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Evidence Based Medicine: The anatomy of an Injury

I. Medical diagnostic tests are used to assess injuries during all phases of the litigation process

Scientific and technological advances have immeasurably increased our ability to observe the brain's neurological function and mental processing. In the wake of these neuroscience developments, courtrooms across the country are seeing a rise in neuroimaging evidence used in all phases of the litigation process, including trial.

However, despite the fact that neuroimaging technology was developed in the 1970s and used widely in the 1980s, the neuroimaging techniques and body of research are still relatively new and subject to "many questions and controversies" which leads to varied results and utilization of studies and evidence that lacks validity.

II. Types of Testing

MRIs

MRI scans are divided into several categories: structural MRIs, which include traditional MRIs and diffusion tensor imaging (DTI), and functional MRIs (fMRIs).

Structural MRI provides information to qualitatively and quantitatively describe the shape, size, and integrity of gray and white matter structures in the brain. Morphometric techniques measure the volume or shape of gray matter structures, such as subcortical nuclei or the hippocampus, and the volume, thickness, or surface area of the cerebral neocortex. Macrostructural white matter integrity can also be measured using volumes of normal and abnormal white matter, providing indications of inflammation, edema, or demyelination, complementing microstructural diffusion weighted MRI to provide a comprehensive picture of white matter integrity.

In structural MRI scanning, an MRI machine creates detailed images of a person's brain anatomy by measuring magnetic changes in the hydrogen protons found in a person's brain tissue. A hydrogen proton is a charged particle in the atomic nucleus that spins on its axis like a small bar magnet. Under normal circumstances, Structural MRIs are used to examine the

brain's anatomical structures, identify any abnormal growth patterns, and track brain development without invasive neurosurgery. Structural MRIs can also be used in conjunction with DTI technology to trace the long-distance connections between neuronal cells in different parts of the brain by distinguishing the differential patterns of water diffusion through neuronal gray matter from neuronal white matter.

Functional MRI scans, by contrast, produce images of brain activity by using MRI technology to detect changes in blood flow. When the brain actively performs a task or reacts to a stimulus it activates brain tissue that needs newly oxygenated blood. Functional MRI scans measure the blood-oxygen-level dependent response changes in order to generate an image, which can be used to infer gray matter is comprised of signal-processing neuronal bodies, and white matter is comprised of signal-transmitting neuronal axons activity patterns in the brain. As a result, parties who want a static image of the brain's anatomical structures should use structural MRI scans, while parties who want a change-over-time visualization of the brain's activity patterns should consider functional MRI scans.

Quantitative EEGs

The American Academy of Neurology defines qEEG as the mathematical processing of digital EEG to highlight specific waveform components, to transform EEGs into a format or domain that elucidates relevant information, or to associate numerical results with EEG data for subsequent review or comparison. Signal analysis includes automated event detection, monitoring in the Intensive Care Unit (ICU), source analysis, frequency analysis, statistical analysis and topographic EEG displays.

Volumetrics

Volumetric brain imaging allows care providers to take notice of and assess neurodegeneration. The technique keys in on several brain structures, such as the hippocampus, ventricles, and brainstem, and compares the volume of those structures to standard norms. These norms are based on factors including age, gender, and history of head trauma. Under this medical theory, volumetrics can reveal patterns in volume loss, linking brain degeneration to common brain disorders such as Alzheimer's disease, epilepsy, and recently discovered chronic traumatic encephalopathy ("CTE").

Neuropsych Testing

Neuropsychology tests take a snapshot of a patient's brain health and analyze how the health of that patient's brain may affect their behavior and thinking skills. These tests can include memory tests (e.g. repeating a list of words), cognition tests (e.g. explaining how two pictures are alike), motor tests (e.g. inserting pegs into a pegboard), and more. In conducting these tests, doctors will attempt to figure out whether a patient's attention span, memory, and problem-solving skills are caused by or linked to brain disorders such as Alzheimer's disease, brain injury, emotional disorders, or simply standard brain changes related to aging.

Utilization of Testing

Tests are utilized to demonstrate injuries ranging from TBI, perception of neuropathic pain, and standard orthopedic injuries.

III. The role of tests during the litigation process.

Medical diagnostic tests are performed pre-suit and throughout the litigation and trial process. Many of these studies are performed by physicians that lack sub-specialized expertise or employ testing that is lacking in demonstrated validity, which invariably results in flawed results. On average, there is a 40% clinical variability in the interpretation of an MRI when performed by a sub-specialized radiologist compared to a general radiologist. Treatment is impacted 25% of the time.

In addition, Diffusion Tensor Imaging can allegedly demonstrate disruption of axial pathways indicating subclinical brain damage. Volumetric studies seek to correlate deficits in executive function to atrophy of areas of the brain. Those advocating Functional MRIs claim to be able to demonstrate that the perception of pain is real and not imagined or exaggerated. QEEGs seek to correlate electrical activity to function and behavior. Questions concerning the reliability of these studies abound and the use of these studies are currently being challenged by the defense bar across the country.

Expert Review by a Sub-Specialized Radiologist

More than 85% of the time a sub-specialized radiologist can review a film and based on the visual information native to the scan, can discern whether an alleged injury was traumatically induced or pre-existing. Obtaining a qualified expert review of the imaging is beneficial for early evaluation to determine the extent of injuries and the validity of the claims.

As cases enter the trial phase, these tests are increasingly being promoted for use in the courtroom by the plaintiff's bar. In part, these tests are being used to demonstrate sub clinical aspects of injuries. In this way, there is a growing trend to use scientifically unproven tests to manufacture evidence of claimed injuries that cannot be proven otherwise. Identifying this "junk science" well before trial is crucial to successfully challenging the introduction of this evidence during the pretrial and trial phase.

IV. Admissibility of Expert Testimony on Medical Diagnostic Tests

Generally, courts can admit expert witness testimony on medical diagnostic tests if (1) the expert satisfies the qualifications requirement,(2) the testimony fulfills the relevance requirement, and (3) the testimony meets the reliability requirement.

Challenging the qualifications of the expert

At the outset every expert witness must be qualified to give ex-pert testimony,89 which in practice raises two issues. The first is whether the expert has enough credentials. The

second is whether the credentials are in "the specialty area in which the ex-pert is to testify." Proponents of MRI expert testimony have previously emphasized their experts' board certifications, current positions in the relevant fields, years of experience in the field, estimated number of MRI-based diagnoses and treatments conducted, and references to supporting medical literature.

In order to decide whether the expert witness's credentials come from the correct specialty area, courts may be willing to dig into the expert's substantive professional experience instead of taking her formal professional titles at face value.

In conclusion, courts evaluating the qualifications requirement have previously focused their qualifications analyses on the experts' professional certifications, current employment, quantifiable and qualitative experiences in the relevant fields, and citations to supporting medical studies.

Challenging the relevance of the evidence

In evaluating relevance courts may ask whether the expert's opinion logically relates to some specific issue in dispute under the substantive law or whether the research basis for the expert's opinion generalizes to a legal issue in a dispute."

Successful challenges to relevance have been held where an expert's proposed testimony is too vague, too insufficiently tied to the case-specific facts, and thus irrelevant.

Challenging the reliability requirement

Applying the test in *Frye v United States* (293 F 1013 [DC Cir 1923]), New York courts permit expert testimony based on scientific principles, procedures or theories only after they have gained general acceptance in the relevant scientific field (*see People v Wesley,* 83 NY2d 417, 422 [1994]). Under the *Frye* test, the burden of proving general acceptance rests upon the party offering the disputed expert testimony (*see Lara v New York City Health & Hosps. Corp.,* 305 AD2d 106 [1st Dept 2003]).

Under *Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993)*, courts evaluating the admissibility of expert testimony appear to take one of three approaches: (1) analyze reliability under the *Daubert* framework through a factors-based approach with express reference to individual *Daubert* factors, (2) analyze reliability under the *Daubert* framework through a totality approach without specific reference to any individual factors, or (3) analyze reliability under the Rule 702 framework by applying either the Rule 702 statutory criteria or the *Daubert* principles.

Factors: Testability

To establish testability, proponents of expert testimony might focus on the "retest reliability" and "reproducibility" of the expert's methodology or conclusions. In *Ruppel v. Kucanin*, (No. 3:08–cv–591, 2011 WL 2470621 (N.D. Ind. June 20, 2011)), for example, the court found that

the plaintiff's expert's DTI method-ology had "high retest reliability" and produced imaging scans of "high reproducibility" based on the expert's testimony. The *Ruppel* expert successfully persuaded the court of his methodology's testability in part by citing to a research study showing that "the scientific methodology of quantitative analysis of FA is reproducible," that "patients who have been scanned 2 or 3 times with slightly different resolutions have show[n] high reproducibility," and that a case study on a former football player also exhibited high reproducibility between DTI scans.

The court in *Ruppel* held that disagreements with the expert's characterization of DTI testability and replicability would not exclude the expert evidence during the pretrial stage and should instead be raised during trial. Interestingly, the *Ruppel* court appears to resolve the battling experts' contrary characterizations of DTI's testability by siding with the expert who had more expertise in the DTI field. The court's reliance on the battling experts' qualifications to resolve the testability issue appears to be a conflict as the expert's qualifications and reliability should act as two separate admissibility requirements.

Factors: Peer review and publication

The challenged attorney may focus on the peer-reviewed articles supporting the experts' statements in order to establish or challenge the reliability of the expert's medical diagnostic testing testimony. For example the *Ruppel* court confirmed that the second expert's DTI method had sufficient peer review because there were eighty-three articles discussing DTI in the context of traumatic brain injury, and eleven supporting articles that "specifically address[ed] the effectiveness of DTI in detecting mild [traumatic brain injury]."

Factors: Known or potential error rate

The theory or technique underlying the expert testimony should have a known or potential error rate as well as quality control standards for the operation of the techniques. Proponents of MRI expert testimony may have their experts highlight the error-minimization protocols and the statistical significance of any residual error rates. In *Ruppel* the court looked favorably upon the second expert's interpretation methods after the expert outlined his error rate protocol, "explained the numerous steps he took to minimize the error rates in his DTI analysis," and asserted that the statistical probability that "clusters of abnormal voxels found in areas of [the plaintiff's] brain were there by chance is next to impossible." The *Ruppel* court also noted approvingly that the error rate of the expert's DTI methodology was "not higher than [those of] other methods commonly relied upon such as [non-DTI] MRIs."

Factors: General acceptance

In demonstrating general acceptance, expert witnesses typically show that their medical testing methods are regularly used in hospitals, are relied upon by peer-reviewed journals, and/or are supported by medical textbooks as reliable methods for reaching similar qualitative conclusions.

Pretrial v. Trial challenges

Proponents may preemptively defend against opposing counsel's allegations that the expert's methodology was unreliable and lacked external confirmation. Proponents may also argue that disagreements over the characterization of the methodology speak to the weight of testimony, not its admissibility, and should be litigated at trial, not during pretrial motions.

Conclusion

There has been a proliferation of the use of medical diagnostic studies in litigation and in court. It behooves the legal practitioner to become well versed in the use and abuse of these studies and with respect to the newer technology, to prevent junk science from being used against their clients. This session will examine the clinical and scientific underpinnings of why discrepancies can exist and how the growth of various "cutting edge" technologies and examine what legal challenges can and have been made in an effort to prevent them being used in court and to be ready and able to attack questionable conclusions when their use is permitted.