EDX and NM Medicine: Looking to the Future as We Address Today’s Challenges

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Dr. Boninger has indicated that his material references an “off-label” use of a commercial product.

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Chair: Vincent J. Tranchitella, MD

The ideas and opinions expressed in this publication are solely those of the specific authors and do not necessarily represent those of the AANEM.
Objectives

Objectives - Participants will acquire skills to (1) Define fraud and abuse, (2) recognize the ubiquitous nature of fraud and abuse as it pertains to EDX medicine, (3) differentiate the various types of fraud and abuse, (4) discuss why hand-held devices and mobile diagnostic labs contribute to fraud and abuse, (5) detect EDX studies performed by methods inconsistent with AANEM standards, and (6) formulate a plan for identifying and dealing with fraud and abuse in your medical community.

Target Audience:

• Neurologists, physical medicine and rehabilitation and other physicians interested in neuromuscular and electrodiagnostic medicine
• Health care professionals involved in the diagnosis and management of patients with neuromuscular diseases
• Researchers who are actively involved in the neuromuscular and/or electrodiagnostic research

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EDX and NM Medicine: Looking to the Future as We Address Today’s Challenges

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Dr. Kuiken received his medical degree and PhD in biomedical engineering from Northwestern University and completed his physical medicine and rehabilitation residency (PMR) at the Rehabilitation Institute of Chicago. He currently serves as director of Northwestern’s Center for Bionic Medicine and is a professor there in the PMR, Biomedical Engineering, and Surgery Departments. Dr. Kuiken’s research team is working to develop a neural-machine interface to improve the function of artificial limbs by developing a technique to use nerve transfers for improvement of myoelectric prosthetic control. By transferring the residual arm nerves in an upper limb amputee to spare regions of muscle, it is possible to make new signals for the control of robotic arms which are related directly to the limb’s original function, allowing simultaneous control of multiple joints in a natural way. Similarly, hand sensation nerves grow into spare skin so, when this skin is touched, the amputee feels like the missing hand is being touched.

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Building Bionic Interfaces

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Upper limb amputation causes a devastating disability. In the United States, an estimated 41,000 people live with arm amputation at or above the wrist; worldwide, this number is in the millions. The functional impairment caused by arm amputation is clear: human hands are incredible tools, and losing a hand greatly limits what a person can do. Although people adapt and can live very full lives with only one intact arm, most tasks are harder, are more time-consuming, and frequently require a work-around. The loss of both hands is even more devastating and can make it extremely difficult to complete even the most basic tasks. The psychological impact of losing one or both arms is also enormous. Depression, anxiety disorders, and post-traumatic stress disorder are seen routinely, if not expected, in people who undergo upper limb amputation. Finally, losing an arm has a profound impact on social interactions; humans talk with their hands, greet one another with a handshake, and hold hands to show affection.

The loss of function caused by upper limb amputation is best treated using an appropriate prosthetic device. There are two general types of upper limb prostheses: body-powered and myoelectric. Body-powered devices, which were invented just after the Civil War and refined following World Wars I and II, work by harnessing shoulder motion: the patient protracts their shoulders to pull on a cable that transfers this movement to the prosthetic joints. These devices are still in use today because they are robust and relatively simple to operate.

Myoelectric prostheses are motorized devices that are controlled using electromyographic (EMG) signals from residual muscles. They work fairly well for individuals with transradial amputations, where signals from the residual hand flexors and extensors in the forearm are used to open and close a prosthetic hand. This operation is intuitive, because hand-control muscles are used to operate the prosthetic hand. However, these muscles are lost with higher levels of amputation, as are muscles that controlled the wrist and, sometimes, the elbow. Patients with transhumeral or shoulder disarticulation amputations must therefore use the very unnatural process of activating their upper arm or chest muscles to control physiologically-unrelated joints in the prosthesis. Also, because many muscles are lost, EMG signals from the one or two remaining muscles must be used to control several different prosthetic functions. This means that the user must sequentially switch the prosthesis through different modes so that the EMG signal can be used to control either the prosthetic hand, wrist, or elbow. Thus, current upper limb prostheses for high-level amputees are cumbersome and awkward to control—and they inadequately restore lost function. This is perhaps best illustrated by rates of prosthetic usage: only approximately 25% of transhumeral amputees and less than 5% of shoulder disarticulation amputees use any prosthetic device.

A variety of robotic arms are available to patients today that include up to three motorized joints: powered elbows, powered wrist rotators, and powered hands that open and close. Prosthetic hands with individually actuated fingers recently have become available. Highly articulated prosthetic limbs with up to 20 degrees of freedom (DOFs) (i.e., movement of one joint along one axis, such as elbow flexion/extension) also have been developed in research settings but are not yet commercially available. The challenge for using all of these devices—especially for high-level amputees—is how to intuitively control multiple DOFs.

To control a multifunctional prosthesis, a neural interface is needed to record motor commands intended for the missing limb, decipher the user’s intended movements, and command the prosthetic arm. Such an interface would allow intuitive control of more complex devices, as prosthesis users would simply use their
natural motor control commands to operate relevant prosthetic joints. In addition, providing closed-loop control by returning relevant sensory signals to the user would correlate prosthesis activity with limb sensation, resulting in an important feedback system and improved control.

TARGETED MUSCLE REINNERVATION

The author and his colleagues have developed a new biological neural machine interface for individuals with amputations called targeted reinnervation. In targeted muscle reinnervation (TMR) the residual nerves from an amputated limb are surgically transferred onto alternative target muscles that are no longer biomechanically functional due to loss of the arm. During the nerve transfer procedure, target muscles are denervated so that they can be reinnervated by these residual arm nerves. The reinnervated muscles then serve as biological amplifiers of the amputated nerve motor commands. Subcutaneous tissue covering the target muscles is removed so that surface EMG signals are optimized for power and focal recording. TMR provides physiologically appropriate EMG control signals to control analogous functions in the lost arm. For example, transferring the median nerve to a segment of pectoralis muscle provides a “hand close” EMG signal. The patient attempts to close his or her missing hand and the segment of the pectoralis muscle reinnervated by the median nerve contracts. The resulting EMG signal is then used to provide a control input to close the motorized hand. By transferring multiple nerves, TMR allows intuitive, simultaneous control of multiple joints in an advanced prosthesis.

TMR surgery has been incredibly successful: 94% of nerve transfers produce usable EMG signals. Using four reinnervated sites to control hand open/close and elbow flexion/extension, patients have shown a marked clinical improvement in performance of selected tasks, including a 2.5-7 fold increase in task speed and have reported that control of their prostheses is significantly easier and more natural. Because additional control sites are created, the need for mode switching is reduced, allowing patients to control joints simultaneously. Patients can control multiple joints in an advanced myoelectric prosthesis using reinnervated muscles and other residual muscles. Videos of several subjects controlling a prosthesis after TMR are available at the Center for Bionic Medicine (CBM) Rehabilitation Institute of Chicago website (www.ric.org/research/centers/cbm/). To date, more than 70 patients have had TMR surgery throughout the United States, Canada, and Austria.

TARGETED SENSORY REINNERVATION

Similarly, targeted sensory reinnervation (TSR) may also be used to provide the amputee a sense of touch in the missing limb. With this technique, a segment of skin near or overlying the target muscles is denervated and the regenerating afferent nerve fibers from the residual hand nerves reinnervate this area of skin. As a result, when this skin is touched, the amputee feels as if their hand is being touched. This has been termed “transfer sensation” and it is an exciting mechanism to potentially provide meaningful sensation to the amputee. For example, sensors on the prosthetic hand could quantify pressure, temperature, and object textures, and actuators in the socket could apply proportional pressure, thermal, and shear stimuli to the reinnervated skin so that the amputee “feels” what he or she is touching.

Providing useful sensory feedback after TSR using haptic devices has proven difficult to develop for clinical deployment. Experiments showing proof of concept have been exciting, but the experimental actuators are large, and placing such actuators in a prosthetic socket has been very challenging. However, research to resolve this issue continues in several laboratories around the world.

PATTERN RECOGNITION CONTROL

The premise of EMG-based pattern recognition control is that muscle activation patterns produce a distinct and consistent response for each intended movement. Most research has been performed at the transradial level of amputation where the remaining forearm muscles produce rich EMG signals that contain control information for wrist and hand movements. First, the user trains a “classifier” by making a series of attempted movements. An array of EMG electrodes records the EMG data from residual muscles, and the pattern recognition algorithm then decodes this initial set of EMG signals to identify the unique characteristics of each movement; the classifier thus learns the subject’s natural EMG patterns corresponding to each movement. Subsequently, for each attempted movement, the classifier can determine what movement the user intends to make and send an appropriate command to the prosthesis. Thus, the user controls the device by simply attempting to perform a normal movement; the result is much more intuitive control of the prosthesis. Classification is repeated at 25-300 ms intervals to provide continuous control.

Pattern recognition involves feature extraction (i.e., retaining the most important discriminating information from the EMG signals) and classification (i.e., assignment of intended movement to one of a subset of possible movements). Pattern recognition control systems usually consist of two parallel routes: determination of movement speed is the same as in a conventional control scheme, whereas function selection involves EMG pattern classification. The controller both selects the corresponding function in the prosthesis and controls the speed in proportion to the sum of the EMG intensity on all monitored channels.

Many classification techniques have been investigated, including linear discriminate analysis, Bayesian statistical methods, artificial neural networks, and fuzzy logic. All report similar classification accuracies (92-98% accuracy), and there is no statistical difference across a subject pool, provided the classifiers are properly tuned and use a good feature set. The author and his colleagues have found that a feature set and classifier combination based on time-domain features and linear discriminant analysis (LDA) is simple and accurate and have tested this combination in amputees using prostheses.

For transradial amputees, the author’s laboratory and others have shown that pattern recognition enables the user to intuitively operate wrist rotation, wrist flexion/extension, and hand open/close and even to choose some different hand grasp patterns. Selection of different DOFs is quicker using this process as users do not have to switch their prostheses into different modes.
This ability to smoothly transition from one movement class to another is termed seamless sequential control. As such, real-time pattern recognition control offers a significant improvement over conventional control because the user can control each DOF by simply attempting the appropriate physiological contraction. In addition, pattern recognition control can potentially restore more DOFs than can conventional myoelectric control.

TARGETED MUSCLE REINNERVATION AND PATTERN RECOGNITION CONTROL

TMR and pattern recognition control are a very exciting combination with strong synergy. In TMR, the brachial plexus nerves that innervate all of the muscles of the arm—including those of the forearm, wrist, hand, thumb, and fingers—are transferred to target muscles. EMG signals from target muscles thus contain data about all possible movements of the hand and arm. This wealth of motor control information can be decoded using pattern recognition algorithms to provide intuitive control of many DOFs. Using an LDA-based pattern recognition algorithm, 16 user-intended movements could be deciphered including movements of the elbow, wrist, and fingers/thumb with 96% average classification accuracy. This high-density recording interface was further optimized by removing redundant EMG channels. The author and his colleagues determined that only 6-12 EMG channels were required to reach high classification accuracies. Thus a clinically feasible number of electrodes is sufficient to access the rich neural control information in the reinnervated muscles and provide accurate control of multiple DOFs. Demonstrations in the author’s laboratory show that patients can reliably control elbow flexion/extension, wrist rotation, and wrist flexion/extension as well as choose from five different hand grasp patterns to operate a prosthesis with much greater dexterity.

Although commercial prostheses are not yet capable of accepting pattern recognition commands, the author’s group demonstrated real-time pattern recognition control of experimental advanced arm systems from the Defense Advanced Research Projects Agency (DARPA) Revolutionizing Prosthetics program in TMR patients. Three patients (one with bilateral shoulder disarticulations and two with transhumeral amputations) were fitted with DEKA Research and Development Corporation’s arm system, which provided 10 DOFs, and The Johns Hopkins University Applied Physic Laboratory arm system, which provided 7 DOFs. All patients demonstrated remarkable control of these devices within a short period of time, including being able to control three to four different hand-grasp patterns. Videos of these patients operating these advanced arm systems with the author and his colleague’s pattern recognition system are available on the CBM website.

There is great potential to further evolve TMR and pattern recognition control technologies. The author’s laboratory is working to develop a microprocessor system capable of performing pattern recognition control with commercially-available limb systems. This controller takes in the EMG signals from the limb, performs the necessary algorithms, and then outputs control signals into the EMG inputs of the arm. Thus, the arm can be controlled with a “front end” system.

POWERED LEG CONTROL

Another exciting area of research is powered leg systems. Motorized lower limb prostheses have only recently become available and many more are in development. These robotic legs also need very robust control systems: any error could cause a fall and result in injury to the user. The author’s laboratory is working to create robust and intuitive control systems for motorized legs using much of the technology evolved for prosthetic arms. EMG signals from the residual limb are integrated or fused with data from mechanical sensors on the prosthesis to develop an intuitive control system that naturally enables the user to move from walking to stairs or ramps or even to sit down. In a non-weightbearing mode, these experimental systems enable the user to reposition the knee and ankle using only EMG input. This is important for tasks such as repositioning the leg to stand or tucking in the leg to transfer into or out of a car.
REFERENCES

Brain-Computer Interfaces: Success from the University of Pittsburgh

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INTRODUCTION

Restoration of upper limb function is a top priority for individuals with tetraplegia. Sophisticated, motorized prostheses are being developed that enable natural upper limb movement and have advanced sensing capabilities. These motorized prostheses can provide function comparable to that of an intact limb, but a high degree-of-freedom control interface is needed. Utilizing brain-computer interfaces (BCIs) is one approach for achieving natural and intuitive control of these devices. As the BCI field progresses, it will be necessary to add tactile and proprioceptive feedback in order to restore full limb control. Work at the University of Pittsburgh has led to unprecedented success in achieving motor control in two subjects with paralysis. This success was due to the efforts of a large team that is unique in that it is focused on multiple different methods of recording brain signals including imaging techniques like functional magnetic resonance imaging (fMRI), magnetoencephalography, electrocorticography (ECoG), and intracortical microelectrode single unit recording. In addition, the authors’ team contains both basic scientists who have had tremendous success with non-human primate models and experts in the clinical application of assistive technology that directly impacts humans. Finally, in addition to working on motor control, the team has a dedicated group working on sensory restoration. This brief discussion summarizes that work.

COVERT ACTIVATION OF MOTOR CORTEX MEASURED WITH ELECTROCORTICOGRAPHY

ECoG data were recorded from four able-bodied subjects who were undergoing subdural ECoG monitoring for intractable seizures. They were asked to execute and observe grasping movements. Three objects (i.e., a ball, hammer, and pen) that required a power grasp, cylinder grasp, and pinch were used. Three of the four able-bodied subjects showed significant, congruent activity in the high gamma band during overt and observed movement. For all three grasps, a significant decrease in sensorimotor rhythm power and an increase in high gamma band power compared to rest was observed, with a similar temporal profile for observed and overt movement. The high gamma band carries significant information about movement, both overt and covert, and therefore may be important for developing a BCI. Across all subjects, strong correlations were observed in normalized spectral power for both the sensorimotor rhythm and high gamma band over the planning and movement phases for overt and observed movement. For the high gamma band, the average depth of modulation was 19.9±7.7% during observation and 25.0±11.3% during overt movement. These experiments established a sound background to begin BCI testing in individuals with disability. Before implantation, the best location for electrodes needs to be determined, and this can be accomplished with observed movement.

MOTOR MAPPING FOR BRAIN-COMPUTER INTERFACE PLANNING

fMRI was used to map motor-related cortical activity as part of the presurgical planning for the studies using implanted BCI recording devices. The first subject, who had a C4 complete spinal cord injury (SCI), participated in the ECoG BCI study. The second subject, who had spinocerebellar degeneration that resulted in complete motor loss below the level of the neck, but intact sensation, participated in the intracortical BCI study. During fMRI, a simple block design paradigm was used where subjects imagined performing single-joint movements along with a video.
Participants imagined performing repeated joint movements to mimic the movement of a first person video of the same task. The goal of this mapping was to identify which areas of the motor cortex were active during attempted arm and hand movements to help direct the surgical placement of recording electrodes.

**ELECTROCOGRTOGRAFy BRAIN-COMPUTER INTERFACE AND SOMATOTOPy IN THE SENSORIMOTOR CORTEX**

The team’s study investigated the feasibility of an ECoG-based BCI system in an individual with a C4 level SCI. ECoG signals were recorded with a high-density 32-electrode grid over the hand and arm area of the left sensorimotor cortex. ECoG signals demonstrated modulation when the participant observed and simultaneously imagined right hand and arm movement even though the participant was unable to generate overt movements. The most prominent modulation patterns were an increase in power for the gamma and high-gamma bands and a decrease in power for the sensorimotor rhythm (10-30 Hz), both tightly coupled in time with movement. Attempted movements of the hand and elbow elicited distinct cortical activity patterns, with the centers of activation being lateral for attempted hand movement and medial for attempted elbow movement on the ECoG grid.

Based on the different cortical activation patterns for different imagined movements, the participant was able to voluntarily modulate sensorimotor cortical activity to achieve high-fidelity, real-time BCI control of 2D and 3D cursor movement. The subject reported that imagining specific movements, such moving a videogame joystick, was more effective than just thinking about “moving his thumb.” That motivated the researchers to study the effect of goal-directed tasks for covert brain mapping. Using imagined movement to drive the computer cursor, the subject achieved a success rate of 87% over 176 trials in the last 2D cursor control session. By the end of training, the participant achieved an 80% success rate for 3D cursor control. On day 27 of the study, the participant controlled 3D movement of a prosthetic arm successfully to hit physical targets and “high five” members of the research team. The subject commented that this was the first time that he reached out to another individual in 7 years. This not only demonstrates the potential utility of an ECoG BCI based on somatotopic organization, but also that BCI control can be translated to various end effectors.

**INTRACORTICAL MICROELECTRODE BRAIN-COMPUTER INTERFACE**

In order to perform activities of daily living, one needs to be able to position the hand in space, orient the palm, and grasp an object. Non-human primate studies have shown that intracortical microelectrode arrays can capture natural movement-related information that can enable these movements. The authors’ research group demonstrated that a person with tetraplegia was able to rapidly achieve control of a state-of-the-art motorized prosthetic limb (i.e., the Modular Prosthetic Limb [MPL], The Johns Hopkins University Applied Physics Laboratory). Two microelectrode arrays were implanted in the motor cortex based on presurgical functional mapping. The neural decoder was trained while the subject observed motion of the MPL under automatic computer control. After 13 weeks of training, robust 7D (3D translation, 3D orientation, 1D grasping) movements were performed routinely. These movements included reaching and grasping tasks, similar to many activities of daily living, which were carried out with coordination, skill, and speed approaching that of an able-bodied person. This BCI allowed the study participant to perform a wide variety of tasks including shaking hands, stacking cones, and eating (Figure).

![Figure. Using an intracortical brain-computer interface, a person with tetraplegia was able to use the motorized prosthetic limb to shake hands (left), stack cones (center), and feed herself (right).](image)

**SENSATION**

Ultimately, the goal of the research here is to restore function to the entire upper limb. The loss of proprioception and tactile cues will make it more challenging for people to take advantage of neuroprosthetic technology designed to restore movement, such as functional electrical stimulation devices, as well as external assistive technology, like exoskeletons and robotic manipulators. Proprioception generally is considered to be crucial in the learning and control of motor action, and loss of proprioception can have a significant effect on a person’s ability to move without visual input. Tactile feedback will be required to allow participants to manipulate compliant or fragile objects, to operate the BCI with limited or obscured vision, and to feel the sensation of performing a movement like a handshake. Motorized prosthetics, as shown in the Figure, are equipped with sensors that detect tactile and proprioceptive information. It may be possible to transmit this information to the BCI user through stimulation of the nervous system.

**THE DORSAL ROOT GANGLION: AN IDEAL TARGET**

The University of Pittsburgh team has developed new techniques for multichannel neural recording and stimulation in dorsal root ganglion (DRG) and cerebral cortex of cats. Stimulating peripheral afferent (PA) neurons is believed to be a desirable option, because it ensures that the sensory information is delivered to and processed by all of the spinal and supraspinal neural circuits normally involved in sensation and control. While there are many alternative sites to consider, the DRG (and adjacent dorsal roots) are the only structures where PA neurons can be accessed in isolation from other neurons or fiber tracts. Since the majority of PA neurons from an entire limb are grouped into approximately two to four adjacent DRGs, they provide a compact target for accessing the complete set of PA neurons for the limb.

Experiments have been performed to record simultaneously from large numbers of neurons in DRG and primary sensory cortex (S1) during passive movement of the hindlimb. Modulated activity of a single DRG neuron and a single S1 neuron during
passive movement demonstrates firing rates for both neurons that covary strongly with ankle joint angle, demonstrating that these neurons may encode proprioceptive information for the ankle. Experiments to determine the minimum current (i.e., threshold) required to excite PA neurons in the DRG and to determine the effect of fiber diameter on the recruitment threshold indicate that a wide range of fiber diameters can be recruited selectively at the low intensities of stimulation used in the DRG. One method to deliver surrogate somatosensory information to S1 is to pattern PA microstimulation (PAMS) on PA activity recorded during natural movements. The researchers refer to this as “replay” PAMS, since the goal is to simulate the natural pattern of PA input that is observed during limb movement. They have demonstrated that cortical activity recorded during center-out movements and corresponding replay stimulation is comparable. While the replay response does not reproduce all of the natural responses in this neuron, it is clear that at least some portions of the movement-evoked response in S1 were reproduced by the replay stimulation. Since many of the S1 neurons were highly correlated with foot speed, it was possible to build a neural decoder that estimated foot speed from S1 activity.

The researchers have demonstrated that replay PAMS can transmit limb-state information to S1 and increasing the amplitude and instantaneous pulse-rate can enhance the response. They also demonstrated that certain combinations of stimulus location, amplitude, and frequency can elicit discriminable responses in S1. Preliminary experiments in cats with chronically implanted DRG microelectrodes have confirmed that modulated activity can be recorded in response to platform perturbations and that these modulations are cosine tuned to the direction of perturbation.

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Weakness in Pompe Disease is Mediated by Lower Motor Neuron and Neuromuscular Junction Dysfunction

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INTRODUCTION

The Dutch pathologist J.C. Pompe established the clinical features of the first reported case of glycogen storage disease in 1932. The index case was a 7-month-old girl who died of severe cardiac hypertrophy and, importantly, was noted to have generalized glycogenosis and vacuolar myopathy. Nearly 30 years after this report, a more detailed understanding of the disease has been established by discovery of the molecular structure and metabolism of glycogen as well as the finding that sub-structures, known as lysosomes, are dysfunctional when glycogen storage results from a key metabolic enzyme deficiency.1,2

Mutations in the acid α-glucosidase (Gaa) gene result in Pompe disease and create a spectrum of disease that encompasses the fatal early-onset form to adult-onset disease. The gene product, acid α-glucosidase or GAA, encodes a lysosomal enzyme which is required for glycogen degradation in the low pH of the lysosome where the neutral glucosidase is inactive.3,4 Excess glycogen enters the lysosome, as do many other cellular components, via autophagic vacuoles (i.e., microautophagy).4 Following processing in the trans-Golgi, GAA is glycosylated in the endoplasmic reticulum producing a 110 kDa precursor protein which must be targeted to the lysosome.5 Lysosomal targeting is accomplished by an elegant system used by all lysosomal proteins in which the molecule acquires mannose 6-phosphate residues in a post-endoplasmic reticulum compartment and ultimately enters the lysosome via receptor-mediated transport.6 While this specific pathway allows GAA to be delivered to the lysosome, there are additional receptors and co-receptors which influence cellular targeting from the cell surface. Both the mannose 6-phosphate receptor and co-receptor for insulin-like growth factor 2, as well as a mannose 6-phosphate-independent pathway, have been described.7,8 The ability of the cell surface receptor to bind GAA and internalize the protein and traffic to the lysosome is the basis for enzyme replacement therapy delivered systemically.

A spectrum of disease results from variable levels of GAA and possibly differential cellular rates of glycogen synthesis which results in extensive glycogen accumulation in all tissues, especially striated muscle, smooth muscle, and the central nervous system (CNS).6,9,10 The disease prevalence has estimated to be about 2000-4000 patients in the developed world and incidence is approximately 1 per 40,000 births. The phenotypic continuum is directly related to the extent of residual enzyme deficiency,11 with complete or near complete deficiency of functional GAA protein in early-onset disease and up to 10% of wild-type activity in late-onset patients.6,9 Carriers of one mutant allele are unaffected.

EFFORTS TO REPLACE GAA PROTEIN BY ENZYME REPLACEMENT THERAPY

The first efforts to replace the missing protein in Pompe disease were hampered by immunogenicity of the protein and insufficient quantity of protein purified from Aspergillus or human placenta. As the biology of lysosomal targeting was more thoroughly understood, it became clear that more potent versions of the recombinant protein could be produced either in transgenic animals6,12 or in cell culture.13 Key clinical studies showed the potential survival benefit of recombinant acid α-glucosidase12,14 and a large randomized study in adults demonstrated an effect which is believed to stabilize the disease (i.e., reduce the rate of decline in co-primary endpoints) but did not show measurable clinical improvement.15 These studies lead to the Food and Drug Administration (FDA) approval of recombinant enzyme replacement therapy (ERT) for Pompe disease in 2006.
An important aspect of the FDA approval is that Myozyme (alglucosidase alfa) represented the first cause-specific approval of biological therapy for a neuromuscular disease. The approval was based on the observation that Myozyme improves ventilator-free survival rate in infants with early-onset disease. Unfortunately, longer-term follow-up of subjects showed progressive loss of independent ventilation and currently 22 of the original 38 subjects in these studies are dependent on mechanical ventilation or have died. Additionally, all subjects demonstrate functional deficits in respiratory function on more detailed testing and further progression of the disease is observed with advancing age. To further clarify the cause of disease progression in the patient population receiving ERT, recent attention has been focused on the neural pathology in Pompe disease, which is not influenced by ERT since the protein does not cross the blood–brain barrier.

CHARACTERIZATION OF NEUROPATHOLOGY IN POMPE DISEASE

Weakness is the principal clinical feature in Pompe disease and historically has been attributed to muscular pathology. CNS pathology in Pompe disease has been established in an early autopsy series and confirmed in a patient in whom an autopsy was performed soon after discontinuation of support by mechanical ventilation, despite use of ERT. Certainly, other neuropsychiatric lysosomal storage diseases lead to cognitive dysfunction and sometimes neuronal cell death; however, in Pompe disease patients there is not a cognitive deficit. In both human and animal models of Pompe, disease there is evidence for glycogen accumulation in the CNS. Glycogen accumulation has been noted in anterior horn neurons and also in the brainstem neurons of a Pompe disease infant. A key finding from this report is that “the most prominent signs of neuronal storage are found in the spinal ganglia, the anterior horns and in all the motor nuclei of the brain stem.” Additional Pompe disease case reports demonstrate glycogen accumulation in the anterior spinal cord and increased soma size (i.e., soma size two to three times normal) of motor neurons. Examples of needle electromyography (EMG) of multiple skeletal muscles in a Pompe disease infant have shown fibrillations and high-frequency discharges, and at autopsy there was evidence of brainstem and spinal cord accumulation of glycogen within neurons.

To better understand all the factors which contribute to weakness in Pompe patients the author’s research team and others have shown that, in addition to intrinsic muscular abnormalities, neural impairment contributes to respiratory and peripheral muscle dysfunction. Recent reports have shown that glycogen accumulation in neurons is associated with apoptosis in cell culture and that spinal neurons appear to be particularly susceptible to excessive glycogen content. The author’s team tested the hypothesis that Gaa−/− knockout mice would exhibit reduced ventilation and this would be reflected by attenuated efferent phrenic motor discharge. It was found not only that Gaa−/− mice exhibit high glycogen content in the spinal cord and phrenic motor neurons but also that efferent nerve inspiratory burst amplitude was substantially lower in these knockout mice compared to control subjects. The contribution of lower motor neuron disease in the respiratory system is emphasized by the fact that direct correction of the glycogen accumulation in the cervical spinal cord can lead to complete correction of the ventilatory deficits in Gaa−/− mice. There is also clinical evidence of implied impairment in neuromuscular transmission, as revealed by polyphasic potentials and myotonic discharges.

Further characterization of the neuromuscular pathology in Pompe disease can be accomplished by additional techniques such as single-fiber electromyography (SFEMG), which allows precise study of the microphysiology of the human motor unit by quantification of neuromuscular jitter. SFEMG tests the single muscle fiber action potentials in the muscle by means of a needle with a 25 μ recording surface during consecutive stimulations or voluntary contractions. The neuromuscular jitter is produced by variation in the time it takes for endplate potentials at the neuromuscular junction (NMJ) to reach the depolarization threshold. Jitter is increased in neuromuscular disease, and the finding may be seen even in muscles without weakness. This finding is therefore subclinical sign of impaired neuromuscular transmission. Detailed neurophysiological testing can contribute to the understanding of the mechanisms of weakness in individuals affected by Pompe disease and provide valuable information about NMJ transmission. Confirmation of a clinical relevance in a mouse model is a powerful tool in understanding disease pathophysiology. A comprehensive evaluation of CNS pathology in the murine Pompe model (Gaa−/− mouse) confirms all of the clinical findings above and the author’s team is in the process of confirming human SFEMG findings in the mouse and new animal models of the disease. Lastly, to confirm the impact of gene replacement in the CNS, the author’s team has shown that correction of GAA deficiency can be accomplished by delivery of adeno-associated virus (AAV) vectors, either directly in the CNS, via retrograde transport from intramuscular delivery, or systemically.

GENE THERAPY STRATEGIES FOR CENTRAL NERVOUS SYSTEM TARGETING IN POMPE DISEASE

AAV vectors have the ability to permanently transduce muscle cells and produce therapeutic proteins. The author’s team has exploited this property for local gene correction, however the finding that certain AAV serotypes are able to transduce both muscle and neural tissue, especially via the systemic route of delivery, has revolutionized the approach to neuromuscular disease where widespread delivery is required. An additional strategy, which might be exploited in the CNS, is the concept that adjacent cells may be altered by GAA protein transduction from a gene targeted cell.

The author’s team first showed that systemic delivery of recombinant AAV serotype 2/1 (rAAV2/1) to Gaa−/− neonatal mice results in life-long correction of skeletal muscles and diaphragm, with normal GAA enzyme activity and resolution of glycogen storage. The clinical significance was confirmed by testing the force mechanics of the soleus and diaphragm muscles, which reached 90% of wild-type peak contractile strength. This approach has also been tested in adult Gaa−/− mice and systemic delivery of muscle-restricted rAAV2/8 or rAAV2/9 vectors significantly reduced glycogen content in striated muscle.
Importantly, AAV vectors based on serotype 9 have been shown to transduce striated muscle at very high efficiency and have been shown to transduce more myofiber types, thereby giving it a potential advantage over other rAAV serotype vectors as a therapeutic vector for muscular dystrophies. AAV9 also has a strong tropism for neural tissue, which directly addressed a key aspect of Pompe disease. Shown in the Figure is the result of intraluminal administration of AAV9–GAA vector to assess the effect on respiratory motor control. Note the change in rate and regularity of hypoglossal bursting when the therapeutic vector is compared to control subjects or those untreated.

Figure. Hypoglossal neurogram recorded following intra-lingual delivery of AAV9-GAA or control vector.

Direct administration of rAAV has shown the highest degree of biochemical and functional correction of the diaphragm in the Gaa−/− mouse model, since the effective dose is highest when delivered directly to affected tissue. Targeted administration of rAAV2/1–cytomegalovirus–human GAA to the diaphragm of Gaa−/− mice leads to wild-type levels of GAA activity, and glycogen levels are normalized in the diaphragm tissue, both in young and aged animals (2 years old) that have established disease. This type of targeted therapy also results in near complete glycogen levels are normalized in the diaphragm tissue, both of Gaa−/− mice leads to wild-type levels of GAA activity, and glycogen levels are normalized in the diaphragm tissue, both in young and aged animals (2 years old) that have established disease. This type of targeted therapy also results in near complete correction of both the muscle and neural pathology to demonstrate that systemic dosing of AA V9-GAA will lead to generalized correction of both the muscle and neural pathology in Pompe disease. The next planned clinical study will validate important clinical endpoints using magnetic resonance imaging assessment of muscle composition, glycogen content, and neurophysiology in adult patients, and, subsequently, early onset patients will be considered for systemic correction as an adjunctive therapy to currently-approved therapy for Pompe disease. Overall, the author’s team has been dedicated to critical evaluation of all the mechanisms that are responsible for the clinical symptoms in this patient population. The clinical approach to developing an effective therapy must be based on those findings and adjusted to refine the therapeutic strategy.

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WEAKNESS IN POMPE DISEASE IS MEDIATED BY LOWER MOTOR NEURON AND NEUROMUSCULAR JUNCTION DYSFUNCTION


INTRODUCTION: THE STAGGERING COST OF HEALTHCARE AND HEALTHCARE FRAUD

Healthcare costs in the United States are staggering, and they continue to rise rapidly. In 2012, for example, the United States government spent $923 billion, or more than $2.5 billion per day, on healthcare. This figure equates to 26.1% of the total federal budget or 5.9% of the 2012 gross domestic product (GDP). The Office of Management and Budget estimates that this figure will increase by approximately 40% to $1.3 trillion by the year 2018. When private healthcare costs are factored into the equation, including private health insurance payments and patients’ out-of-pocket expenses, the numbers are even more staggering. Total healthcare expenditures, both public and private, were $2.7 trillion in 2011, or approximately 17.9% of the country’s GDP.

Although there are no precise estimates, there is little doubt that healthcare fraud, waste, and abuse account for a significant portion of federal healthcare spending. The Federal Bureau of Investigation (FBI) has estimated that healthcare fraud costs the United States $80 billion a year, while Barry Rand, the Chief Executive Officer of the American Association of Retired Persons (AARP), has estimated that healthcare fraud costs the United States $100 billion a year. In a more recent and comprehensive study published by Dr. Donald Berwick, the former Administrator of the Centers for Medicare & Medicaid Services (CMS), it was estimated that fraud accounted for $82 to 272 billion dollars of the 2011 federal healthcare expenditures, and potentially $558 to $910 billion of the total national healthcare expenditures. By any measure, healthcare fraud is a massive drain on scarce federal healthcare resources.

THE BIPARTISAN MANDATE TO CURB HEALTHCARE FRAUD AND ABUSE

Policy analysts, regulators, and politicians may disagree about many of the proposed solutions to the healthcare crisis, including whether it is wise to eliminate covered services, reduce reimbursement rates, cap annual benefits, or shift costs to Medicare beneficiaries. There is, however, one cost control mechanism that has received vigorous and unanimous bipartisan support: eliminating healthcare fraud and abuse. The Obama Administration announced a “zero tolerance” policy for healthcare fraud, and it established the first cabinet-level working group designed to address issues of fraud, the Health Care Fraud Prevention and Enforcement Action Team (HEAT). Congress followed suit by significantly increasing funding for anti-fraud efforts, including support for the Health Care and Education Reconciliation Act of 2010 (HCERA), which added an additional $250 million to the Health Care Fraud and Abuse Control Account between 2011 and 2016. More recently, a bipartisan group of senators introduced a new piece of legislation, the “Preventing and Reducing Improper Medicare and Medicaid Expenditures Act of 2013,” or the PRIME Act, which contains a number of preventative and proactive measures to stop fraud before it occurs.

HEALTHCARE FRAUD ENFORCEMENT INITIATIVES

With a bipartisan mandate to fight fraud, and an influx of funding from Congress, the Department of Justice (DOJ), the Department of Health & Human Services (HHS), and various Medicare contractors have launched new and innovative initiatives to combat fraud. It is important for every physician, including...
members of the American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM), to understand these new anti-fraud initiatives and how they could impact their practice and profession. Indeed, by taking a proactive and vocal role in the government’s anti-fraud efforts, physicians can help eliminate egregious fraud, while simultaneously protecting honest practitioners from unintended negative consequences, including reimbursement rate reductions and onerous audits.

One of the government’s primary enforcement initiatives began in 2007, when DOJ and HHS launched a criminal prosecution effort, known as the Medicare Fraud Strike Force Pilot Program (“Strike Force”) in Miami, Florida, to combat a surge in improper billing for particular medical items and services. The goal of the Strike Force was twofold: (1) to greatly simplify and streamline federal healthcare fraud prosecutions, which historically lasted several months or years; and (2) to concentrate enforcement resources in geographic “hot spots,” medical areas where fraud was most abundant and egregious. One important hallmark of the Strike Force was its use of Medicare billing data, on a near real-time basis, to identify billing spikes and other suspicious billing patterns that were indicative of fraud. With assistance from investigative data analysts, as well as by CMS program experts and contractors, the Strike Force teams identified “hot spots” that warranted further investigation.

The Medicare Fraud Strike Force Pilot Program achieved great success. In a May 2008 speech to the United States Attorney’s Office in Miami, Attorney General Michael Mukasey noted that Miami’s Pilot Program alone brought 120 criminal healthcare cases alleging an astonishing $638 million in fraud, which accounted for 20% of the nation’s federal healthcare fraud prosecutions.

Moreover, in the 12-month period after Strike Force operations began, Medicare claims for durable medical equipment, one of the fraud “hot spots,” dropped in Miami-Dade County by $1.75 billion and payments dropped by $334 million.

Based on the success of the Miami Strike Force, and with $250 million of new anti-fraud funding through the Affordable Care Act, DOJ and HHS expanded the Strike Force, now rebranded as “HEAT” teams, to eight other cities: Los Angeles, Detroit, Houston, New York, Baton Rouge, Tampa, Dallas, and Chicago. In the five and a half years since its inception, Strike Force prosecutors have filed more than 724 criminal cases charging more than 1476 defendants who, collectively, have submitted $4.6 billion of false and fraudulent claims to the Medicare programs. Strike Force prosecutions continue to be data driven, and the DOJ shifts its resources to constantly evolving “hot spots” including home health, community mental health, physical therapy, and Medicare Part D pharmaceutical fraud. Physicians should understand that because of this data driven approach, if unscrupulous and fraudulent providers begin abusing procedure codes affiliated with their specialty, it can result in heightened law enforcement and regulatory scrutiny for everyone, including legitimate providers. This has been the unfortunate result for practitioners of electrodiagnostic (EDX) medicine, as will be discussed in further detail below.

The government’s enforcement efforts are multifaceted and not limited to the Strike Force’s criminal prosecutions. The DOJ has also used a civil statute, the False Claims Act, to collect substantial monetary damages and penalties from Medicare providers. The False Claims Act is analogous to the criminal Health Care Fraud statutes insofar as it imposes liability upon anyone who, among other things, knowingly presents a false or fraudulent claim to the government for payment or approval, or who knowingly makes or uses a false record or statement material to a false or fraudulent claim to the government. A very unique and powerful aspect of the False Claims Act, known as the qui tam provision, permits private citizens (often called “whistleblowers” or “relators”) to bring fraud claims on behalf of the government, and to collect a reward if they do so successfully. Violations of the False Claims Act are subject to harsh financial penalties of not less than $5000 and not more than $10,000 per false claim, plus three times the amount of damages which the government sustains. From 2009 through 2012, False Claims Act suits, many of them initiated by private whistleblowers, led to the recovery of more than $9.5 billion in federal healthcare dollars.

HHS’ Office of the Inspector General (HHS-OIG) has also used various administrative remedies to combat healthcare fraud. Congress has given HHS-OIG authority to exclude individuals and entities from participation in Medicare, Medicaid, and other Federal healthcare programs for engaging in fraud and other misconduct. HHS-OIG has used this authority aggressively; in 2012 alone it excluded 3131 individuals and entities from participating in federal healthcare programs based on a wide-variety of misconduct including criminal convictions related to federal health programs (1199), patient abuse or neglect (212), and license revocations (1463). The impact of an HHS-OIG exclusion is that any items and services furnished by an excluded individual or entity are not reimbursable by federal healthcare programs. Moreover, any items and services furnished based upon the medical direction or prescription of an excluded physician are not reimbursable when the individual or entity furnishing the services either knows or should know of the exclusion. This prohibition applies even when the Federal payment itself is made to another provider, practitioner, or supplier that is not excluded.

The Medicare program’s anti-fraud efforts also include private contractors, known as Zone Program Integrity Contractors (ZPICs), who are responsible for detecting, preventing, and reporting fraud and abuse within their assigned geographic jurisdiction. Broadly speaking, ZPICs perform analysis of Medicare claims data, conduct medical chart review and interviews, conduct site inspections, and complete other investigative tasks to identify potentially fraudulent Medicare providers. When these private contractors detect potential fraud, they can refer the matter to federal law enforcement officials, including the HEAT teams, with whom they work closely. ZPICs can also recommend that Medicare take administrative actions, including imposing prepayment reviews, auto-denial edits, payment suspensions, and revocations to stop additional fraud.

The government also has actively enlisted the assistance of private citizens—including senior citizens, physicians, and putative whistleblowers—in the fight against healthcare fraud. HHS encourages concerned citizens to report suspected fraud to
their national fraud hotline: 1-800-HHS-TIPS. Medicare urges Medicare beneficiaries, who they deem “the most important link in finding Medicare fraud,” to diligently review their monthly Medicare Summary Notice and to immediately report any suspicious charges.4 HHS-OIG also has an incentive program, providing up to $1000 reward or 10% of the overpayments recovered, whichever is less, for tips reported to the fraud hotline.7 Finally, Medicare has encouraged community involvement by organizing volunteer groups of retired professionals and senior citizens, known as Senior Medicare Patrons. These volunteers are trained to recognize and report instances or patterns of healthcare fraud, conduct community outreach, train other seniors, and work cooperatively with law enforcement and regulatory authorities to resolve complaints of fraud.

The government’s most recent anti-fraud measure is a computer technology known as the Fraud Prevention System (FPS) which analyzes near real-time Medicare claims data using models of fraudulent behavior, and that theoretically is designed to allow Medicare to stop fraud before it happens, in the same way credit card companies flags fraudulent purchases and stops the payment before it is issued.2 The FPS system, although a well-intentioned initiative to end the highly-maligned “pay and chase” system, has not yet proven its efficacy and requires additional work. Indeed, CMS awarded $77 million to private contractors to implement the FPS system, yet it stopped only one fraudulent claim, totaling $7591, during its first 8 months of operation.24 In its most recent report on FPS in December 2012, CMS touted its effectiveness and potential but acknowledged it has to improve the methodology used to calculate actual and projected savings and incorporate more and better data.8

FRAUD AND ABUSE CONSIDERATIONS FOR PRACTITIONERS OF ELECTRODIAGNOSTIC MEDICINE

The federal government’s intense healthcare fraud enforcement efforts, together with its increasing reliance on Medicare claims data analysis to identify fraud, have caused certain segments of the healthcare industry to come under increased scrutiny. There can be no doubt that EDX medicine is one such segment. In its 2013 Work Plan, HHS-OIG singled out EDX testing for additional scrutiny because “[t]he use of electrodiagnostic testing for inappropriate financial gain poses a growing vulnerability to Medicare.”12 Moreover, on January 1, 2013, as a result of the misvalued code initiative, CMS introduced the new coding structure for nerve conduction studies (NCSs) and needle electromyography (EMG) tests, while simultaneously reducing the reimbursement rates significantly. Although many of these changes are recent, they reflect concerns that regulators first expressed several years ago. For example, at a House Budget Committee Hearing on July 9, 2003, Dara Corrigan, then Acting Principal Deputy Inspector General of HHS-OIG, testified that NCSs were among the specific areas of the Medicare program that were particularly vulnerable to fraud, waste, abuse, and quality control problems.13 She cited the example of a South Carolina doctor who schemed to defraud the Medicare program by forcing his patients to undergo unnecessary NCSs, and who withheld patients’ medications until they agreed to undergo such tests.11

The case of the South Carolina doctor is hardly unique, and there are many healthcare fraud schemes that involve the abuse and misuse of EDX procedure codes. One particular scheme is exploding in several states, including Florida and New York, which have passed “no-fault” personal injury protection (PIP) coverage, which entitles the insured and any passengers in the vehicle to a minimum amount of benefits, regardless of whether they are responsible for causing the accident.19 In Florida, for example, basic PIP coverage entitles the insured and any passengers in the vehicle to 80% of reasonable medical bills up to $10,000 and 60% of lost wages to be paid.22

This PIP coverage creates perverse incentives for unscrupulous lawyers and “accident clinic” owners who conspire to bill Medicare and private insurance companies for nonexistent or minor injuries, and who aggressively advertise the $10,000 benefit on the radio.17 Although the so-called “PIP fraud” has many variations, it often involves “runners” who are paid to recruit auto accident victims, many of whom do not have any significant injuries, as well as conspirators who participate in “staged accidents.” The scheme is consummated with assistance from co-conspirator doctors who order medically unnecessary therapy and treatments, as well as unnecessary diagnostic tests, for the sole purpose of exhausting all benefits provided for under the law and driving the claims to the maximum amount.20,21 In this PIP scheme, EDX tests are often ordered without documentation of medical necessity, and such tests are rarely referred to specialized outside physicians that are qualified to perform and interpret them. Instead, the EDX tests are performed “in house” by unqualified and untrained technicians who are often supervised by general practitioners or chiropractors. This “PIP fraud” scheme, when combined with other fraud schemes that exploit EDX billing codes, causes billing spikes and suspicious patterns that arouse the government’s scrutiny. The result is that well-intentioned policy makers at CMS, many of whom lack the training to fully understand a specialty such as EDX medicine, feel compelled to respond quickly and decisively to the perceived fraud. Unfortunately, they sometimes implement regulatory “solutions,” such as reducing reimbursement rates, which are ultimately ineffective because the unscrupulous physicians who caused the problem will simply find new codes to bill. Arguably, the only lasting impact is that legitimate practitioners find it cost prohibitive to provide NCSs and needle EMG tests to the patients who truly need them.

Healthcare fraud is a massive and complex problem, and it does not lend itself to easy solutions. Indeed, for the reasons described above, there will always be some natural tension between vigorous healthcare fraud enforcement and legitimate medical practice. Nonetheless, the membership of AANEM should continue to be a vocal, proactive participant in the healthcare fraud debate. By policing your own specialty, reporting known instances of fraud or abuse, educating vulnerable physicians, and offering more rationale and long-lasting solutions to the problem of EDX fraud, you can protect the integrity and profitability of your profession.
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Automated Hand-Held
Nerve Conduction Devices

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INTRODUCTION

In recent years, the pursuit of quality electrodiagnostic (EDX) medicine has been threatened by the increasing use of automated hand-held devices (HHDs) by unqualified practitioners. An HHD is a device that collects nerve conduction data via an automated program, which then utilizes a computer algorithm to provide an “interpretation.” It is true that as technology has advanced, electromyography (EMG) equipment has steadily decreased in size and increased in ease of use. One day soon, most of the equipment may actually fit in the palm of the hand (and therefore justifiably be called a hand-held device, of a sort). The size of the machine and ease of use are not the issues discussed here, since most physicians readily embrace new technology. The major issue with the HHDs in current use is how and by whom they are being used.

USE OF AUTOMATED HAND-HELD DEVICES

HHDs are heavily marketed to primary care providers, chiropractors, orthopedists, and other healthcare providers. True experts in EDX medicine generally have shied away from the use of these devices, since the data provided by them is incomplete and often inadequate to make an accurate diagnosis. HHD companies emphasize that nerve conduction studies (NCSs) are billable procedures, and, in the specific words of one physician brochure, “testing can generate significant revenue.” Though they give a token mention to the added convenience for the patient in not having to see a specialist, the main selling platform is financial, not clinical. The primary appeal of these devices is not that they offer superior patient care, it is that these providers are able to keep the money in their own offices, rather than referring out to a specialist.

POTENTIAL PROBLEMS

The main concern with the use of HHDs is that poor quality EDX testing results in missed diagnoses, incorrect diagnoses, and false-positive diagnoses, which in turn can lead to inappropriate or delayed treatment of the patient. In many such instances, the patient’s problem is not resolved and testing must be performed again. All of these factors may result in decreased quality of care as well as increased medical costs.

Once a clinic, physician, or individual health professional has purchased one of these devices, they can then proceed to train themselves and any of their staff to operate the device. This is often accomplished through audiovisual materials such as DVDs, owner’s manuals, and even YouTube videos. Instruction rarely consists of more than a few hours of material. Although each HHD has slight variations, the general routine begins with the operator applying a biosensor array and then letting the device capture nerve conduction data. The data is then “read” by a computer software algorithm, sometimes sent off to company headquarters or sometimes included with the purchase of the device. The “interpretation” is then sent back via fax or email (if the data was sent away) or in some cases an entire report is generated by the software in the office. The companies that manufacture and sell HHDs are very careful to insist that they do not provide diagnoses, their software merely reads the data and provides an “interpretation.” This nuance is often not fully recognized by the physician in charge, since the “interpretations” are worded just like diagnoses. But, by signing the formal report, the physician becomes legally responsible for the patient’s diagnosis and any subsequent treatment based on said diagnosis.
Although there are many issues with the utilization of HHDDs, the main ones are (1) many of the “operators” are not qualified to perform the testing, (2) the healthcare providers who receive the computer automated “interpretation” often are not qualified to assess the diagnostic accuracy or relevance, and (3) HHDDs themselves are limited in what they can measure as they utilize a “one-size-fits-all” style of testing.

As mentioned previously, little formal training is required to meet the HHDD companies’ qualifications to operate one of their devices. This means that physician assistants, nurses, medical assistants, and even receptionists or clerks can be qualified as operators to perform the testing. In many of the cases that we have reviewed, there is a conspicuous absence of an adequate medical history, physical examination, and differential diagnosis. Of course, physicians who are trained in neuromuscular, musculoskeletal, and orthopedic medicine recognize these shortcomings. As one expert in orthopedics recently emphasized, “clinical examination by a skilled physician is paramount,” in order to accurately diagnose nerve entrapment and other nerve dysfunction.

High quality EDX medicine can involve a situation where a properly trained technician performs NCSs under direct supervision of a physician who is qualified to practice and interpret such tests. But in the case of HHDDs, the supervising physician usually is not qualified to do so. The healthcare provider often does not have adequate EDX or neurophysiologic training to be able to design the studies, interpret them, or understand if the computer algorithm interpretations are consistent with or relevant to the clinical diagnosis. Those of us who are adequately trained to practice EDX medicine know that we need to utilize EDX medicine as an extension of, and not a replacement for, the clinical history and examination. No automated device can replace the evaluation of patients by a well-trained and qualified practitioner. In fact, the American Association of Neuromuscular & Electrodagnostic Medicine (AANEM) Position Statement on the “Proper Performance and Interpretation of Electrodagnostic Studies” reads, “electrodagnostic studies should be performed by physicians properly trained in electrodagnostic medicine, that interpretation of NCS data alone absent face-to-face patient interaction and control over the process provides substandard care, and that the performance of NCSs without needle EMG has the potential of compromising patient care.”

RELEVANT STUDIES

To be fair, the U.S. Food and Drug Administration (FDA) has approved marketing of the HHDDs which are commercially available. However, FDA approval for HHDDs requires only that the device is “substantially equivalent” in an engineering sense to conventional equipment. Neither diagnostic accuracy nor utility (outcomes) of devices are required by the FDA for 501(k) approval, only that the device is substantially equivalent to any other device approved prior to May 28, 1976. A successful 501(k) application by the FDA means only that the device has received clearance for marketing, not that it is sanctioned for approval based upon diagnostic accuracy. But for physicians and patients, a device’s diagnostic accuracy in common use is the most important issue. It is this issue of diagnostic accuracy which brings up the major concerns about the use of HHDDs. HHDDs themselves are extremely limited in what data they are able to gather. HHDDs basically provide preconfigured electrodes which record motor and sensory nerve waveforms and measure latencies, amplitudes, and conduction velocities; some also record and measure F wave latencies. Nobody questions that the HHDDs are able to collect and record these data. It is in the “interpretation” and diagnosis arena where the HHDDs fall short. A few studies support the usefulness of HHDDs in clinical diagnosis, but most of these have been industry-sponsored studies with a possibility of significant or high-level bias. Other independently-funded studies have found much lower diagnostic accuracy, even when HHDDs are used by sophisticated and qualified EDX providers. One study which assessed the usefulness of an HHDD as a screening tool for carpal tunnel syndrome (CTS) in 1695 workers found that the automated system significantly overdiagnosed CTS. Another study of lumbar sacral radiculopathy in 50 patients and 25 control subjects found that a certain HHDD was able to gather decent raw data when performing NCSs. Although the computer-generated interpretations were highly sensitive, the specificity was unacceptably low, resulting in a high false-positive rate of diagnosis in both symptomatic and control patients. In addition, the HHDD completely missed an important diagnosis of another condition in 18% of the patients. This lack of specificity suggests that this HHDD cannot be recommended as a diagnostic test for patients with lower extremity symptoms. This means that many patients tested with HHDDs potentially could be subjected to inappropriate treatment, including unnecessary surgery. In fact, one surgeon commented in a New York Times article that he felt “uncomfortable” performing surgery on a patient who had been diagnosed using an HHDD.

CONCLUSION

Automated HHDDs are novel and interesting devices which attempt to simplify the performance of NCSs. This is a laudable goal, and studies indicate that these devices do collect and record electrophysiological data faithfully and reproducibly. The issue is then not whether these devices can perform limited NCSs—they can, and do it well. The salient issue is whether the automated programs associated with the HHDDs can make “interpretations” which have a high diagnostic accuracy. This is where the HHDDs fall short, and their routine use, especially by individuals who are not experts in EDX medicine, cannot be recommended. Whether there is any appropriate use for HHDDs is unsettled. Potentially, they could be used as a screening tool in the clinic or field to identify individuals with neuropathies such as CTS or diabetic polyneuropathy. However, if individuals were identified in such a setting, the diagnosis would have to be confirmed by a specialist. Clearly, HHDD use is not a replacement for a consultation by a qualified EDX physician utilizing traditional methods of EDX medicine. A qualified EDX physician working with a thorough history and examination can form a differential diagnosis, and then modify testing based on the results he or she is obtaining in real time. If something appears suspicious, he can repeat a particular test, or perform more testing on site. It is the difference between the information someone would obtain from a survey with a standard battery of questions (“one-size-fits-all approach”) versus a face-to-face interview by an expert (traditional EDX model). In the end, such widespread use of HHDDs does not provide the standard of care that the patient both expects and deserves. At
this point in time, quality neurodiagnostic testing can only be provided by traditional EDX methods in the hands of a trained and qualified EDX specialist.

REFERENCES

EDX AND NM MEDICINE: LOOKING TO THE FUTURE AS WE ADDRESS TODAY’S CHALLENGES

Electrodiagnostic Testing by Mobile Laboratories: Challenges to Quality and Proper Resource Utilization

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BACKGROUND

In concept, a service which provides electrodiagnostic (EDX) testing in the referring physician’s office—rather than the patient having to travel to another site—has potential benefits for both the patient and the referring physician. Provision of this type of service is the business model of a mobile diagnostic laboratory. This same outwardly patient- and physician-friendly business model can be the framework for overuse of testing, a pathway for generating excessive expense for the healthcare system, and, in its worst incarnation, the vehicle for fraudulent abuse of the medical payment system for personal gain. The American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM) has been strongly involved in combatting the negative effects of mobile diagnostic laboratory’s that operate in a fraudulent manner.

During 2000-2004, government and commercial healthcare insurance companies began receiving an increased number of claims for EDX testing procedures. The procedures were most often nerve conduction studies (NCSs) and somatosensory evoked potentials (SEPs). Needle electromyography (EMG) was typically not part of the testing. Examination of claims data showed that many of these studies were originating from primary care and chiropractic offices rather than from neurology or physical medicine practices.

PRACTICE MODEL

Mobile laboratories are organized as a commercial enterprise. A physician may be the head of the company, but alternate models include the service being organized by a chiropractor, a technician, or an independent business person. Physicians or chiropractors are solicited by mobile laboratories to have their offices become host sites. Patients who have spinal or limb symptoms are sought for referral. Patients who have suffered personal injury or workers compensation claims may be specifically sought for the testing by some laboratories. Typically, a technician from the mobile laboratory company is sent with an EMG instrument to the referring office. A detailed history usually is not obtained by the technician and a detailed referral may or may not be available from the referring provider. The technician performs an array of NCS type tests, which are often organized into “upper extremity” or “lower extremity” batteries depending on the general nature of the patient’s symptoms outlined by the referring provider. The array of tests performed often includes every motor and sensory nerve accessible for conventional testing in that limb. Bilateral testing appears to be a common practice. SEP responses also may be part of the array of tests performed. Needle EMG usually will not be performed, as this type of procedure cannot be delegated to a technician, and the physician’s office where the test is performed does not have the training to perform the needle EMG. More recently, ultrasound studies have been added to the array of available tests. The referring physician acts as the supervising physician for the technician performing the studies, despite in most cases, the physician having no training or expertise in the tests being conducted.

After the study has been completed, the results are taken back by the technician and then interpreted offsite by a physician in the mobile laboratory company. A report is provided back to the referring provider’s office. The physician in the office where the testing was performed may have the opportunity to add further...
comments to the report and may sign the report. Compensation for the host office comes in the form of being able to submit the technical charge component for the testing. Other types of financial arrangements for such offices can include a lease of the space or a referral fee for each patient sent for testing. The mobile laboratory company submits the professional charge for the testing.

NEGATIVE CONSEQUENCES

Because the testing often includes all the accessible nerves in the limb rather than just the ones directly pertinent to the problem under investigation, the charges are often very high. A charge of several thousand dollars is not uncommon. The highest charge for an individual patient for which this author is aware is $14,000. Whether the full amounts are paid by the insurance companies and whether the patient is balanced billed is not clear.

The details of one of the most egregious examples of fraudulent mobile laboratory activities on record are provided by court documents from a mobile laboratory organized in Cook County, Illinois, which at the time provided testing services in many states. The company was prosecuted by the attorney general of Illinois in 2005. The parties involved were initially found guilty of fraudulent practice by the lower court. Examination of the waveforms from some of the test results showed nothing but artifact was being recorded. The resulting NCS data reported were at times completely worthless. During its existence the parent company submitted $234,000,000 in charges to private insurance companies. (The court document containing the initial complaint from this case cited is included in the bibliography and provides very interesting reading.) The results of the legal process are “sealed,” therefore the final details are not publicly available.

CODING AND SUPERVISION

The American Medical Association (AMA) Current Procedural Terminology code governs the reporting of NCS codes 95904-95913. The codes clearly state that “waveforms must be reviewed on site in real time…” The notes also state the “Reports must be prepared on site by the examiner, and consists of the work product of the interpretation of numerous test results.” Clearly the above arrangement does not comply with the CPT coding guidelines if the physician reviewing the material offsite is not reviewing the material in real time and is not preparing the material on site. Physicians who are properly trained in electrodiagnostic techniques and who encounter mobile laboratories working in their area need to educate payers regarding these requirements.

Supervision requirements are governed by section 410.32(b) of the Code of Federal Regulations. It requires that, with certain exceptions, diagnostic tests covered under §1861(s)(3) of the Social Security Act have to be performed under the supervision of an individual meeting the definition of a “physician.” The level of supervision for NCS testing does not require physician’s presence during the performance of the procedure. Unfortunately, there is no criteria in the Federal Register that clarifies that the supervising physician have any ability to perform the study they are supervising. This allows the general physician to supervise NCS and not be counter to the federal register rules. Supervision requirements are currently not helpful in this situation.

CMS requirements for the supervision of diagnostic and therapeutic services provided to hospital outpatients are more stringent. For outpatient procedures, CMS has stated the supervisory responsibility includes the ability to take over performance of a procedure and the ability to change a procedure or the course of care for a particular patient. The supervisory physician must be clinically appropriate to supervise the service or procedure. A requirement similar to this for NCSs would help to eliminate the fraudulent activities. The supervising physicians supervising the NCSs technicians, do not typically have the skill to step in and perform the studies or adjust the studies based on the patients findings.

AANEM’S RESPONSE TO ABUSIVE AND FRAUDULENT PRACTICE

The AANEM has been actively involved in countering fraudulent activities.

Through the “Recommended Policy for Electrodiagnostic Medicine” position statement, AANEM has defined qualifications for physicians who perform EDX testing and has produced guidelines for the appropriate numbers of NCSs and limbs studied by needle EMG for common diagnoses. The language of the Recommended Policy has been included in many private payor policies.

Through the state liaison program, AANEM has educated a group of physicians who are aware of potentially abusive activity by mobile laboratories and others.

Through both the staff at the national office and through the state liaison representatives, AANEM has developed working relationships with the medical directors of the Medicare Administrative Contractors and the administrative personnel of many of the commercial insurers. In some cases, AANEM members have been asked to critique reports and waveform samples from studies performed in these type settings. Catherine French, MAPL, Senior Analyst of Medical Economic Affairs for the AANEM, constantly fields inquiries from individual physicians and insurers about such issues.

Through activities with the Current Procedural Terminology (CPT) Editorial Panel, AANEM is working to clarify CPTs interpretation that waveforms must be interpreted in real time onsite. AANEM plans to educate payers on this requirement to decrease fraudulent use of NCSs.

Through AANEM’s “Proper” Performance and Interpretation of Electrodiagnostic Studies, AANEM has also encouraged insurance companies to require that needle EMG must be performed along with NCSs for a study to be considered complete.
REFERENCES

Winning the Fight Against Electrodiagnostic Medicine Fraud and Abuse

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INTRODUCTION

As has been presented earlier in this plenary session, fraud and abuse in electrodiagnostic (EDX) medicine has been on the rise over the last decade. Recently, relative value units (RVU) and reimbursement for EDX procedures were significantly reduced, in part due to the overutilization of nerve conduction study (NCS) current procedural terminology (CPT) codes. Most of this overutilization was related to abusive or fraudulent practices of EDX medicine (Blum, personal communication, 2012).

ELECTRODIAGNOSTIC MEDICINE FRAUD AND ABUSE DESCRIPTIONS

While it may be difficult to clearly identify the difference between EDX fraud and EDX abuse, there are some points that help distinguish the two. A key aspect is intent. Abuse involves charging for services that are not medically necessary, do not conform to professionally recognized standards, or are unfairly priced. Abuse may be similar to fraud except that it is not possible to establish that the abusive acts were intentional. Typically, abuse in EDX medicine involves over testing to reach a suspected diagnosis and/or over charging for the testing performed.

Fraudulent practices in EDX medicine usually involve practitioners who know that they are providing poor quality EDX studies, but are enticed by the reimbursement to continue. They often make well-calculated efforts to avoid getting caught (e.g. – using a PO Box instead of a physical address on reports and changing the PO Box every 6 months). There have been several cases where individuals have billed Medicare for services that were never provided or where information was falsified in order to receive payment. When reviewing cases of fraudulent EDX, it is obvious that to these practitioners, the money becomes more important than the quality of the EDX study delivered.

An example of a “gray area” between fraud and abuse is EDX testing performed by someone without the proper training or qualifications. Although this is not traditionally seen as abuse, it is a problem because it impacts patient care and wastes scarce health care dollars when tests need to be repeated by qualified providers. There are some state and federal laws that define who can and cannot perform certain procedures. However, for the most part, the law is silent and simply says that only physicians can practice medicine. The law is also silent on which physicians are qualified to perform which procedures. The tradition is that a medical degree allows a physician to perform any procedures he or she wishes to perform. What typically keeps physicians from crossing into areas for which they are unqualified is the fear of malpractice. It can be argued that unqualified providers abuse EDX procedures because they do not conform to professionally recognized standards and may be more likely to over-utilize procedures. Also, unqualified providers of EDX studies often perform procedures incorrectly or in a manner that makes them less sensitive, and therefore less likely to result in the correct diagnosis. All of these inadequacies of unqualified providers are less due to willful negligence or greed and more due to lack of qualifications and training.

With regard to EDX, practitioners are often lured into these arguably abusive/fraudulent practices by advertising that states, in
Winning the Fight Against Electrodiagnostic Medicine Fraud and Abuse

Direct and Indirect Effects of Electrodiagnostic Medicine Fraud and Abuse

Direct effects of EDX fraud and abuse include poor quality EDX studies, increased cost for these studies, lowered diagnostic sensitivity, inappropriately performed studies, large increases in unnecessary NCSs, and a dramatic increase in the overall number of NCSs being performed nationwide. Most of the increased numbers of NCSs are being billed and/or supervised by practitioners without training in EDX medicine.

Indirect effects of EDX testing fraud and abuse are numerous, and include the recent severe RVU/reimbursement cuts to EDX procedures. These cuts have had a devastating effect on all those that perform EDX studies. The reimbursement cuts have already impacted access to care in some states, and may have a negative effect on the overall quality of the EDX studies being provided as medical practices evaluate the types of services they can afford to offer. The direct and indirect effects of EDX testing fraud and abuse make it imperative that all those practicing EDX medicine 1) are knowledgeable about, and able to identify, any fraudulent or abusive EDX practices and 2) have the tools and the knowledge to effectively combat the fraudulent or abusive EDX practices they encounter.

Comprehensive “Plan of Attack”

The four key components of a comprehensive “Plan of Attack” to combat fraud and abuse are:

1. Educate and Inform
2. Report the Abuse
3. Be the Expert
4. Electrodiagnostic Laboratory Accreditation

Educate and Inform

In the battle against EDX testing fraud and abuse, the first and most important step is education. There are a number of groups that need to be educated about quality EDX standards and abusive and fraudulent practices. These groups include:

- Referral providers
- Insurance companies
- Attorneys
- Patients/public
- Elected officials (federal and state)
- Other EDX providers in your community

The communications, in person, via email, etc., must focus on the goal to enhance and maintain the quality of EDX medical care that is being provided in the community. Topics, including but not limited to the pricing of services, market share, billing practices, or “crowding out” the abusers cannot be legally discussed. The discussion must focus on quality of EDX studies to avoid any antitrust concerns. Also, when discussing these issues with any audience, it is important to keep in mind that the focus should be on education. You must avoid any attempt to coerce insurers, referral sources, or others to comply with your requests or adopt your position. Otherwise, your efforts could be perceived as a boycott or other collective action that could, in turn, trigger antitrust scrutiny.

Be sure to review state laws to determine who can legally perform EDX studies in your state. If, for example, physical therapists are allowed by state law to perform EMGs, the group must be careful in communicating its message regarding American Association of Neuromuscular & Electrodiagnostic Medicine’s (AANEM) position - that needle EMG should only be performed by trained neurologists and physical medicine and rehabilitation physicians. It is also important to check local carrier coverage policies. The coverage policy may include qualifications for those performing the EDX studies or include other requirements that can be used to show what the standard is for providing quality EDX services in your area. Before sending any communication to practices that you believe might not be following AANEM standards, it is best to consult with an attorney to avoid any anti-competition claims. The message must be educational, not a recommendation for a particular action, for example that an individual be fired.

Educating referral providers is especially important, as they determine where patients are sent to undergo EDX studies. Many referring healthcare providers are very interested in better understanding EDX testing abuse because they want the best quality studies for their patients. Unfortunately, others might be receiving a financial gain from referrals to an unqualified provider, in which case they may be resistant to or not care to hear the message. Educating referral providers can be via email, hard copy letter, telephone calls, or by face-to-face office visits. A face-to-face visit is more time consuming, but it will also be more successful. Consider including members of the EDX quality discussion group as co-signers on emails or letters or as part of the visits to the referral providers’ offices. Also, utilize the AANEM materials liberally when discussing EDX quality issues.

Having close to 5000 fellow EDX physicians and the name of a nationally respected organization to underscore and emphasize your statements is invaluable.
Educating insurance companies can take different forms. Telephone, email, letter, or personal visits to claims examiners and especially to fraud and abuse unit personnel can be very helpful. Similarly, meeting with or talking to an insurance company medical director can be very effective. Inquire about talking with groups of claims examiners (and ask fraud and abuse unit personnel to attend) to concentrate your EDX quality education efforts. You may wish to offer your services in reviewing any charts or cases that have questionable EDX practices. By doing this you can become the “EDX expert” in their eyes. It is especially important to refer to AANEM’s position papers, practice parameters, and other materials in these discussions as the AANEM is already seen as the leader in EDX quality by many insurers.

Meeting with and educating attorneys about EDX testing fraud and abuse can be on a one-to-one basis or it may be possible to make a presentation to a group of attorneys. If working with an attorney on a case involving EDX fraud or abuse, take the opportunity to discuss quality EDX services and the explain what is poor patient care. Make yourself available to attorneys in your community if they have cases of suspected EDX abuse. You may even have occasion to review charts for attorneys regarding suspected EDX testing fraud. As mentioned earlier, reference AANEM position papers and other materials as much as possible.

Do not overlook the opportunity to educate patients and community members. You can discuss EDX fraud and abuse individually with your patients and you can speak to community groups. Encourage patients to call their insurance companies if they encounter questionable EDX practices. Also, encourage patients to take this information back to their primary care providers.

Informing your elected government representatives (federal and state) about what constitutes quality EDX testing and the different types of EDX abuse is an important step in combating fraud and abuse in EDX medicine. As you help them understand the magnitude of EDX abuses and how much this costs in lost healthcare dollars, they can become an advocate in the fight for quality EDX testing. You can offer yourself as a resource on EDX issues and physician/medical issues in general.

You can keep them apprised of any EDX fraud or abuse in their legislative district. All of this will help engender a healthy respectful relationship that may prove helpful as AANEM works to mandate EDX quality standards.

Work with technologists and other EDX physicians in your community. Encourage them to 1) request and review previous EDX studies on their patients, 2) be alert to any questionable or fraudulent EDX practices and 3) save records from any identified abusive or fraudulent examinations. These records may be very helpful when reporting the abuse to the proper authorities.

Encourage physicians in your community to explain fraudulent or abusive EDX practices to their referral sources. Emphasize the importance of educating all physicians and other healthcare providers what constitutes quality EDX examinations. Use slides as a “planned aside” during a grand rounds and other presentations, or educate healthcare providers in the community using a newsletter (digital or hard copy). Again, it may be best to consult a lawyer prior to sending out any communications. Encourage other members of your community to follow the other parts of the plan of attack – report the fraud, become the known expert, and accredit their laboratory.

**Report the Abuse**

We, as specialists in EDX medicine, are the best “first line of defense” in the fight against EDX testing fraud and abuse. Our knowledge, our experience, and our proximity allow us to most quickly identify the abuse. What is left then is dealing with the fraud or abuse once discovered. Though it can be helpful in the battle, claims reviewing software cannot always catch the abuse. Likewise, prosecutors or patients cannot be expected to catch the abuse. The responsibility is ours to identify and deal with the fraud and abuse in our specialty of EDX medicine.

How and where do we report the EDX testing fraud or abuse we encounter? There are a number of avenues by which reporting can take place. Usually it is best to “blanket report” by reporting to any and all individuals and agencies on the list in Tables 1 and 2. (It will be very helpful to have contacted these individuals or agencies previously, even if to just introduce yourself and to inform them of your expertise and interest in combating fraud and abuse in EDX testing.)

<table>
<thead>
<tr>
<th>Table 1 Where to Report Private Health Insurance Electrodiagnostic Testing Fraud or Abuse</th>
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<tbody>
<tr>
<td><strong>Private Insurers “Special Investigation Units”</strong></td>
</tr>
<tr>
<td>Special Investigation Units investigate fraud and abuse claims. They are happy to have your expert input (when reporting and afterwards for case review and offering your expert opinion). An internet search of a private insurance company name along with the state name and the term “special investigation unit” can help you find the specific unit to which to report EDX testing fraud or abuse. More information can be obtained at the website for the International Association of Special Investigation Units: <a href="http://www.iasiu.org">www.iasiu.org</a>.</td>
</tr>
<tr>
<td><strong>Private Insurers</strong></td>
</tr>
<tr>
<td>At the website listed (above), follow the links through the tabs labeled “Resources,” “Health Care Anti-Fraud Resources,” and “Report Health Care Fraud” and then click on “insurance company” to get the list of Private Health Care Fraud Contacts.</td>
</tr>
<tr>
<td><strong>Local United States Attorney’s Office</strong></td>
</tr>
<tr>
<td>They deal in particular with Medicare, Medicaid, and TriCare, but they will address private insurances as well.</td>
</tr>
<tr>
<td><strong>Local FBI Field Office</strong></td>
</tr>
<tr>
<td>They are thrilled to get tips from physicians and other healthcare providers. Field office information can be found at the website.</td>
</tr>
<tr>
<td><strong>Local District Attorney or County Prosecutor’s Office</strong></td>
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<tr>
<td>National Healthcare Antifraud Association (NHCAA) See description on next page.</td>
</tr>
<tr>
<td><strong>State Insurance Fraud Bureau</strong></td>
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<tr>
<td>The state list can be found at <a href="http://www.nhcaa.org/resources/health-care-anti-fraud-resources/state-insurance-fraud-bureau.aspx">http://www.nhcaa.org/resources/health-care-anti-fraud-resources/state-insurance-fraud-bureau.aspx</a></td>
</tr>
<tr>
<td><strong>State Board of Medical Examiners</strong></td>
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<tr>
<td>They keep records of providers’ previous illegal activities as well as medical license suspensions or forfeitures.</td>
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<tr>
<td><strong>State Attorney General Office</strong></td>
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<tr>
<td>Contact their Medicaid Fraud Control Unit.</td>
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</table>
Often members believe that reporting the fraud or abuse to the AANEM is the solution. However, this is not the best way to combat fraud and abuse. AANEM’s role is to provide the position papers, educate insurance companies, and to inform legislators about quality care. The AANEM advocates for change with payers and legislators. The AANEM however does not have the investigative power needed to deal with fraud and abuse. The groups listed in Table 1 and Table 2 have the legal authority. They can compel witnesses to be interviewed, issue subpoenas to collect records, and initiate criminal or civil proceedings. These groups also have the ability to issue consequences— they can take away licenses, place the offenders in jail, and levy large fines. AANEM has none of these powers. AANEM can simply remove someone from membership, if they happen to be a member. However, that does not stop the fraud or abuse. Only a government authority can take actions that will be an effective deterrent.

Discussions with Fraud or Abuse Perpetrator

The question often arises as to whether you should discuss any fraud or abuse you identify in your community with the office or individual involved in the activity. Each situation is specific and different, but your prior relationship with the office or individual, your thoughts about whether they may or may not understand what it is they are doing, and how egregious the offense is may all come into the decision making process.

Depending on your prior relationship with the suspected abuser you may want to take two to three other EDX physicians with you (from different groups and specialties). To keep the discussion to the point and focused consider taking a short printed list of bullet points (7-10) that describe quality EDX medicine and identify how the various types of EDX testing abuse do not meet this definition of quality. If possible, take specific examples of abuse from their office or from the community. Point out how this is not the standard of EDX care and how they are legally liable for the lack of diagnostic sensitivity, the inaccurate diagnoses, or lack of an appropriate diagnosis rendered by the poor quality testing. Emphasize that nerve conduction studies and EDX testing are now on the Office of the Inspector General’s (OIG) “hit list” and are being actively sought out and prosecuted. Do not be afraid to let them know the consequences of their abuse. But remember that in tone and in content, your comments should take the form of being “educational,” as previously mentioned.

Sometimes it is enough to inform and educate them about what it is they are doing and what the consequences are to persuade them to stop the activity. Sometimes letting them know the consequences and telling them that you feel it your duty to report them if they continue will be enough to help them decide to cease the activity. Let them know that the decision to report their activity is not a personal one, but rather it is a decision based on the need to maintain quality standards in EDX testing.

In my own community, I have confronted three offices involved in abusive EDX practices. All three stopped the activity when they came to understand what they were doing and how it did not meet the community or national standard of care for EDX testing. Each was surprised to know that they were legally liable for the abuse. In each case, the offenses were being perpetrated as a result of ignorance, and they were grateful to have been made aware of the issue.

Be the Expert

Become the knowledgeable resource for anyone that has questions or concerns about EDX testing. There are a number of characteristics that make you a desirable resource in EDX medicine:
EDX AND NM MEDICINE: LOOKING TO THE FUTURE AS WE ADDRESS TODAY’S CHALLENGES

- Your EDX training as part of a physical medicine and rehabilitation or neurology residency (or fellowship) training program.

- Your board certification in physical medicine and rehabilitation from the American Board of Physical Medicine and Rehabilitation (ABPMR) or in neurology from the American Board of Psychiatry and Neurology (ABPN).

- Your board certification in EDX medicine from the American Board of Electrodiagnostic Medicine (ABEM).

- Your membership in the AANEM.

- Your EDX laboratory being accredited by the AANEM.

- Your knowledge of and ability to reference the numerous resources of the AANEM (i.e., position papers, practice parameters, and other materials published by the AANEM that document the standards of EDX care).

There are a number of groups or individuals that could be helped by your input and expertise in EDX medicine:

- Insurance Companies: Becoming known as the “EDX expert” can be useful to claims examiners dealing with specific cases and also to the policy writing departments (they often have questions and need some expert guidance in the content or wording of EDX policies). Calling claims examiners with EDX concerns and being available to answer their questions will help to establish you as their “go to person” for questions regarding EDX testing. Also, setting up a lecture or discussion with groups of claims examiners may be worthwhile.

- Attorneys: Let attorneys working for private health insurers know of your willingness to help with EDX cases. This can open the door to future cases of EDX testing fraud and abuse coming your way. Also, attorneys working in the field of healthcare fraud and abuse would be happy to have you on their speed dial for questions and concerns that arise.

- Community Physicians: Keep your local physicians and other healthcare providers aware of your expertise and your efforts in fighting EDX testing fraud and abuse. As they begin to view you as the expert they will call you with questions or concerns they have about potential EDX fraud or abuse. The fact that they begin to see you as the EDX expert may increase your EDX patient referrals from them as well.

- Multiple Healthcare Fraud and Abuse Groups and Agencies: Try to initiate contact with every group, agency, or individual on the “Where to Report EDX Fraud and Abuse” listed in the Table 1 and 2. Try to get to know one person at each agency and keep their name and number on file for later use. Freely give out your number and email and let all concerned know you are available to help them with any EDX question or concern they may have.

- Federal or State Elected Officials: As mentioned previously, you can offer your services as an expert and a liaison for EDX medicine and medical practices in general to your elected government representatives (state and federal). As you make yourself available to them they will hopefully reciprocate and involve you in any EDX matters that come to their attention. Later, you may be able to call upon them for help in writing legislation or in other attempts to mandate EDX quality standards.

Once you become the “EDX expert” to any of these individuals or groups, and you have taught them what to look for, they can effectively be your “eyes and ears” to help alert you to any EDX fraud or abuse they encounter.

**Electrodiagnostic Laboratory Accreditation**

The fourth key component of the Plan of Attack is EDX Laboratory Accreditation. This program was developed by the AANEM as a voluntary, peer review process that identifies and acknowledges EDX laboratories for achieving and maintaining the highest level of quality, performance, and integrity based on professional standards. Accreditation provides laboratories specializing in EDX medicine with a structured mechanism to assess, evaluate, and improve the quality of care provided to their patients. The AANEM promotes the accreditation program on an ongoing basis to build awareness and credibility for this important quality and patient care initiative as the recognized standard for EDX medicine.\(^1\) One of the earliest and continued driving forces for developing the EDX Laboratory Accreditation program was the desire of insurance companies to have a means to identify good quality EDX medicine (and in particular to differentiate from laboratories of poor quality) in the hope that this could be used in the reimbursement decision making process. Some insurers have even considered not reimbursing for studies performed in laboratories that are not accredited. At the time of the writing of this manuscript, the AANEM is drafting a position paper that will promote the concept of value-based reimbursement for EDX services.

The EDX Laboratory Accreditation process was built to have multiple mechanisms in place to ensure accreditation is granted only to those facilities that can demonstrate that they are not involved in abusive or fraudulent practices. Recent changes will strengthen that goal by asking applicants to certify that they have not been nor are they currently under investigation for fraud or any other illegal or unethical activities. Most of the application can be completed by an office manager or medical assistant. The medical director must sign off on the accuracy of the information. There are multiple aids and templates on the AANEM accreditation website that can be utilized in the application process. Successfully gaining laboratory accreditation should not pose a problem for AANEM members providing quality EDX services; for those who are ABEM certified it is even faster and more streamlined.

As we look for ways to combat EDX testing fraud and abuse, and as insurance companies search for ways to identify EDX laboratories of the highest quality, the AANEM EDX Laboratory Accreditation is the best means to accomplish these goals. The EDX laboratory accreditation process is rapidly becoming the gold standard.
in demonstrating the highest EDX testing standards. Though laboratory accreditation is voluntary, the movement of insurance carriers to utilize the AANEM EDX laboratory accreditation for proof of quality (and possibly use in reimbursement decisions) strongly suggests that all EDX providers are strongly encouraged to seek accreditation as soon as possible.

REFERENCES

EDX and NM Medicine: Looking to the Future as We Address Today’s Challenges

CME Questions:

1. What are the goals of targeted muscle reinnervation?
   A. To maintain muscle bulk.
   B. To make new sources of EMG for control of prostheses.
   C. To provide muscle force feedback.
   D. All of the above.

2. What are the primary limitations of current motorized upper limb prosthesis?
   A. Limited to control of a single degree of freedom at a time.
   B. With higher amputation levels, control is not related to the control signals function.
   C. Myoelectric prostheses for transhumeral and higher levels of amputation are too heavy.
   D. Current motorized prostheses give very little sensory feedback.
   E. All of the above.

3. Which nerves are used for transfers with targeted muscle reinnervation surgery? Choose all that are correct.
   A. Median nerve.
   B. Ulnar nerve.
   C. Radial nerve.
   D. All of the above.

4. What types of muscles can be used for targeted reinnervation surgery?
   A. Any muscle that the transfer nerve can reach.
   B. Any muscle in the arm.
   C. Any muscle on the chest.
   D. A biomechanically nonfunctional muscle.

5. How do pattern recognition control algorithms for EMG improve the function of prostheses for amputees?
   A. They filter EMG signals for optimum band width.
   B. They allow more degrees of freedom to be controlled and extracts information about user intent.
   C. They allow simultaneous control of multiple motions.
   D. They operate on a Cartesian coordinate system.

6. True or False: A team from Pittsburgh was able to tap into the brain of a person with paralysis and achieve seven degrees of freedom control from a prosthetic arm. This enables the patient to complete functional tasks that required placing the hand in space, orienting the wrist, and grasping.
   A. True.
   B. False.

7. True or False: It is possible to stimulate peripheral afferents and reproduce cortical signals of sensation in an animal model.
   A. True.
   B. False.

8. Stimulation of the dorsal root ganglion may be an ideal site to stimulate for providing sensation from a prosthetic limb because:
   A. It ensures that the sensory information is delivered to and processed by all of the spinal and supraspinal neural circuits normally involved in sensation.
   B. Peripheral afferent neurons can be accessed in isolation from other neurons.
   C. It is a compact target for stimulation, meaning a smaller stimulation device.
   D. All of the above.

9. Which of the following government entities and contractors are involved in efforts to curb health care fraud?
   A. Department of Justice.
   B. Department of Health & Human Services, Office of Inspector General.
   C. Zone Program Integrity Contractors.
   D. All of the above.
10. Which of the following federal statutes allows a “whistleblower,” also known as a relator, to file a fraud claim on the government’s behalf?
   A. Civil Monetary Penalty Law.
   B. Anti-kickback Statute.
   C. False Claims Act.
   D. Stark Law.

11. The Department of Health & Human Services, Office of Inspector General, has authority to exclude a physician from participating in the Medicare and Medicaid programs if that physician:
   A. Has been convicted of a felony health care fraud offense.
   B. Has a conviction related to patient abuse or neglect.
   C. Has furnished items or services to patients of a quality that substantially fails to meet professionally recognized standards of health care.
   D. All of the above.

12. The False Claims Act does not prohibit the following conduct:
   A. The knowing submission of a Medicare claim for services not rendered.
   B. The knowing submission of an “upcoded” Medicare claim, meaning it reflects a more expensive service than what was actually rendered.
   C. The submission of a Medicare claim that, due to error or oversight, reflects that neurodiagnostic tests were administered to a deceased patient.
   D. The knowing submission of a Medicare claim for “worthless services,” meaning they fall far below the medical standard of care and statutory requirements.

13. The Affordable Care Act seeks to curb fraud and abuse by:
   A. Increasing funding to federal law enforcement.
   B. Increasing prison sentences for health care fraud offenders.
   C. Funding an automated computer system to detect fraudulent claims before they are paid.
   D. All of the above.

14. The raw data collected by most hand-held devices (HHDs) is interpreted by:
   A. The technician performing the study.
   B. A computer algorithm.
   C. A board certified EDX physician via fax or email.
   D. Employees at the HHD company.

15. The major issue with HHDs is:
   A. They are too small to capture adequate data.
   B. They are too complicated to use.
   C. They require extensive training to operate correctly.
   D. They are being used by unqualified individuals.

16. Studies suggest that computer algorithm interpretations of HHD tests:
   A. Increased convenience for patients.
   B. Increased revenue.
   C. Tests done with HHDs are superior to traditional methods of NCS.
   D. All of the above.

17. The main reason that most providers purchase HHDs is:
   A. Increased convenience for patients.
   B. Increased revenue.
   C. Tests done with HHDs are superior to traditional methods of NCS.
   D. All of the above.

18. Which of the following is true about HHDs?
   A. They require extensive, specialized training to be able to use.
   B. They are an extension of the clinical history and physical examination.
   C. The tests they perform are able to be modified to each individual patient.
   D. None of the above.

19. A notable and consistent increase in charges for nerve conduction studies from non-neurology and non-physiatry providers began being received by Medicare and commercial insurance companies in which of the following time frames?
   A. Mid-80s.
   B. Mid-90s.
   C. Late-90s.
   D. Early-2000s.
   E. Early-2010s.

20. Which of the following characterizes the type of “mobile” electrodiagnostic laboratory services that have resulted in overuse and resulting excessive charges?
   A. A neurologist or physiatrist travels to another practitioner’s office to perform and interpret EDX testing on-site.
   B. A technician employee of the mobile laboratory company is sent to a practitioner’s office to perform EDX testing and interpretation is done later “off-line.”
   C. An employee of a non-neurology, non-physiatry practitioner performs conduction studies on the practitioner’s patients and the results are interpreted by a computer algorithm remotely.
   D. A vehicle is dispatched by the mobile lab company to bring patients referred for testing by a practitioner to a central testing laboratory.
   E. A technician and a physician employee of a mobile electrodiagnostic laboratory company are sent to a practitioner’s office to perform and interpret EDX testing onsite.
21. The scope of the diagnostic testing performed by a mobile electrodiagnostic laboratory on an individual patient is most often guided by which of the following algorithms?
   A. Review of a referral requisition by a physician in the mobile laboratory company followed by a specific plan for testing by the company’s technician based on the patient problem.
   B. Performance of a standard set of conduction studies and needle EMG on the symptomatic limb(s) by the technician consistent with the referral information.
   C. Performance of a standard set of problem-focused conduction studies on both upper or lower extremities based on the referral information.
   D. Performance of nerve conduction studies on every accessible nerve in either both upper or lower extremities regardless of the referral information.
   E. Performance of nerve conduction studies, somatosensory evoked responses, and needle EMG on all four limbs regardless of the referral information.

22. Which of the potential benefits shown below most often accrues to the practitioner in whose office the mobile lab electrodiagnostic testing is performed?
   A. Charging the professional component of the testing.
   B. Charging the technical component of the testing.
   C. The office space in which the testing is performed can be depreciated at an accelerated rate.
   D. A referral fee can be legally paid by the mobile lab.
   E. None of the above.

23. When talking to others and educating them about EDX quality, you should:
   A. Reference AANEM papers.
   B. Reference only your own personal experiences.
   C. Reference Wikipedia.
   D. Reference your textbooks from medical school.

24. EDX providers should be looking to gain AANEM lab accreditation because:
   A. It is very difficult to obtain and, therefore, very prestigious.
   B. It is a clear signal to insurance companies that the accredited lab performs high quality EDX testing.
   C. It can qualify you to receive government grants.
   D. Both A and B.

25. Which of these is NOT part of the comprehensive “Plan of Attack”?
   A. Educate and inform.
   B. Report the abuse.
   C. Wait until the problem goes away.
   D. Be the expert.