Supporting Decisions with Evidence

Comparing Evidence–Based Medicine and Evidence-Based Adjudication

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Learning Objectives

* Develop a basic understanding of Evidence–Based Medicine goals
* Review Medical Causation Analysis under ACOEM and Reasonableness and Necessity of treatment under ODG
* Review Rules of Evidence relating to scientific opinion testimony
* Discuss the role of the Adjudicator in applying legal standards in workers’ compensation cases
You are fairly familiar with the Rules of Evidence

- We will look at the language of the Federal Rules toward the end of our discussions.
- I will provide some examples from Tennessee law that will be representative of how states apply the principles in their respective Rules

You have not looked closely at Evidence Based Medicine

- We will highlight the principles
- I will point to sources for your deeper study and consideration
The idea of evidence-based medicine is to improve the medical decision-making process by emphasizing the use of scientific research and medical consensus. While it has been around for the last several decades, evidence-based medicine has only recently become widespread in the workers’ comp system.
Scientific research and medical consensus

Jonas Salk – Discovers Polio Vaccine
Commonly used EBM and statistical abbreviations

- **ARI** Absolute risk increase
- **CI** Confidence interval
- **CCT** Controlled clinical trial
- **HR** Hazard ratio
- **NNH** Number needed to harm
- **NNT** Number needed to treat
- **OR** Odds ratio
- **RCT** Randomized controlled trial
- **RR** Relative risk
- **RRI** Relative risk increase
- **RRR** Relative risk reduction
- **SD** Standard deviation
The “Risk Generalization-Particularization” model of medical prediction

“Risk GP the model that many practitioners implicitly rely upon when making evidence-based decisions.”

As described by Jonathan Fuller, at the University of Toronto in Canada, and Luis Flores, a philosopher at King’s College London in England
It “advocates applying the results of population studies over mechanistic reasoning … in diagnosis, prognosis and therapy.”

It “has become dominant in medical research and education, accepted by leading medical schools and all of the major medical journals.”

There are serious problems with the Risk GP Model, especially with its assumptions, which are often difficult to warrant with evidence and will often fail in practice,” Fuller and Flores assert.
If you treat a patient on the basis of data from clinical trials, make sure
- the patient actually is a member of the population sampled.
- the sample of patients in the trial fairly represents the whole population from which it was sampled.

In practice, these requirements are never fully met.

Physicians may assume that the study populations are “sufficiently similar” to the people being treated.
When considering any source of evidence about treatment other than N of 1 RCTs, clinicians are generalizing from results in other people to their patients, inevitably weakening inferences about treatment impact and introducing complex issues of how trial results apply to individuals.
In counterbalance, JAMA points out . . .

Inferences may nevertheless be

* strong if results come from a systematic review of methodologically strong RCTs with consistent results and
* are generally somewhat weaker if we are dealing with only a single RCT unless it is large and has enrolled a diverse patient population
Because observational studies may underestimate or more typically overestimate treatment effects in an unpredictable fashion their results are far less trustworthy than those of RCTs.

Physiologic studies and unsystematic clinical observations provide the weakest inferences about treatment effects.

The Users' Guides have summarized how clinicians can fully evaluate each of these types of studies.
Two fundamental principles of EBM

- One, relating primarily to the assessment of validity, posits a hierarchy of evidence to guide clinical decision making.
- Another, relating primarily to the application of evidence, suggests that decision makers must always trade off the benefits and risks, inconvenience, and costs associated with alternative management strategies, and in doing so consider the patient's values.
In 1992, we described EBM as a shift in medical paradigms.

In contrast to the traditional paradigm, EBM acknowledges that intuition, unsystematic clinical experience, and pathophysiologic rationale are insufficient grounds for clinical decision making, and stresses the examination of evidence from clinical research.
The philosophy underlying EBM suggests that a formal set of rules must complement medical training and common sense for clinicians to effectively interpret the results of clinical research.

Finally, EBM places a lower value on authority than the traditional paradigm of medical practice.

Note: authority = opinion of a professor according to one physician I consulted.
In current health care practice, judgments often reflect clinician or societal values concerning whether intervention benefits are worth the cost. For example . . .

Consider the decisions regarding administration of tissue-type plasminogen activator (t-PA) vs streptokinase to patients with acute myocardial infarction, or clopidogrel (Plavix) vs aspirin to patients with transient ischemic attack.

In both cases, evidence from large randomized controlled trials (RCTs) suggests the more expensive agents are, for many patients, more effective.
In both cases, many authoritative bodies recommend first-line treatment with the less effective drug, presumably because they believe society's resources would be better used in other ways.

Implicitly, they are making a value or preference judgment about the trade-off between deaths and strokes prevented, and resources spent.
Okay, what if we are not doctors?

* Ethical physicians correctly using EBM to manage care of a patient is a good thing.
* What happens when stakeholders in workers’ compensation “interpret” the guidelines?
* What responsibility do adjudicators have in considering the parties positions in the claims?
“The application of evidence-based medicine in workers’ comp is much different from the application of evidence-based medicine in the group health world,”

“In group health the evidence-based medicine guidelines have been scrutinized by the medical professionals as they are limited in scope and typically used to control cost in a hospital setting by limiting reimbursement rates.”
“It’s like a recipe. With evidence-based medicine guidelines, you can quantify exactly how much of each ingredient you put in and therefore enhance your ability to refine, measure, and improve your results over time. At least that is what EBM tries to do,”

“It’s a recipe that applies to, say 80 percent of the population most of the time. The recipe should reduce system costs and facilitate cooperation from both sides of the business — payers and providers alike.”
Reasonableness and necessity of treatment: Why all the fuss?

* Protect the worker from procedures and treatments
  * that are unlikely to work, or
  * come with low benefit and high risk
* Protect the payer from cost of
  * Patient accommodation
  * Duplicated or non-competitive pricing of services
  * higher cost of branded products
Ranks every procedure it covers given a specific diagnosis by the following four codes

* **Green flags** indicate the procedure is recommended based on prevalence, medical consensus, and historical claim outcomes.

* **Yellow flags** indicate the procedure is a common treatment for that diagnosis and should be allowed on a limited basis with a restriction on the number of times it should be performed.
Red flags denote low prevalence in workers’ comp and that the treatment is not necessarily indicated based on current scientific research, i.e., recommendation is to review.

Black flags indicate inappropriate care and possibly denial of service.
"These publications are guidelines, not inflexible proscriptions, and they should not be used as sole evidence for an absolute standard of care. Guidelines can assist clinicians in making decisions for specific conditions and also help payors make reimbursement determinations, but they cannot take into account the uniqueness of each patient's clinical circumstances."

http://www.odg-twc.com/preface.htm#COPYRIGHTPAGE
As explained in the first paragraph above, these are guidelines, and there will always be cases that fall outside of the guidelines.

Carriers need to make medical decisions when a health care provider has requested or rendered treatment outside of or in excess of the guidelines.

Carriers should not deny this treatment only because it is not mentioned or recommended in the guidelines.

In considering the medical necessity of the medical care at issue the carrier should consider:
INSTRUCTIONS FOR CARRIERS

* (1) extenuating circumstances of the case that would warrant additional treatment including the rationale for procedures not addressed in ODG;
* (2) patient co-morbidities;
* (3) objective signs of functional improvement for treatment conducted thus far for the injured worker;
* (4) measurable goals and progress points expected from additional treatment; and
* (5) any additional evidence provided by the health care provider to support the medical necessity of the medical care at issue.
Unlike group health or Medicare Medicaid, an employer is responsible for medical treatment “caused” by the employment.

States have different standards by which causation is judged
- Primarily Caused By
- Contributed to
- Could be caused by

All states require medical evidence of causation in all but the most obvious work injuries
Six step evaluation method

- Evidence of disease: What is the disease? Is the diagnosis correct?
- Epidemiological data: Does quality data support a relationship to work?
- Evidence of Exposure: Primarily objective
ACOEM – 6 step method

- Other relevant factors: all risk factors outside of employment
- Validity of evidence: confounding or conflicting data
- Evaluation and Conclusions: Is presence of work-related disease supported by data?
Publication of National Association of Workers’ Compensation Judiciary

Article at page 5

Shoulder Pain at Work: Causation Analysis

Joel Weddington, MD, Charles N. Brooks, MD, Mark Melhorn, MD, and Christopher R. Brigham, MD
Case 2: Aggravation of rotator Cuff Tear at work (p. 7)

* 61-year-old right-handed female working as NICU nurse since 1981
* August 2013 reported increasingly sore right shoulder, elbow, forearm and wrist; unable to move shoulder back to put on coat or hold heavy objects above shoulder height
* Pain began gradually since January 2013
* She believed symptoms caused by new work station after EMR system implementation
Absent the repetitive charting on an elevated tray and given studies that show a high incidence of asymptomatic rotator cuff tears in this age group, the patient might have remained asymptomatic indefinitely were it not for her occupational activities.

What would be the result under your legal standard?
What do Judges need to know about expert testimony?

- Admissibility
  - Qualifications
  - Analytical Cohesion
  - Methodology (Daubert)
  - Foundational Reliability
- Sufficiency
  - Lay witnesses
  - Certainty
  - Presumptions
  - Legal realism
If specialized knowledge will substantially assist the trier of fact to:
* Understand the evidence, or,
* Determine a fact, and
* A witness is qualified by knowledge, skill, experience, training, or education
* If not, then it’s out!!
* Where the statute requires medical evidence, lack of admissibility would defeat the claim.
Daubert is a 1993 U.S. Supreme Court case establishing the admissibility of expert opinion in federal cases.

It has (basically) been adopted in most states by Rule or ruling.
What does Rule 702 mean?

* The court must make a “reliability” decision
  * (a) Witness qualified to testify
  * (b) The testimony is based on sufficient facts or data;
  * (c) The testimony is the product of reliable principles and methods; and
  * (d) The expert has reliably applied the principles and methods to the facts of the case.
When is an expert’s methodology sound?

- When it has been tested
- When it has been subjected to peer review or publication
- When we know its rate of error
- When it is generally accepted in the scientific community (Frye standard circa 1923)

- Some add when the expert’s research has been conducted independent of litigation.
Are issues of causation, reasonableness and necessity of treatment testable?

Physician's causation opinions are almost never published in Journals.

Most peer review on causation, reasonableness and necessity of treatment is in the context of litigation.

That leaves general acceptance in the field
An expert may base an opinion on facts or data in the case that the expert has been made aware of or personally observed.

If experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject, they need not be admissible for the opinion to be admitted.
If the facts or data would otherwise be inadmissible, the proponent of the opinion may disclose them to the jury only if their probative value in helping the jury evaluate the opinion substantially outweighs their prejudicial effect.
“Facts or data he has been made aware of”

* In this respect the rule is designed to broaden the basis for expert opinions beyond that current in many jurisdictions and to bring the judicial practice into line with the practice of the experts themselves when not in court.

* Thus a physician in his own practice bases his diagnosis on information from numerous sources and of considerable variety, including statements by patients and relatives, reports and opinions from nurses, technicians and other doctors, Most of them are admissible in evidence, but only with the expenditure of substantial time in producing and examining various authenticating witnesses.

* The physician makes life-and-death decisions in reliance upon them. His validation, expertly performed and subject to cross-examination, ought to suffice for judicial purposes.
Unless the court orders otherwise, an expert may state an opinion — and give the reasons for it — without first testifying to the underlying facts or data. But the expert may be required to disclose those facts or data on cross-examination.
Qualifications of the expert
The circumstances of their examination
The information available to the expert
The evaluation of the importance of that information by other experts.
The next four slides are taken from an order and summarizes the opinions of separate physicians relating to causation of carpal tunnel in the same patient.

The law requires a determination that the employment was more than 50% the cause of the condition or the need for treatment.

Consider to what extent the opinions are helpful and reliable.
Dr. Renfree noted, “We talked about causation today as well and she seems very well versed into the year and date of when Tennessee [law] stated that repetitive motion was not related to work-type injury nor was typing or utilizing the keyboard.”
Dr. Renfree went on to say “… I explained that her carpal tunnel syndrome was not greater than 51% related to her work activity. We discussed that carpal tunnel syndrome [may] be very multifactorial such as genetic and especially in light of the fact that she has underlying diabetes and hypothyroidism.”
The patient has an underlying history of hypothyroidism as well as diabetes mellitus. Both of which can place the patient at an increased risk of developing carpal tunnel syndrome. However, she also does repetitive activity at work. Given her electrodiagnostic studies on exam, she has fairly significant carpal tunnel.
While I cannot say this definitively, I think most likely the patient’s occupation and work requirements have contributed to her carpal tunnel syndrome if not the sole cause of her carpal tunnel syndrome. I do believe that work likely contributes greater than 50% of the patient’s risk and symptoms.
Well, how about that?

* Which was helpful to the adjudicator?
* What information would the adjudicator appreciate being added?
* How would the adjudicator rule on causation?
* What would be key language in the order?
* Was the testimony indicative of opinions supported by Evidence Based Medicine?
Almost Done!

QUESTIONS
THANK YOU