EVIDENCE-BASED MEDICINE AND TREATMENT GUIDELINES

Marjorie Eskay-Auerbach, MD, JD
meamd@mindspring.com

1

Overview

- What is EBM? Why does it matter?
- What is the process of EBM?
- What are the Most Common Guidelines?
  - Proprietary
  - National Guideline Clearinghouse
  - State Developed/ Adopted
- How does it apply to WC?
  - Treatment Guidelines

2

Disclosure

- Editorial Advisory Board for Official Disability Guidelines(thed. 2006) & ODG Treatment in Workers Comp (4thed. 2006), etc.
- Advisory Board for the Medical Disability Advisor, Reed Group, 2009
- Contributor, AMA Guides to the Evaluation of Permanent Impairment 6th
- No financial interest in any guidelines

3

Thanks to:

Jerome Schofferman, MD
SpineCare, Daly City, CA

Resources:
ACOEM Guideline Training

4

Evidence-Based Medicine A New Concept?

- The concept of modifying clinical practice based on results of research has been in place for hundreds of years
- In the 20th century and going forward it has evolved to impact almost all fields of healthcare and policy
- EBM currently applied requires a structured approach

5

EBM - Definitions

- "The conscientious, explicit and judicious use of *current best evidence* in making decisions about the care of the individual patient. It means integrating individual clinical expertise with the best available external clinical evidence from systematic research."

Sackett, 1996, 2000

6

Available Evidence

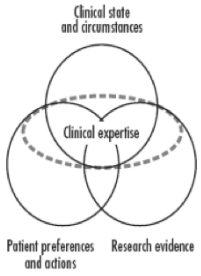
- Perfect evidence is not always available
  - Identify and evaluate the evidence that IS available
    - Treatment outcomes
    - Does it support a conclusion eg. surgical treatment is more effective than medical treatment in improving survival

7

Definitions

- Patient Care Model
- "The integration of best research evidence with clinical expertise and patient values"

Sackett et al 2000



8

Rationale for Application of EBM

- Variance in practice ⇒
  - Regional
  - Among health care payors
- Cost Variation and Escalation of Care
  - No outcome improvement
  - Dissociation of care from outcomes

Little evidence that this results in better outcomes

- Eg. Rx of low back pain in WC vs PP

9

Variance in Practice

- Treatment based on:
  - Experience rather than evidence
  - Old learning
  - Anecdotes
  - Generalizing from a single case
  - New treatments embraced before adequate study

10

Alternatives to EBM

- Eminence-Based
  - The more senior the physician the less important the evidence
- Vehemence-Based
  - The stronger the opinion the less important the evidence
- Eloquence-Based
  - The better the speaker, the less important the data

Isaacs and Fitzgerald. BMJ 1999;319:18-25 11

More Alternatives to EBM

- Experienced-based

Making the same mistake over and over until you're really good at it

(Einstein: doing the same thing again and again, expecting a different result)

12

More Alternatives to EBM

- Experienced-based
- Personal Anecdotes based
  - One case
    - "In my experience…"
  - Two cases
    - "In case after case…"
  - Three cases
    - "In my series…"
- Financially based

13

Alternatives to EBM

- ~~Eminence-Based~~
- ~~Vehemence-Based~~
- ~~Eloquence-Based~~
- ~~Providence-Based~~
- ~~Diffidence-Based~~
- ~~Nervousness-Based~~
- ~~Confidence-Based~~
- ~~Experienced-Based~~
- ~~Anecdotally-Based~~
- ~~Financially-Based~~

There are no GOOD alternatives to EBM

14

One End of the Spectrum

clinicians, industry

- I can't just stand there; I have to do something
- If I wait for Level I-II evidence, I may deny effective RX for years
- New is probably better
- Cost doesn't matter; the public wants the best care and latest innovation

Modified from: R Deyo, M.D. NASS 2006

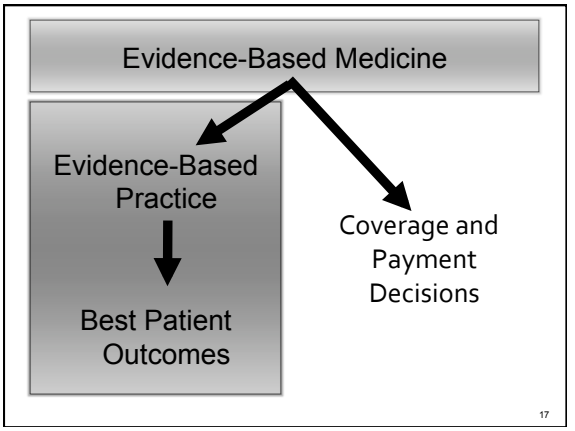
15

Other End of the Spectrum

economists, insurers, "academics"

- If no good evidence, harm may be > good
- Early results usually more favorable than later
- Society cannot afford unproven Rx.
  - Medicare's going broke
  - Private insurance is expensive

16



17

Evidence Based Medicine

- IS NOT
  - Selecting an article to support a position
  - Selecting a few articles for support
  - Reprinting abstracts without critical appraisal

18

Evidence –Based Medicine

- IS
  - An objective graded assessment of the ENTIRE body of high quality literature on a given topic

19

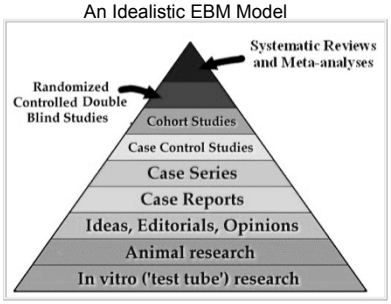
EBM's value

- Contributes to *improved analysis of the evidence*
  - Principles and methods for evaluating evidence
- Allows for decisions consistent with the evidence
  - Consider quality of evidence
  - Best available evidence
    - expert opinion and clinical judgment

20

The Evidence Pyramid

An Idealistic EBM Model



- **Important not to confuse Levels of Evidence with Quality of Evidence or Importance**

21

Levels of Evidence

22

Systematic Review	Meta-analyses
▪ Structured review of lit	▪ Structured review of lit
▪ Inclusion and exclusion criteria	▪ Inclusion and exclusion criteria
▪ Assess study design quality	▪ Assess study design qualtiy
▪ Assess methodological quality	▪ Assess methodological quatlity
▪ Compile & summarize results	▪ statistical analysis of results of grouped studies
▪ GOAL: determine what the current evidence is on a specific topic	▪ GOAL: draw conclusions from the results of the analysis of grouped data

23

Clinical or Practice Guidelines

- "Systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances"
  - National Institute of Medicine, 1990
- Purpose is "to make explicit recommendations with a definite intent to influence practice"
  - JAMA, 1995

24

Clinical Practice Guidelines

- Quality improving strategies
  - Evidence based
  - Consensus based
- User-friendly statements that bring together the best external evidence (EBM) and other knowledge necessary for decision making about a specific problem

25

EB Guidelines ≠Consensus

- Guidelines: documents to improve clinical practice, gathering the best evidence available
- Consensus: general agreement (unanimity) – issues discussed until broad agreement

26

EB Guidelines vs. Consensus

- There is no need for consensus once the level of evidence is high
- What is a high level of evidence?
  - Systematic Review +/- metanalysis
  - Randomized study of good quality
  - Observational studies
- Consensus is reserved for those issues with low levels of evidence

27

Guideline Development

- Evidence Based Guidelines
  - Define a population
  - Identify strength and weaknesses of the data/ study
  - Describe strength of the evidence
  - Separate opinion from evidence

28

Essential Properties of Clinical Practice Guidelines

- Define practice questions
- identify decision options and outcomes
- Explicitly identify, appraise and summarize the best evidence about prevention, diagnosis, prognosis, therapy, harm and cost-effectiveness

29

What is the Process of EBM?

1. Identify a patient-oriented/ practice-oriented problem of interest
2. Develop a specific clinical question that targets the problem
3. Review the available evidence
4. Appraise the evidence → decision
5. Integrate the evidence into your practice
6. Assess your outcomes (if appropriate)

30

Process in EBM
Devising Clinical Question

Patient	Disease entity, risk, population
Intervention	Test, maneuver, prevention or treatment
Comparison Group	Single intervention preferred
Outcomes	Function, harms objective, subjective findings

31

What is Available in WC?

- Medical treatment guidelines
  - ODG, ACOEM, State guidelines (CO, WA, MA)
- Return to work guidelines
  - ODG, Milliman USA, Medical Disability Advisor
- Impairment guidelines
  - AMA Guides

32

EBM Guidelines

- Content
  - Treatment guidelines (ACOEM, ODG)
  - Disability Durations (ODG, Med Disability Advisor)
- Format
  - Computer based- automated
  - Paper format, on line, interactive software
- All are COST EFFECTIVE ($100- 3 per user)

33

How is EBM used in Guidelines?

- Language and Specificity of Diagnosis
  - Eg. Lumbago vs. Facet Related Pain
- Discussion
  - Example: Spine Fusion, with Radiculopathy
    - Does not treat radicular pain
- Compromise
  - Example: guidelines recommend 2 PT visits, 3 approved
- Focus on treatment that works

34

EBM in Occupational Med/ WC

- Diagnosis and testing
- Work-relatedness
- Treatment
- Pain Management
- Disability management and RTW
  - May be independent from medical care
- Impairment evaluation

35

EBM and Occ Med/ WC

- Compared with similar dx groups in general medical care
  - 10-fold differences in resource use
  - Inappropriate use of invasive procedures
  - Use of PT, opioids and chiropractic care for prolonged durations
- High prevalence of testing and rx unsupported by the lit or general med. practice patterns

36

EBM and Occ Med / WC

- Most MSK research is NOT OCCUPATIONAL
  - Work relatedness not addressed
  - Blinding of interventions is a problem
  - Effects on disability RTW (outcomes) not discusses
  - Litigated cases often excluded
  - Disability management not addressed

37

EBM and Occ Med / WC

- Caveat: much of the MSK literature compares interventions so it cannot be determined whether the effects observed are better than the natural course of the condition

38

State Adoptions of WC Guidelines

- Many states have their own written guidelines (AR, CO, CT, MA, MN, RI, WA)
- Problems that may exist
  - Not necessarily evidence-based
  - Tend to be more political
  - Colorado/Washington, MA may be exceptions
- Some dropping own guidelines and adopting national guidelines (CA, FL, OH, TX)
- Laws/rules adopting Utilization Review guidelines under consideration in many states

39

National Guideline Clearinghouse (NGC)

- The NGC, created by AHRQ (Agency for Healthcare Research and Quality) in partnership with AMA and AAHP
- http://www.guidelines.gov
- May 1, 2006 access to 1,903 guidelines from different organizations
- Some are focused on workers' comp (can browse site)

40

Use of Treatment Guidelines

- It is a new "language" for physicians
  - Some are resistant
- Utilization review/ management
- Clinical practice
  - Sets a standard
  - Reduced variability

41

Positives - Treatment Guideline Use

- Not "cookbook medicine" - treatment options are often cited if they are appropriate
- Allows for the application of science, not opinion or hearsay
- EBM makes this non-adversarial and ultimately defensible in any setting

42

CA Experience

- Projection
  - "UC Berkeley Study projects impact of ACOEM Guidelines in CA to be a 36.7% savings or $3.1 billion" (Neuhauser, 2003)
- Actual (effect of multiple reforms)
  - "California Workers' Comp Insurance Ragint Bureau recommends another 5% rate drop, bringing the cumulative reduction in rates to 41.7% since 2003" (WCIRB 07/22/05

43

Question: Acupuncture for Foot Pain

- What does ACOEM state?
  - ACOEM 2nd Edition, Chap 14 p. 371, states "invasive techniques (e.g. needle acupuncture…) have no proven value"
  - Would we make exceptions… YES
    - Chronic pain, Asian background
  - Limit number of treatments
    - If no clear positive objective response --> no more therapy

44

ACOEM: Spine Surgery

- ACOEM 2nd Ed., Ch 12, pp. 305-307
  - Recommends surgery only with failure of conservative treatment and objective documentation of pathology that can be addressed by surgery
  - Multiple other comments re: specific rx
    - Discectomy
    - IDET
    - Fusion (no good evidence for rx of acute low back pain)

45

ACOEM Update Process

- Adoption of more meticulous strength of evidence rating methodology
- Systematic identification of high-quality original research studies – multiple databases
- "hand search" by trained health science researchers
- Grading for design and analysis

46

ODG - Another option

- Organized differently
- More focused
- More documentation for the comments
- Not better - just different
  - (CONTENT IS THE ISSUE NOT LAYOUT)
- Hardcopy/ online/ automated

47

Official Disability Guidelines

CONTENTS

Section A (Treatment Guidelines)
I. ODG Treatment Index
Section B (Return-to-Work Guidelines, including links to the Treatment Guidelines)
I. ICD-9 Index
II. Keyword Index
III. CPT® Index
Section C (Impairment Guidelines)
I. IAIABC Contents
Section D (Front matter)
I. Preface
II. How to use this site
III. Editorial Advisory Board
IV. Foreword

48

Acupuncture for low back pain

Tulder MW van, Cherkin DC, Berman B, Lao L, Koes BW

This review should be cited as: Tulder MW van, Cherkin DC, Berman B, Lao L, Koes BW. Acupuncture for low back pain (Cochrane Review). In: *The Cochrane Library*, Issue 3, 2002. Oxford: Update Software.

A substantive amendment to this systematic review was last made on 24 February 1999. Cochrane reviews are regularly checked and updated if necessary.

Background: Although low back pain is usually a self-limiting and benign disease that tends to improve spontaneously over time, a large variety of therapeutic interventions are available for the treatment of low back pain.

Objectives: The objective of this review was to assess the effects of acupuncture for the treatment of non-specific low back pain.

Search strategy: We searched the Cochrane Complementary Medicine Field trials register, the Cochrane Controlled Trials Register (1997, issue 1), Medline (1966 - 1996), Embase (1988 - 1996), Science Citation Index and reference lists of articles.

Selection criteria: Randomised trials of all types of acupuncture treatment that involves needling for subjects with non-specific low back pain.

Data collection and analysis: Two reviewers blinded with respect to authors, institution and journal independently assessed trial quality and extracted data.

Main results: Eleven trials were included. The methodological quality was low. Only two trials were of high quality. Three trials compared acupuncture to no treatment, which were of low methodological quality and provide conflicting evidence. There was moderate evidence from two trials that acupuncture is not more effective than trigger point injection or transcutaneous electrical nerve stimulation (TENS). There was limited evidence from eight trials that acupuncture is not more effective than placebo or sham acupuncture for the treatment of chronic low back pain.

Reviewers' conclusions: The evidence summarised in this systematic review does not indicate that acupuncture is effective for the treatment of back pain.

49

Guidelines - Problems

- Problem Areas
  - New technology, rare procedures
  - Complex diagnoses, multiple diagnoses
  - Issues not dealt with by a specific guidelines
    - Consider other resourdes

50

How Can We Know if there is Evidence?

- We are obligated to keep up to date
- What we don't know can hurt us and our patients
- Consequences
  - Longer time off work
  - Poorer heath outcomes
  - Higher probability of permanent disability

51

What to Do When the Evidence is Lacking?

- Obtain the most current evidence
- Evaluate and weigh that evidence
- Integrate it with your clinical expertise
- Apply it to the patient considering his/ her particular values and circumstances

52

Advantages to EBM Guidelines

- Becomes the standard for EVERYONE in the system
- Improve OUTCOMES
  - Do what works!
  - Reduce excessive/ unnecessary utilization of medical services
  - Reduce morbidity/ Reduce care
- Reduce administrative "friction" by being clear to providers about what treatments will get paid for -> focus on care

53