

William B. Patterson Memorial Lecture

Evidence in OEM: The Art of RE-Learning What We Think We Already Know

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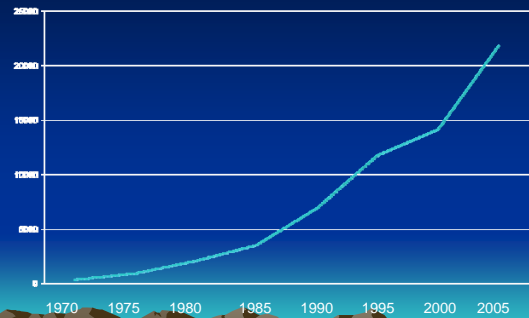
Simple World

- Formal medical & OSH educations
- Imparted knowledge, largely through collective “wisdom”
- Graduate with the state-of-the-art knowledge base to assess, analyze, synthesize, diagnose, evaluate, treat, and **prevent**.

The Challenges

- Curricular issues
 - Some subjects not well taught
 - Scope of OSH/OM/OHN practice is beyond the curricular bounds
- Accuracy of the understood knowledge
- Pace of new knowledge

Pace of Knowledge Proxy (RCTs)



Greater challenges

- The collective wisdom was....
 - Weak
 - Stated to be known (or well known, or better yet, “proven”...)
 - Robust
 - Limited
 - Not synthesized
 - Not evidence-based

Reprogramming Memory

- Perhaps most challenging of tasks for adult learners

Reprogramming Memory

- Perhaps most challenging of tasks for adult learners
- May be even more difficult with repetition of “knowledge” or pseudo-knowledge
 - Teaching colleagues, doctors, nurses, secretaries, medical students, residents
 - Teaching patients, family, friends, neighbors

Guidelines:

Part of the Solution

Why Guidelines?

- ✓ Ensure that patients receive **consistent, high quality health care**
- ✓ Control costs by reducing unexplained variation in care
- ✓ Provide a baseline for the physician to ensure payment for treatment

Evidence-Based Medicine

“A set of principles and methods intended to ensure that to the greatest extent possible, medical decisions, guidelines, and other types of policies are based on and consistent with good evidence of effectiveness and benefit.”

Eddy DM. Health Affairs. 2005;24(1): 9-17.

IS **NOT**:

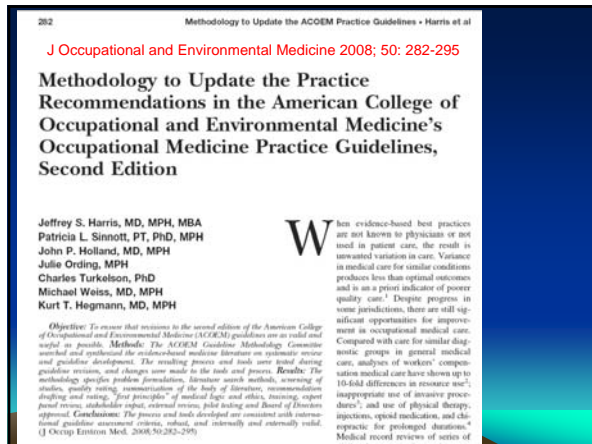
- Selecting an article to support a view.
- Selecting a few articles for support.
- Reprinting abstracts without critical appraisal.

IS:

- An **objective, graded** assessment of the **ENTIRE** body of **high quality** literature on that topic.

How Can You Tell if Guidelines Are Evidence-based?

1. Is there a published, detailed, and understandable **methodology**?
2. Are the conclusions **scientifically verifiable**?
3. Were the reviews and recommendations developed by professionals with **appropriate training and credentials**?
4. Were findings made by **individuals or by broad-based physician panels**?



Methodology

1. Exhaustive Literature Searches for **Randomized Controlled Trials (RCTs) or Crossover Trials**
2. Articles Critiqued
3. Summary Tables Compiled
4. Articles Graded
5. Strength of Article Assigned
6. Summary Evidence and information forwarded to Evidence-Based Practice Panel
7. Guidance (Semi)-Finalized
8. External Peer Review
9. Guidance Finalized

Methodology

Exhaustive Literature Searches for **Randomized Controlled Trials (RCTs) and Crossover Trials:**

- The National Library of Medicine's MEDLARS database (Medline)
- EMB Online
- The Cochrane Central Register of Controlled Trials
- TRIP Database
- CINAHL (Nursing, allied health, physical therapy, occupational therapy, social services)
- EMBASE
- PEDro: Physiotherapy Evidence Database

Systematic Review Process

- Articles Identified
- Articles Critiqued: MD, PhD
- Summary Tables Compiled
- Articles Graded
- Articles, analyses, and summary tables forwarded to the Evidence Based Panels

RCT Article Grading (0-11 points)

1. Randomization (0, 0.5, 1.0 pts.)
2. Allocation concealed (0, 0.5, 1.0)
3. Baseline comparability of groups
4. Blinding of patients
5. Blinding of provider
6. Blinding of assessor
7. Avoid co-interventions

RCT Article Grading (0-11 points)

8. Compliance Rate
9. Dropout Rate
10. Timing of Assessments
11. Intention to Treat Analysis

Note Bias rating (0, 0.5, 1.0) is also included, but **not** in the 0-11 point grade

Strength of Evidence

- A: Strong evidence-base:** Two or more high-quality studies.
- B: Moderate evidence-base:** At least one high-quality study, or multiple moderate quality studies.
- C: Limited evidence-base:** At least one study of moderate quality.
- I: Insufficient Evidence:** Evidence insufficient or irreconcilable.

Evidence-based Recs.

Strongly Recommended	"A" Level Evid.
Moderately Recommended	"B" Level Evid.
Recommended	"C" Level Evid.
Insufficient For (Consensus-based)	"I" Level Evidence
Insufficient-No Recommendation (Consensus-based)	"I" Level Evidence
Insufficient Against (Consensus-based)	"I" Level Evidence
Recommended Against	"C" Level Evid.
Moderately Recommended Against	"B" Level Evid.
Strongly Recommended Against	"A" Level Evid.

LOW BACK PAIN

NSAIDs 28 High or Moderate Quality RCTs

- ACUTE LBP: **Evidence (A)**
- Subacute, chronic, post-operative LBP, sciatica **Evidence (B)**.
- Acute radicular pain syndromes, scheduled dosage, rather than as needed, generally preferable. PRN prescriptions reasonable for mild or moderate, chronic radicular pain. **Evidence (C)**
- Consider concomitant prescriptions of cytoprotective medications for those at risk. No substantial differences between meds. **Evidence (C)**
- Acetaminophen for LBP with or without radicular symptoms, particularly for those with contraindications for NSAIDs. Modestly less efficacious. **Evidence (C)**

Chronic LBP. Antidepressants. 9 high or moderate quality RCTs

LBP: Norepinephrine reuptake inhibitor antidepressants (TCAs, e.g., amitriptyline) – Evidence (A)

Radicular pain: Evidence (C)

Selective serotonin reuptake inhibitors, (e.g., paroxetine, as well as bupropion and trazodone) Strongly Not Recommended, Evidence (A)

Muscle Relaxants. 38 RCTs

- Second line treatment in moderate to severe LBP NOT controlled by NSAIDs.
 - Generally, prescribe nocturnally initially (and not during work or operating vehicles).
 - Caution: history of depression, personality disorder, substance/alcohol abuse. Cyclobenzaprine's structure resembles tricyclic antidepressant and less addiction.
- Moderately Recommended, Evidence (B)**
Acute Radicular Pain: Second or third line agents.
Recommended, Insufficient Evidence (I)
- NOT recommended for chronic use in subacute or chronic LBP (other than acute exacerbations).
NOT Recommended, Insufficient Evidence (I)

"A lot of relief" or "complete relief"
Cyclobenzaprine 10 mg vs 5 mg vs placebo

(Please see ACOEM Practice Guidelines text for copyrighted Figure that ACOEM received permission to reprint.)

Borenstein DG *Clinical Therapeutics*. 2003;25(4):1056-73.

"A lot of relief" or "complete relief"
Cyclobenzaprine 5 mg vs 2.5 mg vs placebo

Borenstein DG *Clinical Therapeutics*. 2003;25(4):1056-73.

Mattresses, Water Beds and Sleeping Surfaces

- **3 RCTs** on sleeping surfaces. (All LBP patients)
- No quality studies on water beds or advice to sleep on the floor.
- No recommendation on mattresses
- **Dogma to sleep on firm mattresses may be wrong.**
- By analogy, sleeping on the floor may be incorrect as well.

No Recommendation, Insufficient Evidence (I)

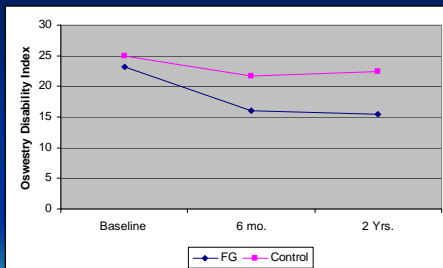
- No quality evidence for other optimal sleeping surfaces (e.g., bedding, water beds, and hammocks).
- **Recommended that "patients select mattresses, pillows, bedding or other sleeping options that are most comfortable for them."**

No Recommendation, Insufficient Evidence (I)

Exercise

- **66 RCTs**
- Most articles mixed various forms of exercise
- Most study's quality is moderate (or low)

Exercise: Oswestry Scores for Fitness Group versus Controls



Frost H *BMJ* 1995; 310(6973): 151-154

Exercise: AEROBIC

- Recommended for all patients, although most quality evidence is on chronic LBP.
- Recommend structured, progressive walking program.
- Some controversy about bicycling (biomechanics: lordosis). Also, back muscles less active.
- No quality evidence on other exercise, but direct correlation between benefit and amount of aerobic activity that results in higher METs.
- Prescribe what they will adhere to.
- Cardiac disease, or significant potential should consider pre-exercise evaluation. [ACSM's *Guidelines for Exercise Testing and Prescription* (7th edition)]

Exercise: AEROBIC

- Chronic LBP: Walking at least four times per week at 60% of predicted maximum heart rate (220-age=maximum heart rate). One successful study benchmarked twenty minutes during week 1, 30 minutes during week 2, and 45 minutes after that point.
- Acute or Subacute LBP: Graded walking program, often with distance or time as minimum benchmarks. E.g., start with 10-15 minutes twice a day for one week, and increase in 10-15 minute increments per week until at least 30 minutes per day is achieved.

Strongly Recommended, Evidence (A)

- Aerobic exercise believed highly important for post-operative but no quality data.

Recommended, Insufficient Evidence (I)

Stretching and Flexibility

- Acute LBP: Specific stretching exercises are somewhat helpful for acute LBP. Aerobic exercise should be first line treatment
- Either slump stretch-related exercises or directional preference stretching exercises are recommended.
- Generic stretching exercises are not recommended.

Recommended, Evidence (C)

- Stretching exercises as isolated prescription or program for preventing LBP not recommended.

NOT Recommended, Evidence (I)

Strengthening and Stabilization Exercises

- Evidence of efficacy of aerobic exercises appears greater and should be initiated first
- Develop home exercise program.
- Some may need supervised program (e.g., lacking motivation, or with fear avoidant beliefs)

Recommended, Evidence (C)

- Strengthening of abdominal muscles is a frequent goal
- NO quality evidence effective for treatment or prevention
- Other treatment strategies have efficacy.

NOT Recommended, Insufficient Evidence (I)

- Fear Avoidance Belief Training and principles appear important and should be incorporated

Recommended, Insufficient Evidence (I)

Cryotherapies

- 2 RCTs
- No quality evidence of efficacy.
- Acute LBP: Self applications of low tech recommended
- Moderate to severe acute LBP: reasonable to attempt, but threshold to discontinue lower. Active modalities are far preferable to passive modalities for rehabilitation of non-acute LBP.

Recommended, Insufficient Evidence (I)

- Routine use in healthcare provider offices or home use of high tech devices not recommended. Single use of low tech cryotherapy for severe exacerbations are reasonable to try.

NOT Recommended, Insufficient Evidence (I)

Heat Therapies

- 8 RCTs
- Recommended for acute, subacute and chronic LBP.

Recommended, Evidence (C)

- Application by healthcare provider in conjunction with exercise program may help acute LBP.
- Education for home applications part of treatment.
- Self-applications are recommended
- Application by healthcare provider not recommended as can perform this independently.
- Provider based treatment of acute LBP not over 4 visits.
- Self-applications may be periodic, and include different regimens. For example, 15-20 minutes, 3-5 times/day.

Recommended, Insufficient Evidence (I)

Manipulation & Mobilization (32 RCTs)

Criteria: Clinical Prediction Rule Definition of Positive

Duration of current LBP	Less than 16 days
Extent of distal symptoms	No symptoms below the knee
FABQ work subscale score	Less than 19 points
Segmental mobility testing	At least one hypomobile segment in the LS Spine
Hip internal rotation range of motion	At least 1 hip with >35 degrees of internal rotation range of motion

†Those patients with a positive Clinical Prediction Rule are considered more likely to respond to manipulation.

Adapted from Childs MJD, et al. Ann Intern Med. 2004;141(12):920-3. W-165-166.

Clinical Prediction Rule versus Oswestry Disability Questionnaire score

(Please see ACOEM Practice Guidelines text for copyrighted Figure that ACOEM received permission to reprint.)

*Lower scores represent less disability.
Childs MJD, et al. *Ann Intern Med.* 2004.

Manipulation and Mobilization

- Acute and subacute LBP: **Manipulation for selective acute LBP patients based on the Clinical Prediction Rule**

Moderately Recommended, Evidence (B)

Manipulation for Acute or Subacute LBP negative for the Clinical Prediction Rule

Recommended, Evidence (C)

- Chronic treatment: no evidence of efficacy
- No evidence for prophylactic treatment

NOT Recommended, Evidence (I)

Manipulation and Mobilization

- Radicular: Nearly all studies excluded clear cases
- Yet, many patients with “leg pain”
- Manipulation is not recommended for the treatment of radicular pain syndromes with neurological deficits.

NOT Recommended, Insufficient Evidence (I)

- No quality studies showing neck adjustments/manipulations effective in LBP treatment
- High velocity rotary cervical spine manipulations previously done had rare, severe complications.

NOT Recommended, Insufficient Evidence (I)

Injection Therapies

Epidural Steroid Injections (12 RCTs)

Epidural glucocorticosteroid injections are an option for second-line treatment for acute flare-ups of spinal stenosis, although the evidence is less robust than it is for herniated discs.

- *Indications* – Symptoms of spinal stenosis of at least 1-2 months (after NSAIDs and progressive exercise).
- *Frequency/Duration* – Evaluate each injection, rather than a series of 3.
- *Indications for Discontinuation* – Resolution of the symptoms of spinal stenosis, or decrease in symptoms to a tolerable level.

Recommended, Insufficient Evidence (I)

Epidural glucocorticosteroid injections are not recommended for acute, subacute, or chronic LBP in the absence of significant radicular symptoms.

NOT Recommended, Evidence (C)

Epidural glucocorticosteroid injections versus placebo, unilateral sciatica of 1-18 months (n=228)

(Please see ACOEM Practice Guidelines text for copyrighted Figure that ACOEM received permission to reprint.)

Arden NK et al. *Rheumatology.* 2005;44:1439-1494.

Score=9.5/11

Traditional Acupuncture Vs. Minimal Ac. Vs. Wait Listed Controls (n=301)

(Please see ACOEM Practice Guidelines text for copyrighted Figure that ACOEM received permission to reprint.)

Brinkhaus B. J. *Alternative Complementary Med.* 2006;12(7):648-57.

Acupuncture (20 RCTs)

- Acute, subacute or radicular LBP: No quality evidence.
- Other treatments are efficacious.

NOT Recommended, Insufficient Evidence (I)

- Chronic LBP: Select use recommended as an adjunct to more efficacious treatments
- Should have clear objective and functional goals to be achieved.
- E.g., adjunct to a conditioning program that has both graded aerobic exercise and strengthening exercises. Acupuncture is an adjunctive treatment. Primary attention should remain on the conditioning program.
- Not recommended for those not involved in a conditioning program, or who are non-compliant with graded increases in activity levels.

Acupuncture

- Treatments have ranged from weekly for a month to 20 appointments over 6 months
- Norm is up to 8-12 sessions. Initial trial of 5-6 appointments would appear reasonable in combination with a conditioning program of aerobic and strengthening exercises. Future appointments should be tied to improvements in objective measures and would justify an additional 6 sessions, for a total of 12.
- Resolution, intolerance or non-compliance, including non-compliance with aerobic and strengthening exercises.

Recommended, Evidence (C)

Hazards of Suboptimal Guidelines

Case Studies in the Criticality of a Robust Methodology: Exercise for LBP

	ACOEM (n=88)	Other (n=37)
Activity	Maintain as active as possible	"Prescribe decreased activity"
Aerobic Exercise	Most important exercises. Detailed guidance	Recommended. Not clear when, what, how much
Stretching	Non-specific does not work Recommend slump-stretch or directional stretching	?Non-specific recommended? Slump stretch not recommended. Directional stretch??

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	ACOEM	Other
Acetaminophen	Not as effective, (but OK to use)	"...acetaminophen is comparable"
Oral corticosteroids	Acute radicular (Recommended, Evidence C)	"Not recommended" ... "do not appear effective"
SSRI anti-depressants	Not recommended	Recommended
Spinal cord stimulators	Not recommended (for LBP)	Recommended
"Disk herniation"	Depends on symptoms	"Initial conservative medical treatment"

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Bed Rest: “A critical review of guidelines for low back treatment”

“With regard to the recommendations, there was consensus for some of the interventions for acute pain (analgesics and NSAIDs, maintaining physical activity, and **avoiding excessive bed rest**), but explicit recommendations were lacking or ambiguous for 41% of the interventions

Eur Spine J. 2006 May;15(5):543-53. Epub 2005 Oct 11

Bed Rest

- Acute Low Back Pain - though bed rest is non-invasive, is costly and associated with high morbidity – **Not Recommended (A)**
- Subacute and chronic LBP – **Moderately Not Recommended (B)**
- Other low back problems – **Not Recommended (I)**
- Stable Spinal Fractures – **Not Recommended (I)**
- Unstable Spinal Fractures – **Recommended (I) ***
- Radicular pain syndromes, including sciatica – **Not Recommended (C)**
- * Hazard of mobilization in this setting theoretically catastrophic

Other Topics

Noise Induced Hearing Loss

- What are the attributable fractions for noise? Age? Tobacco? Cholesterol?
- Are there differences in susceptibility by age? Co-morbid factors?
- Should there be different preventive means for different individuals?
- Should we address non-occupational risks in addition to occupational factors?

Occupational Asthma

- When to remove worker from exposure of concern at work?
- When to allow return to exposure of concern at work? Under what, if any, conditions?
 - Worker wants to RTW
 - Worker does not want to RTW

These challenges will be increasing!

Opioids

- Are they effective for treatment of pain?
 - Acute?? Subacute?? Chronic??
- Are they safe?
 - Acute?? Subacute?? Chronic??
- **Should someone on acute/subacute/chronic/intermittent opioids be allowed in safety sensitive positions???** Other meds? Interactions? Diagnoses?

Opioids. 22 RCTs

- Quality evidence other meds and treatments are superior. **NOT Recommended, Evidence (C) [routine use]**
- Acute, severe LBP: recommended as adjuncts (especially NSAIDs, muscle relaxants, progressive aerobic exercise, and directional exercise).
- Caution in prescribing opioids for those with history(ies) of depression, personality disorder, substance addiction, or abuse, including alcohol, tobacco.
- Generally at night or when not at work and not > 2 weeks.

Recommended, Evidence (C)

- Post-operative rec. adjunct to more effective treatments.
- Post-op. management, brief opioids as adjuncts often required, especially lumbar fusion and other procedures.
- Limit use to 2-3 weeks (or few mos. for major surgeries).

Recommended, Evidence (C)

Re-Learning What we Know

Reprogramming Memory

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- May be even more difficult with repetition of “knowledge” or pseudo-knowledge
 - Teaching colleagues, doctors, nurses, secretaries, medical students, residents
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Possible solution(s)

- CME: produce fertile soil
- **Quality** Guidelines: sow the seed
 - **Re**-review Guidelines: watering
- Integrate in ABPM and other exams
- Develop patient prescriptions patterned after the Guidelines (or other sources of quality EBM)

Re-write our Pseudo-knowledge

- Pick off **1 diagnosis at a time**. Start with “the big one.”
- A priori, assume pseudo-knowledge is prevalent.
- Attitudes: Look forward to a new “Voyage of Discovery.” Encourage others to eagerly seek “new” knowledge
- Slow, careful thoughtful response to queries
- Consult the evidence frequently to verify accuracy

Correct our Scientific Delusions

- Ensure each and every instruction is accurate
- Electronic tools
 - Patient instructions pre-set
 - Modify where needed
 - Benchmarking
 - Total Quality Management/Quality Improvement (including Peer Review)
- ✓ Move the classroom to the clinic

Acute LBP Treatment

1. Progressive walking program. Begin walking 100 feet twice a day and increase the distance walked each day.
2. Change position frequently, avoiding prolonged sitting, standing or lying down
3. Stretch in the direction that reduces the symptoms (not in the direction that increases the symptoms)
4. Heat pad 15-20 minutes, 3-5 times/day
5. Ibuprofen on a regular basis
6. Muscle relaxant at night as needed (e.g., Flexeril)
7. [Opioid PRN at night for severe pain]

Thank You!!