The Vibratron is a device developed at Albert Einstein College of Medicine in conjunction with Pfizer, Inc., to quantify the ability of human subjects to detect vibratory stimuli at the distal extremes of their upper and lower limbs. The instrument is currently manufactured and distributed by Chemto Tech, Inc., 60 French Ridge Road, New Rochelle, NY 10801.

(2) The Vibratron incorporates identical vibrating rods, constructed from hardened rubber, which protrude through a Plexiglass plate and can be contacted by either the hands or feet. Vibration is achieved by driving the electromagnetic unit of one of the rods from a variable voltage source. The amplitude of vibration is directly proportional to the square of the applied voltage. A dual position switch connected in series with the vibrating units controls which surface will actually vibrate. A second switch, which does not interface with the power supply, is used to mimic the sounds and motions associated with switching the vibrating surfaces. An analog meter, divided into fifty equally spaced divisions, records the amplitude of the applied voltage. For greater accuracy, the sensitivity of the meter can be increased by a factor of five for the low voltage values. This can be accomplished by using the "High-Low" switch on the surface of the meter.

3. Testing Procedure

- a. Thresholds should be measured unilaterally and on the same side for the index finger and the great toe. The side selected should be the same as that used for electrophysiological (nerve

conduction velocity) procedures; i.e. the dominant limb should be used unless contraindicated by localized pathology (e.g., injuries, history of entrapment, etc.).

- b. The methodology of testing is a "two alternative forced choice procedure". For each trial the subject is REQUIRED to determine which of the two rods is actually vibrating. The position of vibration is under experimental control, determined by a randomization sequence. The intensity is controlled by both an analog knob, positioned below the meter, and the high-low switch.
- c. Prior to testing, all subjects should be allowed an adaptation period of between 10 and 15 minutes during which they can become accommodated to room temperature. At this time each subject should be given an opportunity to become familiar with the testing apparatus and with the expected vibratory sensations. During this period, the experimenter can instruct the subject as to the appropriate length and force with which to contact the vibrating rod. An ideal duration for contact is approximately one second, while the force should be sufficient to blanch the nail. This adaptation period allows the experimenter to determine the appropriate voltage level at which to begin testing. A number of vibration intensities should be set and sampled by the subject. For the initial trial, the experimenter should set the voltage at a level detectable by that subject 100% of the time. For many subjects in the 20 to 50 year age range an initial voltage setting of 40 volts (high range) is sufficient. This level should be increased for subjects with suspected neuropathy, for older subjects or when testing the feet. For each trial both the voltage setting and the subject's choice should be recorded in the appropriate columns on the data sheet.
- d. At the beginning of each testing session the subject should be issued the following instructions: "Please press your finger against each rod in sequence for approximately one second. During each trial you will be allowed to touch the rods only once. Only one of the rods will be vibrating and you must decide whether it's on the right or on the left. The task will become increasingly more difficult and I understand that you will be guessing on many of the trials."
- e. To determine accurate vibration thresholds, the experimenter must be concerned with the following details:
 - (1) The subject should be consistent in the location of touch and in the approximate force applied to the vibrating surface. Instructions such as "please press more firmly" can be issued during testing to insure trial-to-trial consistency.

- (2) Throughout testing, the sounds and motions associated with changing the stimulus position should be presented between each trial. For the conditions where the stimulus position remains unaltered, the "dummy" switch MUST be used. Both the active and "dummy" switch can be used between trials to mask the actual positioning of the stimulus.
- (3) The subject must take care not to contact the rods or Plexiglass surface between trials.
- (4) At the higher voltage settings, the subjects may report a slight vibration in the "silent" rod. This is due to cross vibration between rods. In these circumstances, the subject should be instructed to select the rod vibrating with greatest intensity.
- (5) The subject should be carefully screened from viewing the instrument settings or the data sheet.

4. Testing Algorithm

- a. If the subject is correct on the initial trial, the voltage setting should be reduced by approximately 10% for the next trial and this process should be continued until the first error. This percentage is not an exact requirement, but rather a guideline. When the subject makes his/her first error, the identical voltage setting should be repeated twice for a total of three trials at that level. If the position of the stimulus is correctly identified on two of the three trials, the voltage setting should be lowered 10%. If errors are made on two of the three trials, the voltage setting should be raised 10%. If errors are made at two successive settings at a given level, the third stimulus is NOT NECESSARY. All levels below 2.0 volts (10 on low setting) should be repeated twice, even if the subject selects the correct stimulus position.
- b. Testing is completed when the subject has made a TOTAL of five errors. A single error often appears early in the testing sequence. This anomalous data point is compensated for in the data analysis procedure.

5. Data Analysis Procedure for Voltage Threshold

The first step in calculating the voltage threshold is to determine the voltage settings of the five errors and the five lowest correct scores. The highest and lowest values of the ten scores are eliminated and the mean of the remaining eight scores determine the voltage threshold. When dealing with scores in the low setting range, the values must be divided by 5 to convert to the actual voltage and then averaged as above. The thresholds, measured in volts, can then be converted into micron values using

the chart included in the Vibration Operating Manual. For this study, the calculations will be done by the technicians.

6. Normal Values

The mean vibration threshold for the index finger in the normal population between 18 and 65 years of age is 4.26 volts with a standard deviation of 1.61 volts. The mean vibration threshold for the great toe in the same population is 6.97 volts with a standard deviation of 3.18 volts.

7. Dominant Hand Index Finger

- a. Clean rods and blue plate with alcohol pads.
- b. Turn machine on.
- c. Start with "Hi-Lo" switch on high.
- d. Meter reading 20 on black scale.
- e. Proceed with test, decreasing by 10% if correct.
- f. Throughout testing both active switch (R side) and/or dummy switch (L) side of machine must be used between trials - to mask the actual positioning of the stimulus. If correct on two out of three trials, decrease voltage; if errors on two out of three trials, increase voltage setting.
- g. After reaching 10 on Hi scale, change Hi-Lo switch to Lo and set scale (Black) to 45, and continue with test.
- h. Beginning at 10 (low setting) repeat voltage twice at same meter level.
- i. Test is complete when total of five errors are made.

8. Dominant Great Toe

Place Vibratron on floor and repeat same procedure.

9. Data Collection

- a. As the QPS test is performed, the technician will enter the results onto the data collection form. The final test results, in voltages, will be calculated from previously entered results. At the conclusion of the test, the data will be reviewed by the technician for errors and subsequently will become a part of the hardcopy medical record.
- b. The following procedures will be followed for the collection and reporting of test data:

- (1) At the beginning of the day, the day's scheduling report will be distributed to the staff. This report will list each participant that is to have a QPSI exam for the day. The report does not list the participants in the order to be examined; however, it does show the schedule number (1-23) assigned to the participants.
- (2) The scheduled participant will arrive.
- (3) The technician will check off the participant on the daily schedule. This will provide an ongoing record of participants that have or have not been examined.
- (4) The technician will record the participant's medical record number, the date, the technician's ID# and the exam start time on the data collection form.
- (5) The technician will perform the QPSI examination. As the exam is done, the technician will enter the results onto the data collection form. A series of predetermined measurements have been established for the exam. As each measurement is administered, the technician will enter the correctness of the participant's response. After the participant has been incorrect for five trials, the technician will calculate the results.
- (6) After the technician has completed entry of the results, he/she will enter the exam completion time.
- (7) The technician will review the printed results. If errors are found, the technician will go to the incorrect answer and correct it.
- (8) Once the technician is satisfied with the accuracy of the exam, he/she will verify the printed narrative by signing it.
- (9) The technician will take the data collection form to the nursing station and place it in the appropriate exam slot.
- (10) The technician is now ready for the next participant and will continue with steps 3-9 until all participants for the day have been examined.
- (11) After all participants have been examined, the daily schedule should be taken to the Clinic Manager and filed.

10. Supervision

Testing will be performed by electrodiagnostic technicians. Immediate supervision overseeing the testing by the technicians will be the registered nurses and the Clinic Manager.

11. Quality Control

The Clinic Manager will be responsible for administrative coordination of the quality control program, under the supervision of the Special Assistant for Quality Control and Scientific Affairs. The neurophysiology exams will not be duplicated in deference to participant convenience but the Clinic Manager will personally observe each technician for one entire QPS and nerve conduction velocity test per week. Documentation of the observations will be made on a quality assurance observation form, one copy of which will be included in the participant's medical record, a second copy of which will be kept in a locked file cabinet in the office of the Special Assistant for Quality Control and Scientific Affairs. In addition, 10% of each week's data from these exams will be sent Dr. Joseph Arezzo, Albert Einstein University, New York, NY, for his review. Dr. Arezzo will periodically visit the study site to observe technician performance, check machine calibration, and review an additional 10% of the data.

12. Backup

- a. A third Vibratron is available as a backup.
- b. Backup technicians will be provided from the pool of electrodiagnostic technicians who are cross-trained for NCV, QPS, audiometry and visual testing.

13. Subject Problems

If, during the course of testing, a participant decides to terminate or refuse the vibration threshold tests, the Clinic Manager will be notified. The participant then will be reminded of the importance of completing the test, recognizing that the individual has the right to refuse. If the participant, at that time, still decides not to continue the test, a refusal with the signatures of the participant and the Clinic Manager will be entered into his record.

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IV. Medical Examination Manuals

L. Quantitative Peripheral Sensory (QPSII) - Thermal Threshold

1. Introduction

The assessment of thermal thresholds provides a measure of function within the small A-delta and unmyelinated C fibers of the peripheral nerve. Dysfunction in these fibers is prominent in peripheral neuropathies associated with diabetes, kidney failure and some neurotoxins.

2. Supplies

- a. Small standard screwdriver
- b. "D" cell batteries
- c. Distilled water
- d. Purification agent

3. Testing Equipment

- a. The Pfizer Thermal Tester (PTT) is a device developed at Albert Einstein College of Medicine in conjunction with Pfizer, Inc., to quantify the ability of human subjects to detect changes in temperature at the distal extreme of their upper and lower limbs. The instrument is currently manufactured and distributed by Sentsortek, Inc., 154 Huron Ave., Clifton, NJ 07013.
- b. The PTT incorporates identical thermal plates, constructed from nickel-coated copper that can be contacted by either the hands or feet. Thermal electric cooling or heating is achieved using the Peltier effect and water perfusion. Temperature can be set to within 0.1 °C over a 50.0 °C range and can be adjusted at a rate exceeding 1.0 degrees per sec. During testing, one plate is maintained at a level of 25.0 °C, while the temperature of the second plate is adjusted using a series of fixed step digital controls. The difference in temperature between the plates is continuously available on a digital display, accurate to 0.1 °C.
- c. Model NTE-2 is a sophisticated testing instrument which provides a means of measuring an individual's sensitivity to temperature differences which exist between the tops of two stages.
- d. Each stage is driven by a thermoelectric (peltier effect) module; these modules have the unique ability to provide temperatures both above and below room temperature.
- e. Temperature of each stage can be adjusted by its associated controller, which also maintains stage temperature at the set point. The digital readout on each controller also indicates

the actual temperature of its controlled stage. A Sensortek model TH-7D Differential Thermometer gives a direct reading of the temperature differences between the stages. In operation, a wide temperature difference is set at the start. This is successively reduced by adjustment of the "Active" controller, until the individual can no longer detect any difference between the stages. The actual temperature difference can then be read in degrees and tenths of degrees, directly from the readout of the differential thermometer. No calculations are required.

- f. For stable operation, the thermoelectric modules each require a trickle of cooling water. This is supplied from the Pump and Tank Unit.
- g. Although the NTE-2 is a sophisticated electronic system, it does not require the user to have detailed technical knowledge of the system and is designed for high reliability as well as ease of operation.

4. Machine Setup Procedure

a. Water Pump and Tank Unit

- (1) Unscrew cap. Fill reservoir with two gallons of distilled water.
- (2) Do not operate pump unless tank has been filled with water. Pump may be damaged if run dry.
- (3) AC line cord should be connected to the SWITCHED OUTLET on the rear of the "Passive" controller. This ensures that the water is always flowing when the control unit is turned on.
- (4) Check water level periodically during operation to ensure that water level is within 3 inches of the lip of the container.
- (5) Use only distilled water. This avoids discoloration of tubing due to organic matter in untreated water. Addition of a purification agent is recommended.
- (6) To prevent water spills, all water connections are automatically self-sealing when disconnected.

b. Selecting the Power Supply

- (1) The module controlling AC power is on the back panel, bottom left. There are four settings:

- (a) 100V for unusually low power situations
- (b) 120V
- (c) 220V
- (d) 240V

Be sure selector is set for your requirements.

- (2) Slide clear plastic panel to left. If correct voltage is not visible on card, card must be pulled out and replaced so that correct voltage is visible.
- (3) To change position of card, eject fuse by pulling on the FUSE PULL lever. Pull card forward, rotate and reinsert.
- (4) Replace fuse and slide plastic cover back to the right.
- (5) Attach a line cord to each controller.
- (6) Insert the line cord from the "Passive" controller into the SWITCHED OUTLET on rear of the "Active" controller.
- (7) Insert the line cord from Pump and Tank Unit into SWITCHED OUTLET on the rear of the "Passive" controller. If the power switch for the "Passive" controller is left on permanently, both the "Passive" controller and the pump unit will be activated when the "Active" controller is switched on.

c. Attaching Water Tubes

- (1) Pump and Tank Unit is supplied with two long (5 feet) water tubes and one short (18 inches) water tube. All connections are self-sealing when disconnected to prevent water spills. To connect, push in firmly. Squeeze to disconnect.
- (2) Connect one of the long tubes from OUTLET of pump to water INLET on rear of "Active" controller.
- (3) Connect the second long tube from INLET (RETURN) of pump to water OUTLET on "Passive" controller.
- (4) Connect 18-inch tube to OUTLET on rear of A to INLET on rear of "Passive" controller.

d. Connecting the TH-7D Thermocouple Thermometer

- (1) Two (3 feet) thermocouple extension leads are supplied with the TH-7D. Connect one extension lead to the SENSOR OUTPUT on the rear of each controller. Thermocouple connectors are polarized and fit in one direction only.

- (2) Connect sensor output from "Passive" controller to the lower input on the TH-7d.
- (3) Connect sensor output from "Active" controller to the upper input on the TH-7d.

e. Connecting the Thermal Plates

- (1) Each plate is electronically matched to one of the controllers and care should be taken during setup to ensure that the stage supplied with the individual controller is connected to it. (The system will function correctly if the pairings are reversed. The matching simply provides an extra level of accuracy in calibration.)
- (2) Mount plates on ball-joint bases using the screw thread on underside of plate. Plates can then be set in any convenient position using the clamp on the side of the universal joint.
- (3) Insert water tubes from each stage into WATER INLET and OUTLET connectors in the front panel of the matching controller. These tubes are interchangeable - direction of flow is not important.
- (4) Insert polarized electrical connector from each plate into POWER OUTPUT socket on front of matching controller.
- (5) Twist locking nuts to lock connectors to controllers.
- (6) Insert thermocouple connector into socket labelled SENSOR B - PLATE.
- (7) Switch SENSOR INPUT to B position.

f. Connection to AC Power Supply and "Switch-On"

- (1) Connect AC line cord from "Active" controller to an AC outlet and turn "Active" controller on.
- (2) A buzzing noise from water pump indicates that pump is running. Remove the tank cap and check that water is flowing.
- (3) Indicator lights on both controllers and on the pump and tank unit will light.
- (4) If any lamp fails to light, switch off and check fuses.

5. Operating Instructions

a. Adjustment of Base Temperature on "Passive" Controller

- (1) All parts of the system must be connected and turned on.
- (2) Digital display on "Passive" controller shows temperature of matching stage.
- (3) Depress RUN/SET switch to SET position and hold down while adjusting SET BASE TEMP with screwdriver. Base temperature should be set to 25.0 °C within 0.1 °C.
- (4) Release RUN/SET switch and allow stage to stabilize at set temperature. This should take 1-2 minutes.
- (5) Further slight adjustments to temperature may be made to provide exact setting.

b. Adjustment of Base Temperature on "Active" Controller

- (1) Set all switches under SET DIFFERENTIAL TEMPERATURE to center 0 position.
- (2) Depress RUN/SET switch to SET position and hold down while adjusting SET BASE TEMP with screwdriver. Base temperature should be set to 25.0 °C within 0.1 °C.
- (3) Release RUN/SET switch and allow stage to stabilize at set temperature. This should take 1-2 minutes.
- (4) Further slight adjustments may be made to provide the exact setting.

c. Differential Temperature

- (1) Switch TH-7D Differential Thermometer ON. Thermometer will now read the temperature difference between the two stages to within 0.1 °C. (The temperature displayed on the front of each controller indicates the absolute temperature of each stage.) The differential temperature should be adjusted to 0.0 °C by using a screwdriver to adjust the base temperature on the passive controller.

d. Setting Differential Temperature Between Stages

- (1) The rotary switches on the front of the "Active" controller will adjust the temperature of the matching plate. Controls adjust in 5.0, 1.0, or 0.1 increments and the sum of all settings provides the required differential temperature. Both positive and negative temperatures can be set. Full adjustment range is 20.5 °C either side of the base temperature previously set in Section 5a.
- (2) The TH-7D Thermometer will read differential temperature between the two plates with respect to the base temperature of set on the "Active" and "Passive" controllers.

e. Measuring Absolute Temperature

- (1) The digital display of either controller may be used as a readout for the external temperature sensor. In order to do this, the sensor must be switched to "Sensor A."
- (2) Insert probe (sensor) connector into socket marked SENSOR A - EXTERNAL. Read absolute temperature on controller display.
- (3) During measurement with external sensor, the temperature of the plate is not controlled. Switch SENSOR INPUT back to B and allow plate temperature to stabilize again.

f. Warning Light

- (1) As a protective feature, both audible and visual warnings of operating failure are provided on each controller.
- (2) Switch off immediately if warning light comes on or if buzzer alarm is heard.

g. Controller Specifications

	<u>ACTIVE CONTROLLER</u>	<u>PASSIVE CONTROLLER</u>
OPERATING RANGE	20-30 °C (preset adjustment)	20-30 °C (preset and ± 20.5 either side of nominal set point in switchable 0.1 steps.)
CONTROL ACCURACY	± 0.1 °C	
DIGITAL READOUT RESOLUTION ACCURACY	0.1 °C ± 0.1	
AMBIENT OPERATING RANGE	15-45 °C	
SET POINT	Continuously adjustable with flat-bladed screwdriver	
INPUT POWER REQUIREMENTS	100-120V AC 60Hz 100W 200-240V AC 50Hz 100W	
SIZE	8" high x 7" wide x 15" deep	
WEIGHT	28 lbs.	

OTHER FEATURES

Spring loaded switch
indication of set point.

Safety shut down with warning
lamp in case of fault condition
such as thermocouple sensor
breakage, lack of cooling water or
electronics failure.

Self-sealing water connectors
Auxiliary AC switched output

h. Differential TH-7D Thermometer

DIFFERENTIAL RANGE	±20 °C
RESOLUTION	0.1 °C
ACCURACY	Better than ±0.1 °C
AMBIENT OPERATING RANGE	15 TO 45 °C
BATTERY LIFE	More than 1500 hours with 4 "D" size alkaline batteries
DISPLAY	1" high LCD
SIZE	6" wide x 3-3/4" high x 6-1/4" deep
WEIGHT	3-1/4 lbs.
CONTROLLER PLATE SIZE	2" x 1-3/4" x 1-1/4" thick
WEIGHT	14 ozs. including leads
TEMP. CONTROLLED SURFACE AREA	2" x 1-3/4"
RANGE	0 - 50 °C
LEAD LENGTH	5'
OTHER FEATURES	Built in over-temperature sensor for safety. Built in feedback sensor, type T, copper-conductant. Self- sealing water connector. Adjustable tilt stand.

6. Maintenance

- a. For information on routine maintenance, refer to the Equipment Manual and/or the maintenance information located near the equipment itself.
- b. Thresholds should be measured unilaterally and on the same side for the index finger and great toe. The dominant limb should be used unless contraindicated by localized pathology (e.g., injuries, history of entrapment, etc.).
- c. The methodology of testing is a "two alternative forced choice procedure." For each trial the subject is required to determine which of the two plates is actually colder. The position of the colder plate is under experimental control, determined by a randomization sequence. The intensity sequence is similarly under the control of the experimenter and is determined by a testing algorithm (see below).
- d. Prior to testing, all subjects should be allowed an adaptation period of between 10 and 15 minutes during which they can become accommodated to room temperature. At this time each subject should be given an opportunity to become familiar with the testing apparatus and with the expected thermal sensations. During this period, the experimenter can instruct the subject as to the appropriate length and force with which to contact the plates. An ideal duration for contact is approximately one second, while the force should be sufficient to blanch the nail. This adaptation period allows the experimenter to determine the appropriate voltage level at which to begin testing. A number of temperature differences should be set and sampled by the subject. For the initial trial, the experimenter should set the differential temperature at a level detectable by that subject 100% of the time. Ideally, the temperature should be set high enough so that the subject will have several correct responses before his first incorrect response. For many subjects in the 20 to 50 year age range, an initial temperature of 10 °C is sufficient. This level should be increased for subjects with suspected neuropathy, for older subjects or when testing the feet. For each trial both the temperature setting and the subject's choice should be recorded in the appropriate columns on the data sheet.

7. Testing Algorithm

- a. If the subject is correct on the initial trial, the temperature setting should be reduced by approximately 10% for the next trial and this process should be continued until the first error. This percentage is not an exact requirement, but rather a guideline. When the participant makes his first error, the identical setting should be repeated twice for a total of three trials at that level. If the temperature difference is

correctly identified on two of the three trials, the temperature setting should be lowered 10%. If errors are made on two of the three trials, the temperature setting should be raised 10%. If errors are made at two successive settings at a given level, the third stimulus is not necessary.

- b. Testing is completed when the subject has made a total of five errors. A single error often appears early in the testing sequence. This anomalous data point is compensated for in the data analysis procedure (see below).

8. Data Analysis Procedure

Thermal Threshold - The first step in calculating the thermal threshold is to determine the temperature settings of the five errors and the five lowest correct scores. The highest and lowest values of the ten scores are eliminated and the mean of the remaining eight scores determines the thermal threshold.

9. Normal Values

The mean thermal threshold for the index finger in the normal population between 18 and 65 years of age is 0.73 °C, with a standard deviation of 0.44 °C. The mean thermal threshold for the great toe in the same population is 0.97 °C with a standard deviation of 0.70 °C.

10. Data Collection

- a. As the test is performed, the technician will enter the results onto the data collection form. The final test results, in degrees, will be calculated by the technician from previously entered results, as described in "Thermal Threshold" above. At the conclusion of the entry process, the completed form will be reviewed by the technician for errors and subsequently will become a part of the hardcopy medical record.
- b. The following procedures will be followed for the collection and reporting of medical data:
 - (1) At the beginning of the day, the day's scheduling report will be distributed to the staff. This report will list each participant that is to have a QPSII exam for the day. The report does not list the participants in the order to be examined; however, it does show the schedule number (1-23) that the participants have been assigned.
 - (2) The scheduled participant will arrive.
 - (3) The technician will check off the participant on the daily schedule. This will provide an ongoing record of participants that have or have not been examined.

- (4) The technician will record the participant's medical record number, the date, the technician's ID# and the exam start time on the data collection form.
- (5) Participant Instructions: At the beginning of each testing session, the subject should be issued the following instructions: "Please press your finger against each plate in sequence for approximately one second. During each trial you will be allowed to touch the plates only once. Only one of the plates will be colder and you must decide whether it's on the right or on the left. The task will be increasingly more difficult and I understand that you will be guessing on many of the trials." To determine accurate thermal thresholds, the experimenter must be concerned with the following details:
 - (a) The subject should be consistent in the location of touch and in the approximate force applied to the thermal plates. Instructions such as "please press more firmly" can be issued during testing to ensure trial-to-trial consistency.
 - (b) The time interval between trials should be standardized at approximately 15 seconds. It physically takes longer to set a new temperature level that requires crossing the zero point (i.e., -2.6 to +2.3) as compared with one on the same side of the zero point (i.e., -2.6 to -2.3). This factor must not be reflected in the time period between trials since it can provide a nonthermal clue.
 - (c) When testing at the same level as the previous trial, the sounds and motions associated with temperature change should be faked by the experimenter.
 - (d) The subject should be carefully screened from viewing the instrument settings or the data sheet.
- (6) After the technician has completed entry of the results, he/she will record the exam completion time. The data collection form will contain both the raw data results and the calculated measurements.
- (7) The technician will review the results. If errors are found, the technician will go to the incorrect answer and correct it.
- (8) When the technician is satisfied with the accuracy of the exam, he/she will verify the narrative by signing it.
- (9) The technician will take the data collection form to the nursing station and place it in the appropriate exam slot.

(10) The technician is now ready for the next participant and will continue with steps 3-9 until all participants for the day have been examined.

(11) After all participants have been examined, the daily schedule should be taken to the Clinic Manager and filed.

11. Supervision

Testing will be performed by electrodiagnostic technicians. Immediate supervision will be by registered nurses who will have been trained to operate the equipment. Direct overall supervision will be by the Clinic Manager and technical supervision by the department head of Neurology.

12. Quality Control

The Clinic Manager will be responsible for administrative coordination of the quality control program, under the direction of the Special Assistant for Quality Control and Scientific Affairs. The neurophysiology exams will not be duplicated in deference to participant convenience, but the Clinic Manager will personally observe each technician perform one entire QPS and nerve conduction velocity (NCV) test per week. Documentation of the observations will be made on a quality assurance observation form, one copy of which will be kept in a locked file cabinet in the office of the Special Assistant for Quality Control and Scientific Affairs. In addition, 10% of each week's data from these exams will be sent to Dr. Joseph Arezzo, Albert Einstein University, New York, NY, for his review. Dr. Arezzo will periodically visit the study site to observe technician performance, check machine calibration, and review an additional 10% of the data.

13. Backup

- a. A third PTT is available as backup. For further information on maintenance and calibration of the equipment, see the Equipment Manual.
- b. Backup technicians will be provided from the pool of electrodiagnostic technicians who are cross-trained for NCV, QPS, audiometry and visual testing.

14. Subject Problems

If, during the course of testing, a participant decides to terminate or refuse the thermal tests, the Clinic Manager will be notified. The participant then will be reminded of the importance of completing the test, recognizing that the individual has the right to refuse. If the participant, at that time, still decides not to continue the test, a refusal will be entered into his record.

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IV. Medical Examination Manuals

M. Radiology

1. Introduction

The chest x-ray will be taken by the radiology technician. A standard 14x17 inch chest x-ray in the PA position with nipple markers will be performed on all examinees. Board-certified radiologists will review and interpret all roentgenograms. Reporting of results will be in accordance with the procedures identified in the data management section.

2. Equipment and Supplies

- a. Kodak R-P X-Omat processor
- b. X-ray/H-G Fischer, Inc. console
- c. Film and processor chemicals purchased from Southwest Radiographics

3. Procedures

The following procedures will be followed for the conduct and reporting of the radiographic examination:

- a. At the beginning of the day, the day's scheduling report will be distributed to the staff. This report will list each participant that is to have a Radiology exam for the day. The report does not list the participants in the order to be examined; however, it does show the schedule number (1-23) that the participants have been assigned.
- b. The scheduled participant will arrive.
- c. The technician will check off the participant on the daily schedule. This will provide an ongoing record of participants that have or have not been examined.
- d. The technician will prepare the necessary identification data for the film.
- e. The technician will perform all chest x-rays following the guidelines of the American College of Radiology (ACR) (manual available in the x-ray suite).
 - (1) The normal standard position and film sizes will be followed as closely as possible so that uniform sets of films for each examination will result. Judgment must be used in some cases with handicapped examinees which may, by necessity, rule out routine examinations. At the same time, every effort must be made to secure films of the highest quality for accurate diagnosis.

- f. After all films are taken and developed, the radiologist will begin his/her interpretations. The technician will assist the radiologist with the index code lookups.
- g. As each film is interpreted, the technician will record the medical record number assigned to the participant on the data collection form. In addition, the name of the participant, the date, the technician's ID #, the exam start time, and the exam status will be entered.
- h. The radiologist then records the participant's exam interpretation on the data collection form, which has been designed for input of all relevant findings. The American College of Radiology Index (The American College of Radiology. Index for Roentgen Diagnosis. 3rd ed. Chicago: Waverly, 1975) of standard diagnosis codings will be utilized to code significant findings. Complete copies of this manual are present in the Radiology Department of Lovelace Medical Center. The portions of the manual pertinent for interpretation of chest x-rays are present in the Veterans' Health Study x-ray room and have been appended to this manual (Appendix I). If an abnormality is present, the ACR Index will be referenced to obtain the correct code. This code and its translation are recorded on the data collection form.
- i. After the technician has completed entry of the results, he/she will record the radiologist ID#, and the exam completion time.
- j. The radiologist will review the results. The data record will contain the translation for the codes entered, thereby providing ease in the identification of errors. If errors are found, the technician will go to the incorrect answer and correct it.
- k. The radiologist may have comments or impressions regarding the examination that he/she wishes to highlight. In these cases, the radiologist will handscribe on the bottom of the final narrative any such remarks.
- l. Once the radiologist is satisfied with the accuracy of the interpretation, he/she will verify the narrative by signing it.
- m. The radiologist is now ready for the next participant film and will continue with steps f-1 until all participant films for the day have been interpreted.
- n. The technician will take the completed data collection forms to the nursing station and place them in the appropriate exam slot.
- o. After all participants have been reviewed, the daily schedule should be taken to the Clinic Manager and filed.

4. Supervision

- a. Supervision is provided by the Radiology Department, Clinic Manager, and Medical Director. Problems or questions related to the technical performance or quality of the chest x-ray itself should be directed to a radiologist in the Department of Radiology.
- b. Logistical problems or questions more directly related to the study (i.e., problems with participants, scheduling, obtaining supplies, etc.) should be addressed to the Clinic Manager, or after consulting the Clinic Manager, to the Medical Director.

5. Quality Control

One randomly selected chest x-ray per day will receive an independent blind reading by a board-certified radiologist. In order to minimize radiation exposure, the chest x-ray itself will not be repeated. The original interpretation and the "blind" interpretation will be compared by the Medical Director. If there are discrepancies between the two interpretations, the Medical Director will read the chest x-ray himself, and attempt to reconcile the discrepancy. Any problems will be corrected immediately by consultation with the two interpreting radiologists.

6. Backup

- a. Backup x-ray equipment will be provided by LMCI, Radiology Department, and Southwest Radiographics, 4610-A McLeod Rd. NE, Albuquerque, NM, telephone: (505) 883-9605.
- b. Backup radiologists and technicians will be provided by LMC, Inc., Radiology Department. All technicians will have received training suitable for performing their duties as required by the Lovelace Medical Center Radiology Department.

7. Subject Problems

If, during the course of testing, a participant decides to terminate or refuse the radiographic examination, the Clinic Manager will be notified. The participant will then be reminded of the importance of completing the test, recognizing that the individual has the right to refuse. If the participant, at that time, still decides not to continue the test, a refusal will be entered into his record.

8. Appendix I

- a. American College of Radiology Index of Standard Diagnosis Coding