



# American Association of Sensory Electrodiagnostic Medicine

## Practice Policy Guidelines

January 2010 - Volume 26

### Sensory Pain Fiber Electrodiagnostic (EDX) Medicine Guidelines

**1.** Pain and other sensory disorders, especially spine related pain, make up the second largest group of patients seeking medical consultation. The expenditure for treatment of chronic pain and failed neck and back surgeries is staggering. Back pain alone is estimated to have a total annual cost of over \$100 billion. Recently, methods have been developed to directly assess the nerve fibers transmitting pain, allowing earlier positive outcomes and reduced cost. These guidelines represent the expert consensus by physicians certified in pain fiber electrodiagnosis. The purposes include prevention of over utilization, confusion and misconceptions by third party payers, and clarification of coding.

**2.** The AASEM Practice Guidelines match the April 2002 AMA EDX Guidelines as far as the description of the procedure. Pain fiber nerve conduction studies (pf-NCS) is fast becoming a mainstream medical procedure that is not duplicated by any other medical technology. Physicians and researchers formed the AASEM in 1999 to give users the ability to share information and to form a consensus for its application. The AASEM is now a nationally recognized medical organization meeting CME requirements. The members include present and past Directors of Pain Management at Johns Hopkins, LSU, UCLA and Kaiser Permanente. Pain and Rehabilitation Specialists are represented with affiliations to all the major medical schools and three V.A. hospitals. No conflict exists with the American Association of Neuromuscular Electrodiagnostic Medicine (AANEM) or the American Academy of Neurology (AAN) both of whom are concerned with large motor fiber and sensory A-beta diagnosis, whereas the AASEM focuses exclusively on small pain nerve fiber (A-delta and C-Type) EDX.

**3.** "Pain is Now America's Leading Public Health Problem" NBC NEWS SPECIAL REPORT – January 2006

**40% Of all medical visits are for pain** - National Institute of Health (2002)

**43% Of pain patients develop chronic pain-** NEWSWEEK (June 2007)

**50% Of back surgeries end in failure** - NEWSWEEK (June 2007)

How pf-NCS can help: Pf-NCS allows physicians to stop working in the dark when it comes to treating pain. Conventional EMG/NCV and NCSs were developed by the U.S. Military during World War II to identify cut and crushed large myelinated motor and A-beta fibers, and are unable to assess pain fibers. The August 2008 *Newsweek* published an article titled: "Is Medicare Healthy?" which forecasts that by 2011 funding covering hospital stays will start running out and by 2019 will be gone. A major concern is that new technologies improve care but drive up costs so funds will run out even sooner. Pf-NCS is one new technology that will not drive up costs, and will certainly dramatically reduce costs. It offers this because it is a functional measurement that can be used to detect pathology in its earliest stages when conservative treatment can help avoid the onset of chronic symptoms. It is not dependent on gross myelin loss as required by EMG/NCV. Most important, pf-NCS can localize the source of pain better than symptoms, physical exams, EMG/NCV and MRI.

## Background

### Context of Pf-NCS in Pain Management and Prevention of Chronicity and Failed Back Surgery

**4.** Basic Pain Fiber Pathological Physiology: Only A-delta (Fast Pain) fibers and the C-Type (Slow Pain) fibers transmit pain signals. Over 90% of A-delta fiber signals reach the sensory cortex, while fewer than 10% of the C fibers do. During the Epicritic Phase of nerve A-delta fibers synapse with spinal cord motor neurons to pull us away from the source pain, then quickly down-regulate. The Protopathic Phase sees the excellent localizing A-delta fibers down-regulate while the poor localizing C-Type fibers up regulate. A recent

study confirms that as pain increases A-delta sensitivity decreases, which means as a patient's subjective pain increases he is less and less likely to be able to localize the source of his pain. Concerning this misdirection Guyton & Hall Textbook of Medical Physiology, 11<sup>th</sup> Edition 2006, page 600 states: "It explains why so many patients have serious difficulty localizing the source of some types of chronic pain."

## 5. Limitations of Conventional Diagnostic Methods

Guyton's statement does not reflect how this affects the patient. Patients do not announce; *"I am having serious difficulty localizing the source of my pain."* The patient simply localizes pain to the wrong nerve, and very often to the wrong side. It is impossible for the physical examination to differentiate between referred somatic pain and the actual source of pain. Pain, whether referred or at its source, causes local muscle contraction with reduced motion. If there is any concomitant anatomical deviation the examiner will most likely conclude he has discovered the cause. If no anatomical correlation is found the examiner is likely to conclude the patient is malingering or a hypochondriac.

6. The idea that symptoms and physical exams cannot localize nerve injury is not unfounded conjecture. The medical literature clearly fails to support the widespread assumption that symptoms and physical examinations can accurately detect which nerve is causing pain, especially the most common types of neck and back pain. Add the fact that over 50% of normal subjects have asymptomatic disc and facet anatomy, and that EMG/NCV is guided by the physical exam, and it becomes easy to understand why pain interventions have such a dismal record.

## 7. Symptoms and Physical Examination

The Massachusetts General Hospital Handbook of Pain Management (2<sup>nd</sup> Edition - 2002) States on page 382: "In most cases (over 50%) of neck and back pain the anatomical and physiological diagnosis remains unclear." Page 380: "History and physical examination have a limited role in the diagnosis of back and neck pain but are important in ruling out serious pathology. The etiology of pain in a significant number of patients with back and neck pain may remain unknown. Nonspecific back or neck pain is a legitimate diagnosis."

## 8. MRI:

New-England Journal of Medicine (July 1994)  
University of California at Irvine Medical Center MRI study finds 52% of 98 asymptomatic subjects without any history of injury had diagnosable bulging discs, herniated discs or both.

Pain Medicine & Management (McGraw Hill - 2005)  
Page 28: "Pain cannot be imaged."

## Electromyography (EMG) and Nerve Conduction Velocity (NCV)

9. A desperate need to detect severed or crushed nerves in military personnel during World War II spurred the U.S. Army Medical Corps to develop EMG/NCV. These tests are based on changes in conduction caused by myelin loss in large motor and A beta (Light Touch) fibers. Concerning EMG/NCV the Massachusetts General Hospital Handbook of Pain Management (2<sup>nd</sup> Edition - 2002) states on page 353: "These tests cannot assess the small pain fibers (A-delta & C-Type) or access the pre-dorsal root ganglionic (DRG) fibers causing most radicular pain." The Spine (5<sup>th</sup> Edition, Saunders - 2006) states on page 218:

"Whenever a patient, whose sole complaint is pain (affecting the limbs, neck or back), is referred for an EDX examination, there is the

expectation that there has been some concomitant damage to large nerve fibers that will register on the EDX exam. As is noted later, with chronic lesions this is usually an unrealized hope."

Neurology for the Non-Neurologist (Wiener & Goetz, Lippincott - 2002) states on page 23: "EMG and NCV in neck, shoulder and back pain, in the absence of motor deficit, is costly, time consuming and seldom benefits the patient."

## Over 90% of pain patients have no motor deficit

Natural selection has positioned sensory fibers in the outer layer of major nerve bundles, which allows them to act as an early warning system. The large motor fibers are centrally located, which is preferable since positioning in outer layer would result in the first sign of entrapment being muscle weakness and poor coordination, which is not conducive to survival.

## 10. Pain NCS - Two Amplitude Measurements

It has been known for decades that A-delta fibers consistently diminish in function following injury, making them an excellent marker for identifying and localizing sensory pathology. The pf-NCS is the first EDX capable of measuring diminished A-delta function and, thereby, identify nerve injury.

11. Pf-NCS is not an automated test. The examiner controls the intensity output and the data is typed into a software program that does not make a diagnosis, it simply places the data in a graphic chart for easy visualization of the differences between the controls and pathology. The data goes into a Microsoft Word document for editing and for the examiner's diagnostic impressions. The pf-NCS is not based on detecting velocity changes which are dependent on myelin loss, which the A-delta fibers have too little of and are too small for such tests. The pf-NCS is, rather, a measure of the function of the A-delta nerve fibers and is not dependent on the nerve's anatomical integrity. Being a highly sensitive functional test it has the advantage of detecting pathology in its earliest stages before the onset of chronicity. The problem with large fiber EDX is that it is dependent on myelin loss to slow velocity, which in most pain patients never develops.

12. In pf-NCS, the amplitude of the stimulus and action potential are measured. The amplitude of the action potential verifies the stimulus has caused firing. Generally there is an amplitude surge of >20 millivolts. Recruitment occurs if the minimum stimulus amplitude causing an action potential is maintained. If the stimulus is slightly less than that causing an action potential then there is no recruitment, thus allowing a second method to verify conduction. Recruitment sets in sooner in a compromised nerve so it is useful in verifying pathology.

13. Each patient's unique normal range is calculated by averaging the stimulus amplitudes of nerves in a region. Nerves exceeding this unique normal range identify the sensory pathology. Generally, it can be said that the more the amplitude exceeds the normal range the greater and more severe the pathology. However, in some chronic cases disinhibition may lower the relative hypo-function, so as in any other diagnostic procedure correlation with the patient's history and with any other findings is necessary.

## 14. Electrode Placement

Three electrodes are used in pf-NCS. A large grounding electrode, a small 1 cm in diameter testing electrode, and a compound referenced electrode for detecting the

action potential. Placement depends on the region and nerve. Generally, the test electrode is placed over a standardized site situated over a major nerve that originates from a specific nerve root.

## **Pf-NCS Reporting & Coding**

### **15. AMA EDX Guidelines Are Inclusive Of Pf-NCS**

The April 2002 AMA EDX Guidelines recognize that EDX medicine is too complex to be practiced by cookbook protocols and clearly anticipates technological progress and innovation. Concerning all types of nerve conduction studies (NCS Motor 95900, 95903 and Sensory 95904 page 2 states: "There is no single, universally accepted, specific protocol or set of procedures employed for each diagnostic category. . . . new information may require modification of the initial study design to include other unplanned procedures and may require consideration of different alternative diagnostic possibilities." The AMA guidelines do not exclude any type of sensory fiber, therefore, it is inclusive of all types of sensory fibers.

### **16. AMA Copyright Issues**

Due to copyright limitations the April 2002 AMA CPT EDX Guidelines cannot be directly quoted. Therefore, these guidelines will avoid direct quotes except for brief underlined excerpts. Endnotes referencing the AMA CPT EDX Guideline's page dealing with the preceding section are given for reference by the reader. CMS interpretations of the AMA Guidelines are not copyright protected so direct quotes will be given with endnotes for the CMS source.

### **17. Who Performs Pf-NCS**

NIH data shows that 40% of all patients seeking medical consultation do so because they are in pain. Most of these patients first consult their family doctor or a physician with whom a relationship has been formed. Seldom does a patient self refer to specialist in pain disorders. Many patients delay in the hope that the pain will go away, but delay increases the risk of developing chronicity. AMA Guidelines states that conventional EDX are performed by "neurologists and physiatrists trained in neuro-muscular diagnosis, as well as by internists, primary care physicians, neurological and orthopaedic surgeons, and other healthcare providers." (Direct quote - AMA Page 2)

**18.** Medicare states licensed providers can perform EDX, and "physicians and therapists performing EDX without certification may be subject to review of their studies." (CMS Part B Bulletin January 2006)

**19.** The AASEM supports that the AMA's "other healthcare providers" includes rheumatologists, podiatrists, chiropractors, physical therapists and any licensed practitioner who routinely encounters pain patients. Early stage diagnosis can prevent possible long term problems. This is much more efficient and cost effective than present practices which result in 43% of pain patients developing chronic symptoms and over 50% of back surgeries ending in failure. Even if the physician initially seen does not treat, it is overwhelmingly in the best interest of the patient that he rule in or out nerve pathology so a timely, informed referral can be made to the appropriate specialist.

### **20. Over Utilization Prevention**

Over utilization can be avoided by adhering to a protocol based on symptoms and a history that clearly supports a strong probability of nerve pathology. A balance must be reached between testing early enough to detect pathology before chronicity begins and not testing patients who are not pf-NCS candidates. The earlier nerve pathology is identified the more likely intervention will be successful, but this does not mean that every patient complaining of pain should be tested. The physician must consider the history and circumstances surrounding the onset of symptoms. A twisted knee or ankle sprain is certainly not cause to suspect nerve entrapment, unless sufficient time has passed without indications of resolution, which could suggest that the pf-NCS is appropriate.

**21.** Pf-NCS is used to rule in or rule out sensory pathology and to identify the nerve and/or nerve pathway involved. The test need not be positive to support its necessity, since it is equally important to rule out pathology as it is to detect pathology.

### **22. Pf-NCS Indications**

The following support the necessity for a pf-NCS (Symptoms include pain, numbness and paresthesia):

1. Radiating symptoms following trauma.
  2. Symptoms resistant to conservative care.
  3. Radiation exacerbated by motion or position.
  4. Axial symptoms for longer than two months.
  5. Symptoms with concomitant weakness.
  6. Determine distribution of sensory dysfunction.
  7. Estimate the severity of sensory abnormality.
  8. Determine the progression or rate of recovery.
  9. Aid in prognosis of sensory disorders.
  10. Localization for peripheral or spinal blocks.
  11. Aid targeting of large fiber EMG/NCV.
- (AMA Page 2-3)

### **23. Motor Deficit Considerations**

Page 3 of the AMA Guidelines gives the 3 stages of the NCS. a) Diagnose the probability of nerve pathology. b) Perform the NCS. c) "Completion of indicated needle EMG studies." The operative word is INDICATED. Needle EMG is not indicated in pain without motor deficit. However, if motor deficit is present the pf-NCS should be performed first to more effectively localize the involved nerve tract and thus improve the targeting of the EMG/NCV.

**24.** Lesions causing sensory symptoms may be located in one or more peripheral nerves, nerve roots, predorsal nerve-root ganglionic (Pre-DRG) fibers, spinal cord, brain stem, or brain. Therefore, the pf-NCS should not be employed as a screening tool, but compliment a comprehensive history and other indicated evaluations. (AMA page 1)

**25.** Following an initial pf-NCS, differentiation of the lesion site is possible by testing above and below the suspected site of entrapment, and/or testing the contralateral side for comparison. (AMA Page 4)

### **26. Evidence Based Medicine**

Nerve root lesions/entrapments affect proprioceptive signals from the associated vertebral ligaments, tendons, facets and joint capsules. The spinal cord centers controlling the small intrinsic muscles of the

spine are termed “servo-assist units” by Guyton. These centers require proprioceptive signals to coordinate the coupled motion (tilt and rotation of each vertebra). Nerve root lesions disrupt these signals and cause abnormal vertebral motion. In the cervical spine this is viewed in A.P. x-ray films with the patient’s head laterally tilted without rotation. In the lumbar spine, views are taken with the patient laterally bending without pelvic rotation. In most cases the spinous processes above and below the involved nerve-root rotate in reverse from normal motion. Retests and a single film can confirm improvement. This correlation offers excellent objective evidence of radiculopathy.

**27. Bilateral Testing**

“Bilateral testing is often necessary and reasonable for comparison purposes.” Pf-NCS is generally performed bilaterally to maintain sensitivity which has been shown to approach 100%. (AMA Page 4)

**28. Maximum Number of Nerves Tests Necessary**

Using the patient as his own control has a distinct advantage over comparison with population averages on a bell-shaped curve, which yields about 67% sensitivity. Generally only the side of suspected pathology is billed for a maximum of 6 nerves. One nerve is reported regardless of the number of branches tested on that nerve, e.g. C6-7 radial n., C8-T1 ulnar n.

**Presumptive Diagnosis Nerves**

Cervical Plexopathy . . . . .	6
Lumbosacral Plexopathy . . . . .	6
Carpal Tunnel . . . . .	2
Guyon’s Canal . . . . .	2
Cubital Tunnel . . . . .	2
Ankle Entrapment . . . . .	3
Polyneuropathy . . . . .	7

(AMA page 8)

**29. Repeat Testing**

As a general rule repeat testing is necessary in one of the following clinical situations:

1. A reasonable time passes without symptom change.
2. Symptoms change or become worse.
3. To gauge prognosis after sufficient time has past.

**30.** It is not generally acceptable or reasonable to test a patient who seems to have recovered and is symptom free. Repeat tests do not necessarily require testing of all previously tested nerves. Often only the abnormal nerve can be tested for comparison with the previous measurement.

**31.** The pf-NCS does not require a previous NCS 95900 or 95903 study before it is performed. It bears repeating that NCS is a generic term. Concomitant motor deficit is uncommon in the majority of pain patients. To avoid confusion the pf-NCS should be reported as such to differentiate it from NCV.

**32. Acceptable Diagnostic Codes**

Following a history and preliminary examination the examiner should take into account the strong likelihood his patient may have referred symptoms. Presumptive diagnoses should be broad enough to allow testing to localize unsuspected lesions in the region of interest. For example, in many neck and back cases a

presumptive diagnosis of plexopathy is more appropriate than presuming a specific nerve root is responsible for symptoms. Once pain fiber dysfunction is localized then complimentary examinations can be focused to arrive at a final diagnosis. In some instances a symptomatic diagnosis may be more reflective of the situation, such as ICD-9 code 729.5 “pain in limb” or 782.0 “disturbance in skin sensation” and can be used until a final diagnosis is determined. In some cases a specific final diagnosis is not possible, and the symptomatic diagnosis may remain the final diagnosis. (AMA Page 2)

**33. Scope of Pf-NCS**

Non-EDX experts often expect EDX procedures to conform to fixed protocols, but this is not the case in electrodiagnostic medicine. It cannot be practiced by cookbook, rigidly standardized protocols.

**34.** Electrodiagnostic medicine is composed of three nerve conduction study (NCS) categories all of which are generically termed “NCS” They are motor 95900, 95903 and 95904 sensory NCS. The etiology of a common complaint, such as sensory paresthesia (pain, tingling and numbness), may be localized in the brain, spinal cord, nerve roots, plexus, or peripheral nerves of the limbs. Even though many EDX examiners may study a problem in equivalent ways, “there is no single, universally accepted, set of procedures or protocol for each diagnostic category.” (AMA pg. 2)

**35. Sensory NCS (95904)**

“Sensory NCSs (95904) are performed by applying electrical stimulation near a nerve and recording the response from a distant site along the nerve. Response parameters include amplitude, latency, configuration, or conduction velocity.” The physician determines which response or combination is required in a particular case. It is noted that this descriptor is plural (NCSs – are performed) The only way this can be plural is to pick and choose from the responses. At least one is required to be within this descriptor, but not all are required. (AMA pg. 3)

**36.** The following 95904 descriptor is given in CMS Memorandum CAG000106-R July 2003: “In NCS (sensory 95904) a skin electrode provides a neural stimulus and a more distally placed electrode records information from the resulting action potential (e.g., conduction velocity, latency of response and amplitude of response).” In conformity with the AMA CPT 95904 descriptor, CMS does not require all responses. This is shown by the use of the term “e.g.” meaning for example, which denotes that one or more of the listed responses fulfills the descriptor.

**37. The pf-NCS Interpretation**

None of the presently available pf-NCS devices use an automated protocol/analysis. Interpretations are performed by the examiner. The examinations are performed by a physician, therapist or staff member under the physician’s supervision.

**AASEM Medical Literature Review**

**Study #1 Predicting Nerve-Root Pathology with V-SNCT (Pf-NCS prototype) Present pf-NCS is not a V-sNCT.**

**38. Internet Journal of Anesthesiology Vol. 6 #1 – 2002** Randall Cork, MD, PhD et al of LSU Pain Center This 3 year peer-reviewed study selected chronic and failed back cases where it was strongly suspected that nerve-root adhesions had developed. Epidurogram performed on 49 patients, 25 of which were failed back surgery cases. The results found that physical neurologic exam had 61.7% sensitivity while pf-NCS had 94.6% sensitivity compared to visualized adhesions. Specificity was equal at 71+ 1%. Dr. Cork has gone on record that surely the specificity is much higher, since in his opinion the pf-NCS is the gold standard and not epidurogram.

#### **39. AASEM Investigation:**

Hodgkins and Huxley won the Nobel Prize in Medicine for discovering the voltage-gated Na and K ion channels in 1963. Though for decades every physiology textbook has explained that the action potential (voltage), nerve impulse, is produced by these voltage-gated channels this is not widely understood. An example of this is the fact that a CMS panel, made up of two MDs and a MD, PhD, published Memorandum CAG00106R (July 8, 2003) which stated that the CMS team felt it was an unproven theory that nerves are sensitive to voltage. They also dismissed the LSU study because "It was not clear how the patients were selected or if the examiners were blind to the results of the other examinations." However, the first line under Methodology states; "After IRB approval and informed consent, patients with L5 or S1 radicular back pain scheduled for lysis of epidural adhesions were studied." CMS failed to understand that IRB approval requires examiners to be blind, and the second half of the sentence clearly states the criteria for patient selection. Dr. Cork was not contacted even though CMS regulations allow contact for clarification.

#### **40. AASEM Findings:**

The LSU study meets the 3 criteria of Class I Evidence

- Broad spectrum of subjects with the condition
- Results compared to a "gold standard" Objective visualization on epidurogram
- Blind assessments

#### **41. Study # 2 Getting to the Nerve-Root of Fibromyalgia**

*Annual Scientific Meeting of the American Society of Regional Anesthesiology and Pain Medicine- 2002* Randall Cork, MD, PhD et al of LSU Pain Center The pf-NCS was performed on patients diagnosed with fibromyalgia. Over 50 patients were found to have previously undetected radiculopathies. They were treated and follow-up evaluations made on ten after 6 to 12 months. All ten were found to be free of fibromyalgia symptoms.

#### **42. Pf-NCS Diagnosis of Piriformis Syndrome**

*Annual Scientific Meeting of the American Society of Regional Anesthesiology and Pain Medicine- 2002* Randall Cork, MD, PhD et al of LSU Pain Center This study based on performing pf-NCS on 50 patients, found an 80% probability of concomitant piriformis entrapment if abnormal function was present in the L5 and S1 on the ipsilateral side.

#### **43. Pf-NCS Objectively Proves Pain Severity**

A soon to be published AASEM funded study will be presented at its 2010 annual conference. The study is a multi-center retrospective comparison of over 100

pairs of A-delta pf-NCS graphs and their respective VAS ratings. Time intervals ranged from 3 days to 19 months. The study demonstrates that as VAS ratings increases A-delta fiber sensitivity decreases, so the increasing pain is due to poor localizing C fiber activity. This means that as pain increases so too does the likelihood that the patient will incorrectly localize the source of nerve-root pain. This also supports the ability of the A-delta pf-NCS to identify which nerve-root is causing pain and other sensory symptoms. Additionally, this supports that the A-delta pf-NCS can verify presence of subjective pain.

**44.** Another study to be presented at the AASEM 2010 conference compares EMG-type EDX with the pf-NCS. Not surprisingly, the pf-NCS is many times more effective at detecting sensory pathology than EMG-type test.

#### **45. Pf-NCS Objectively Proves Pain Severity**

*American Association of Sensory Electrodiagnostic Medicine- Annual Conference – 2006*

Randall Cork, MD, PhD et al of LSU Pain Center Retrospective study of 53 patient charts. The finding:

- Significantly decreased pf-NCS scores after lumbar interventional procedures ( $p < 0.001$ ).
- Lumbar Pain Patients - Paired T-test indicated significant changes in McGill Pain Questionnaire & Oswestry Disability Questionnaire with  $p = 0.012$  and  $p < 0.001$  respectively.
- Transforaminal ESI & Interlaminar ESI resulted in decreased pf-NCS ( $p < 0.05$ ).

Conclusions:

Pf-NCS - direct sensory test that assesses peripheral sensory nervous system by measuring voltage intensity which initiates membrane potential changes to propagate nerve impulses. Allows physician to identify a target & assess results of interventional pain procedures. In his presentation, Dr. Cork stated that LSU Pain Center has reduced MRI by at least half since using pf-NCS, and he considers it the true "gold standard" for pain fiber diagnosis.

#### **46. Pf-NCS Correlates With Abnormal Coupled Vertebral Rotation in Lateral Bending Radiographs**

*American Academy of Sensory Electrodiagnostic Medicine - 2007: J. Hedgecock, PhD.*

Patient series consistently found reverse spinous process rotation (reversed coupled motion) of the vertebral segment above and/or below the level of nerve-root pathology identified by pf-NCS.

#### **47. Chronic Prostatitis Causing Pelvic Pain Due To Sacral Entrapment**

American College of Surgeons – 2008

Mohammed Badruddoja, MD, MS, FRCS, FRACS Study found that 44 of 53 patients with chronic prostatitis had L5 or S1 pathology of the A-delta fibers on pf-NCS. Of 29 treated with uroplasty (neuromodulation) 21 were asymptomatic in 12 weeks. Conclusion: Pelvic pain due to Chronic Prostatitis is very likely due to Lumbosacral nerve root entrapments.

#### **48. AASEM Findings Summary:**

Break-through technologies have historically met resistance, and pf-NCS is no exception. Why look for a solution to a problem that few will admit even exists? A major obstacle has been the fact that many physicians

are under the misconception that conventional EMG/NCV can diagnose pathology of pain fibers.

Researchers take it for granted that a test that directly measures pain fiber function is better than EMG/NCV which cannot test these fibers, so there is no need for a study. However, recently mainstream news organizations have turned a spotlight on pain and the failures of conventional methods. It is now seen that pain is a major medical, as well as economic, problem. Governmental bodies have taken up the call. Presently several studies are underway at major universities and medical institutions, designed to directly compare pf-NCS with EMG/NCV and MRI. It is unconscionable that insurers would say pf-NCS is investigational.

**49.** Only the FDA has the authority to designate a device or method as being investigational. Additionally, as stated above, EMG/NCV cannot even test pain fibers, yet insurers willingly cover these tests.

**50.** Early studies support pf-NCS is a vast improvement over conventional methods. The pf-NCS is following the same trajectory as MRI, which early on was looked upon by third-party payers as a medical billing gimmick, whereas, now it is considered an essential element in diagnosing neck and back pain. The pf-NCS is the only technology offering the "evidence based" medical assessment that has been missing in pain management. The economic savings it offers and increased accuracy it offers in targeting early stage interventions is unprecedented. The demand for this technology should cause it to be fast tracked as a standard of care. Insurers who encourage its use stand to save billions of dollars which are presently being spent on misdirected treatment and ongoing care for failed pain patients.

## 51. Misconceptions – pf-NCS Devices

None of the presently available pf-NCS devices are handheld, and all require simultaneous use of both hands. Without doubt this is the most ridiculous excuse for non-coverage. Most pf-NCS devices are capable of producing computer generated graphs and printouts of the amplitudes and other configurations. Since pf-NCS detects pathology independent of myelin loss and pain fibers are too small, velocity and configuration are not part of the pf-NCS.

## 52. Sensory Nerve Conduction Threshold

A common misstatement by third-party payers is that pf-NCS is the same as "sNCT - Sensory Nerve Conduction Threshold using Current Perception Threshold" for which CMS issued a non-coverage NCD 160.23, April 1, 2004. The NCD states "sNCT is a psychophysical assessment. . . perception test". It then states "This test (sNCT) is separate and distinct from tests measuring amplitude . . . All pf-NCS devices measure the amplitude of the action potential.

## 53. Hayes Summary & Report

In March 2009 Hayes, who is totally funded by the insurance industry, published a report on the Neural-Scan, a device used to perform pf-NCS. This report is made up of fabrications and misstatements. Below are listed the erroneous facts:

Page 2:

A. Hayes cites studies using a different type of measurement (Neurometer) to show the ineffectiveness of the Neural-Scan. The Neurometer uses a completely different physiologic measurement and measures a different component of the electrical signal.

B. Hayes cites a study using the Neural-Scan's prototype but fails to explain anything about the study. Facts: The study appeared in a peer-reviewed publication (The Internet Journal of Anesthesiology).

This is a Class 1 study in which the examiners were blind. It found the technology has 95% sensitivity identifying nerve-root pathology. Hayes fails to mention that the pf-NCS technology is many times better than that which insurers consider to be the gold standard, EMG/NCV, which cannot test pain nerve fibers. In fact, EMG in the absence of motor symptoms, which is the case in the vast majority of pain patients, has only shown 29% sensitivity. Hayes leaves all this out.

C. Hayes cites a non-existent 2003 CMS document that is purported to name the Neural-Scan. This document does not exist, and the Neural-Scan did not exist until August of 2004.

D. Hayes cites opinions from insurance company executives that the Neural-Scan is a QST device.

**54. QST:** Small pf-NCS is different and distinctive from Quantitative Sensory Testing (QST), which employs naturally occurring stimuli that are innate to humans, such as temperature, pressure or vibration. Also, QST requires the patient to judge a change in stimulus intensity. In comparison, pf-NCS employs an electrical stimulus, which is not innate to humans, and does not require the patient to judge a change in stimulus intensity, such as feeling colder or warmer, etc. In the pf-NCS even without measurement of the action potential, no subjective judgment of the intensity is required.

## 55. BILLING EXAMPLES

Massachusetts General Hospital Pain Handbooks states: "*In most cases (over 50%) of neck and back pain the diagnosis is unclear.*" In light of the above, a presumptive diagnosis of plexopathy makes sense, because it allows regional testing to detect hidden lesions and make a final diagnosis, which is the strength of the test.

### ALL INSURANCE TYPES

### Bilateral Symptoms or Contralateral Findings

#### Cervical

##### HCFA FORM

##### SPACE 21

1. 353.0 cervical plexopathy
2. 953.0 cervical nerve root injury

#### Lumbar

##### HCFA FORM

##### SPACE 21

1. 353.1 lumbar plexopathy
2. 953.2 lumbar nerve root injury

## 56. Reasonable % of 95904 Studies by specialty:

70%: Neurologists, Physiatrists, Pain Mgmt/Rehab, Spine Surgeons

70%: Physical Medicine/Therapy, Chiropractic

30%: General Practice, Family Practice, Internal Medicine