

Evidence : What is it?
How can it result in better care for patients?

Kathryn L. Mueller, MD, MPH, FCOEM
Medical Director,
Colorado Division of Workers' Compensation
Professor, School of Medicine and School of Public Health
University of Colorado

Topics

- ❖ What is evidence?
- ❖ Why does evidence differ between guidelines?
- ❖ What is the evidence for spinal injections?
- * How can evidence affect patient care and costs in WC?



Guidelines....
Why Bother?



The Art of Medicine

- * Know the science
- * Establish the correct diagnosis
- * Understand your patient's needs – cultural and educational background, health care expectations, and personal goals
- * Establish a treatment plan that the patient is committed to and will increase function.



DIVERSITY IN MEDICAL CARE LEADS TO DISASTER!!



Health status - Back and Neck Expenditures

- * Medical Expenditure Panel Survey 1997-2005, age and sex adjusted
- * Increased \$4695 to \$6096
- * Non-spine medical increased \$2731-\$3516
- * # with self-reported physical functioning increased 20.7-24.7%
- * Mental health and work, school or social limitation also increased

Martin BI, JAMA 2008 Feb 13

Low Back Pain Management 1999-00 – 2009-10

- * Several trends in opposition to guidelines
- * NSAIDs or acetaminophen down compared to opioids – increased 19.3-29.1%
- * CT/MRI increased 7.2-11.3%
- * MD referrals increased 6.8-14%
- * No change PT – 20% , x rays 17%

Mafi, JN, JAMA Intern Med, Jul 29, 2013

Workers Comp is different!!!

- * Historically the majority of most premium costs are disability
- * Providers are in charge of ordering and determining return to work/function
- * A philosophy of return to function is essential to management of claims and patient recovery
- * Most physicians are not trained to focus on functional recovery – they focus on curing disease

Guideline Types and History

- * Oriented toward Practice and Treatment
- * Utilization review type
- * In General Health Utilization Review alone has not controlled costs
- * Good practice obviates the need for number only control in most cases



Why did Colorado and ACOEM choose primarily practice guidelines?

- * Most cases “go wrong” early
- * Colorado saw “medicalization” of many cases
- * Many problems with vague or inaccurate diagnoses continue to be treated
- * Emphasizing disability management, accurate diagnosis, and conservative care for most musculoskeletal injuries, has controlled cost in Colorado
- * ACOEM Guidelines emphasize accurate diagnosis, return to function, and active patient involvement in recovery

Overall Practice Patterns Matter

- * Most guidelines follow internationally accepted recommendations for care
- * Ours differ by adding more information on achieving functional recovery and covering more topics
- * Guidelines must teach disability management – *return to function*



What should guidelines accomplish?

- * Provide high- quality, scientifically – based medical care
- * Improve the quality of the outcome by assuring an increase in patient function and return to work
- * Decrease the unnecessary expense of utilization review

Utilization Review

- * Without guidelines each insurance company may set its own levels of approved care
- * Utilization review is frequently performed for issues that clearly meet any evidence standards and thus result in
 - * Less timely care for patients
 - * Uncompensated time for providers
 - * Increased litigation over the legal concept of reasonable and necessary.



Recommended state regulations

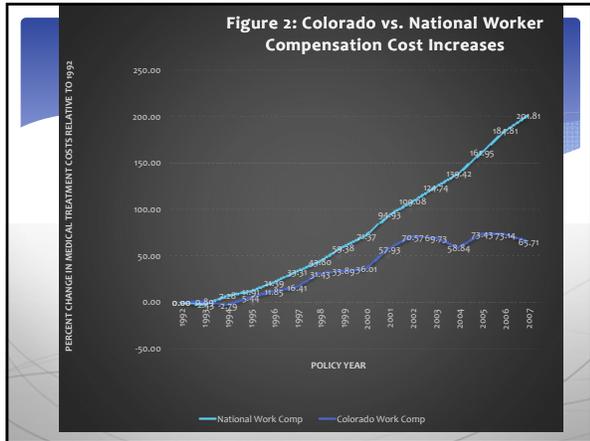
- * When Care is within guidelines **it must be covered**
- * Utilization review should **not** be done for these cases
- * For care outside of the guidelines, physician review would be necessary to determine coverage
- * Some mechanism for penalties must be available for insurers who are not covering treatment in the guidelines.



Low Back Employer Program tracking costs and guidelines

- * Navistar – 14,787 low back claims
- * Rated compliance with various guidelines including early MRIs early surgery chiropractic treatment
- * Both Medical costs and Indirect costs – disability and lost time
- * Results showed adherence to guidelines significantly decreased total costs when guidelines were adhered to
- * Allen, H JOEM 2014 (10)



Quality Improvement & P4P

- * Physicians should practice in a uniform manner nationally consistent with evidence-based medicine
- * NCQA criteria, e.g. low back
- * Other evidence of compliance with nationally accepted evidence-based medical guideline
- * Electronic records with ability to follow quality criteria and transmit to multiple systems
- * Care by quality physicians should automatically be paid for – Washington state

Focusing purely on E&M code requirements may be counterproductive

Guideline Quality and Methodology

How to evaluate guidelines

Why do recommendations differ between guidelines?

- * Evidence based
 - * System used to rate articles
 - * Read the actual definitions of each category. Do they follow generally accepted definitions?
 - * Consistency with which articles are graded
 - * Check accompanying tables. How often are categories listed as not applicable or do they appear to be incorrectly rated?
 - * Critical Review of statistics
 - * Is there an epidemiologist, statistician, or MPH involved with evaluation?

Quality Analysis of Evidence

- * Design bias
 - * Blinding
 - * Biological plausibility of intervention
 - * Comparison groups
 - * Outcomes measured
 - * Number in trial, arms of trial or cohort
 - * Statistical significance of results
 - * Clinical significance of results
 - * Association v. causation
 - * Criteria used in systematic reviews



Why do recommendations differ between guidelines?

- * Consensus – based
 - * Group not controlled by issuing organization
 - * Multi-disciplinary group without industry alliances and balanced for practice type
 - * Face – face meetings may be preferable
- * Values
 - * Long term outcome versus short
 - * Function versus pain
 - * Risk of side effects/ morbidity versus mortality
 - * Cost

Can evidence direct us? How to assess the quality of studies



Levels of Evidence

- * Meta-analysis
- * Randomized, controlled trials
 - * Comparison to placebo or no therapy
- * Prospective cohort studies
- * Retrospective cohort studies
- * Observational
- * Case-control studies
- Case series reports



Importance of Randomized Controlled Trials

- Class 1 Recommendations from American College Cardiology & American Heart Association Clinical Practice Guideline
- 619 Recommendations 80% 495 down graded.
- Likelihood of being down graded due to lack of RCT based on opinion rating (odds ratio, 3.14, 95% CI 1.69-5.85, $P < .001$).
- Based on observational studies 3.49 CI, 1.45-8.41; $P = .005$).

Guideline Recommendations & Inclusion of Medical Evidence

- ❖ **“Some evidence”** – at least one adequate scientific study.
- ❖ **“Good evidence”** – multiple adequate scientific studies or relevant high-quality scientific.
- ❖ **“Strong evidence”** – multiple relevant and high-quality scientific studies.
- ❖ **Consensus** – judgement of experienced professionals

Likelihood of Change with New Research

- * **Strong evidence** – very low likelihood
- * **Moderate evidence** – possible
- * **Low level evidence** – probable
- * **Consensus** – most likely

Common Evidence –based systems

- * **Cochrane** – reviews – lack professional review
- * **American Academy of Orthopedic Surgery**
- * **British Medical Journal / Clinical Evidence**
- * **NICE**
- * **National Guideline Clearinghouse** – has become stricter than previously but you will find conflicting info



Case #1

A 58 year old male otherwise healthy who supervises a construction crew. Over the last month he has increasing back pain as they have been operating short handed and he has been working directly on construction of a site. While bending over at work to repair some scaffolding he suddenly experienced a severe increase in pain with radiation down the left leg and numbness. Past history of occasional left sided back pain.

Case #1

P.E.
*General – in moderate discomfort from pain unable to flex more than 30° without severe pain.
Left SLR - + with radiation into the lateral foot at 58°.
Right SLR - + with the same findings.
Sensation – decreased lateral calf and foot.*

Case #1

Reflexes – 0/4 left ankle 2/4 right ankle

Motor

- 2/5 left planter and 5/5 right planter flexion
- Rest of lower & upper extremity 5/5 except left knee flexion 4/5.

Questions

1. Are any imaging tests needed?
2. What should initial treatment be?
3. When should injections be considered?



Overview of Care – Low Back Pain Neurological

- * Seventy percent of patients with radicular pain and non-surgical treatment are likely to have marked reduction in pain at 4 weeks with a 60% return to work.
- * After 8 months, over 90% would be expected to have an excellent outcome and return to work.
- * 20% will have a recurrence of symptoms (Casey, 2011).

The Clinical Course of Low Back Pain: A Meta-Analysis Comparing Outcomes in Randomized Clinical Trials (RCTs) & Observation Studies - Artus et al, BMC Musculoskeletal Disorders 2014

Methods:

70 RCTs and 19 cohort studies;

- LBP symptoms had followed similar course in RCTs and cohort studies: a rapid improvement in the first 6 weeks;

Results:

- No statistically significant difference in pooled SMC between RCTs and cohort studies at any point 6 weeks to RCTs.

Imaging MRI

- * Recommended in 1st 6 weeks if progressive neurological deficit, cauda equina, atypical representation, significant trauma, possible neoplasm - Recommended - (I)
- * Not recommended for radicular presentation in 1st 6 weeks unless surgery or injections planned - Evidence C
- * An option for chronic pain after 3 months of conservative treatment- Recommended (I)

Imaging

- *How can you use the evidence info to talk with your patient?
- *An emphasis on testing only to determine a treatment change



Injections – Diagnostic Epidural Steroid Injections (ESIs)



- * **Strong evidence** epidural steroid injections have a **small average short term benefit** for leg pain and disability for those with sciatica (Pinto, 2012).
- * **Good evidence** the addition of steroids to a transforaminal bupivacaine injection has a **small effect** on patient reported pain and disability (Ng, 2005; Tafazal, 2009).

Epidural Corticosteroid Injections for Radiculopathy & Spinal Stenosis

Date Synthesis

- 30 placebo-controlled trials epidural injections for radiculopathy, and 8 trials for spinal stenosis;
- Epidural associated with greater immediate-term reduction in pain (scale of 0 to 100, -7.55 [95% CI, -11.4 to -3.74];
- Function (standardized mean difference, -0.33[CI, -0.56 to -0.09]; SOE low

Epidural Corticosteroid Injections for Radiculopathy & Spinal Stenosis

- Short-term surgery risk (relative risk, 0.63 [CI, 0.41 to 0.92]; SOE low).
- Effects were below predefined minimum clinically important difference thresholds, and no longer-term benefits.
- No clear effects of epidural for spinal stenosis.

Reference: Roger Chou, MD, Annals of Internal Medicine 2015

ACOEM INJECTION THERAPY

- *An epidural glucocorticosteroid injection is recommended as an option for treatment of acute or subacute radicular pain syndrome. Its purpose is to provide a few weeks of partial pain relief while awaiting spontaneous improvement.*
- *Recommended (I)*



Awareness of Lack of Effectiveness of Spinal Injections

- * Multiple evidence based guidelines find no evidence for long term benefits of spinal injections
- * Cochrane, British Medical Journal, ACOEM, Academy of Neurology,
- * JAMA editorial recommends against
- * New York Times Sunday magazine recommends against use

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Injections – Diagnostic Epidural Steroid Injections (ESIs) Eval



- * Epidural injections
- * Multi-planar fluoroscopic imaging is required
- * All injections should be preceded by an MRI or a CT scan.
- * Indications
 - * Patient with radicular findings due to herniated disc, meets all of the indications for surgery at approximately 6-8 weeks post active therapy, one epidural may be attempted at the patient's discretion.

Injections – Diagnostic Epidural Steroid Injections (ESIs) Eval

- * For rare, acute ruptured (herniated) disc with clear objective radiculopathy if, after one to two weeks of initial oral analgesic and conservative treatment, the patient:
 - * Has continued pain interfering with most ADL function; and
 - * Unable to tolerate the required movements to participate in therapy, and
 - * Pain greater in the leg than in the back, and
 - * Pain following a correlated radicular pattern



Colorado Rule 18

* 18-6 G (6) Pre and Post Functional Assessments

- * Qualified evaluators include nurses, physician assistants, medical assistants, therapists, or non-injectionist physicians.

Preferably done later by non-injectionist personnel, but it *can be* by the injectionist.

Rule 18

Three elements required:

- A brief commentary on the procedure
- At least 3 objective, diagnostically appropriate, functional measures identified, measured and documented
- There shall be a trained physician or trained non-physician health care professional detailed report with a pre- and post-procedure pain diagram

Overview of Care - Spinal injections

- * Are unlikely to provide long-term relief for sacroiliac joint, facet conditions, or stenosis. They should not be done without prior imaging. 
- * Both the specialist referred to and the authorized provider must discuss and document the possible complications.

ACOEM OPIOIDS

- Acute Pain (Up to 4 Weeks) Routine use of opioids for treatment of Non-Severe Acute Pain
 - *Strength of Evidence - Strongly Not Recommended, Evidence (A)*

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ACOEM OPIOIDS

- Dispense only that which is required. The maximum daily oral dose recommended for opioid-naïve, acute pain patients based on risk of overdose/death is 50mg morphine equivalent dose (MED) 
- *Strength of Evidence - Recommended, Evidence (C)*

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Answers

1. No initial imaging unless red flags or need for injection.
2. NSAID's, opioids limited to 3-7 days initially, muscle relaxants, PT, oral steroids only after shared decision making.
3. Initial activity – walking as much as possible limiting sitting, no bending at waist or lifting.
4. Injections optional



Question

When should surgery be considered?



Therapeutic Procedures Operative - Discectomy



* **Good evidence** after 6 weeks of active therapy those patients with persistent radicular leg pain and an image-confirmed disc herniation have better functional outcomes than non-operative patients. More likely within the first 2-3 months. Non-operative groups also improved significantly over 2 years (Weinstein, 2006, Chou, 2009).

Guidelines

- * Proven to result in better outcomes in patients
- * Proven to decrease medical and disability costs
- * In the correct environment they can result in less utilization review and litigation thus decreasing delays in care



QUESTIONS ????

Orthopedist recommendation

- * Grade 1 spondylolisthesis is noted at L3/L4 however the orthopedist believes the pain generator is the L4/L5 disc based on discogram results
- * The discogram is positive for L4/5 pain.
- * The orthopedist is recommending a fusion at L3/L4 and L4/L5
- * What else should be considered in this case?

What do guidelines say?

- * All guidelines recommend some type of yellow flag screening.
- * Most guidelines recommend a psychological evaluation prior to non-instability surgery.
- * Several guidelines, including ACOEM, do not allow surgery for discogenic pain
- * Colorado does but requires a psychological evaluation – not merely a screening test.

Provocation Discography



- * *Discography is accepted but rarely indicated*
- * *Discograms have a significant false positive rate. It is essential that all indications, pre-conditions, special considerations, procedures, reporting requirements and results are carefully and specifically followed.*

Provocation Discography

- * **Indications**
 - * *History of functionally limiting, unremitting low back pain of greater than four months duration, with or without leg pain, unresponsive to all conservative interventions and meets all of the criteria for spinal fusion.*

Provocation Discography

- * Patients with mild back pain, 3 points or less on a 10 point VAS measurement should not be considered for invasive treatment.
- * Good evidence a positive discogram does not predict positive results from a fusion to the extent that documented spondylolisthesis does (27% success rate compared to 72% success rate), (Carragee, 2006).

Provocation Discography

- * Psychosocial evaluation has been completed.
- * Some evidence discography in patients with somatoform disorders is likely to create a risk of development of persistent low back pain in the year following the procedure (Carragee, 2000).
- * Informed decision making should always be documented. Discography should never be the sole indication for surgery.

Provocation Discography

- * Positive -minimum criteria
 - * Stimulation of the target disc reproduces concordant pain; and
 - * Pain is registered as at least 7 to 10-point VAS, and has increased significantly from the baseline value; and
 - * Pain is reproduced at a pressure of less than 50 psi above opening pressure; and
 - * Stimulation of at least on adjacent disc does not produce pain at all.

How would you discuss these with the patient?

- * Options for surgery
- * Need for psychological review
- * Personal Goals

Surgery

- * Guidelines differ on this because there is not good science supporting treatment for discogenic pain and fusion surgery does have a risk associated with it
- * Review likely time off work for recovery
- * Review necessary physical therapy post op.
- *

Follow up visit – Patient questions

- * She feels that the psychological evaluation was very helpful as they suggested several techniques for coping with pain and that has allowed her to progress further in her exercise routine. No impediments for surgery were identified.
- * Her employer is willing to work with her doing recovery and provide some less strenuous employment for that period
- * She has read about the disc replacement and wonders about this instead.

What are requirements for disc replacement?

- * In general instability can be a contraindication
- * Probably better for younger patients
- * Requires an abdominal and spine procedure.
- * Frequently these eventually become fused
- * Main advantage is decreased recovery time and increased spine motion.



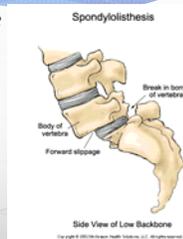
Therapeutic Procedures Operative

- * Good evidence decompression and fusion with or without instrumentation of lumbar stenosis with degenerative spondylolisthesis leads to better 2 year outcomes for patients whose symptoms are severe.
- * Patients who choose non-operative treatment can also expect their symptoms to improve non-surgical treatment, and non-operative treatment, (Weinstein, 2007).



Therapeutic Procedures Operative

- * Some evidence fusion is likely to have a higher beneficial effect compared to multidisciplinary rehabilitation for patients with isthmic spondylolisthesis, as differentiated from those without the condition who suffered from chronic low back pain (Wood, 2011).



Therapeutic Procedures Operative - Fusion



- * *Good evidence intensive exercise for approximately 26 hours per week for four weeks combined with cognitive interventions emphasizing the benefits of maintaining usual activity, produces functional results similar to those of posterolateral fusion in patients with chronic non-radicular back pain and no stenosis or instability after one year (Brox, 2003).*

Therapeutic Procedures Operative



- * *Some evidence lumbar fusion produces better symptomatic and functional results in patients with chronic non-radicular pain when several months of conservative treatment have not produced a satisfactory outcome (Fritzell, 2001; Chou, 2009).*
- * *Some evidence that morbid obesity increases hospital length of stay, mortality, and postoperative complications after spinal fusion surgery, with concomitant increases in hospital costs (Kalanithi, 2012).*

Therapeutic Procedures Operative

- * **Pre-operative Surgical Indications:**
 - * *All pain generators adequately defined and treated; and*
 - * *All physical medicine and manual therapy interventions are completed; and*
 - * *X-ray, MRI, or CT myelography demonstrate spinal stenosis with instability or disc pathology, requiring decompression that may surgically induce segmental instability or a positive discogram; and*

Therapeutic Procedures
Operative

- * Spine pathology is limited to two levels; and
- * Psychosocial evaluation with confounding issues addressed; and
- * Injured worker refrains from smoking for at least six weeks prior to surgery.



Long-term follow-up of spinal fusion vs conservative care

- * 92% follow-up rate of 294 patients
- * 12.8 years of follow up (range 9-22)
- * Results reported here based on “as-treated”
- * No significant difference for VAS back or leg, Oswestry disability index, or pain frequency
- * Global assessment of outcome significantly worse due to 53% vs 18% reporting “unchanged”
- * Work status identical – 61% not working (Sweden)
- * Non-significant increase in pain medication use among fusion patients – 46%/33%

* Hedlund, Spine Journal 16 (2016)
