Guidelines as Living Documents

Montana State Fund 18th Annual Medical Conference

June 1, 2018

Disclosures

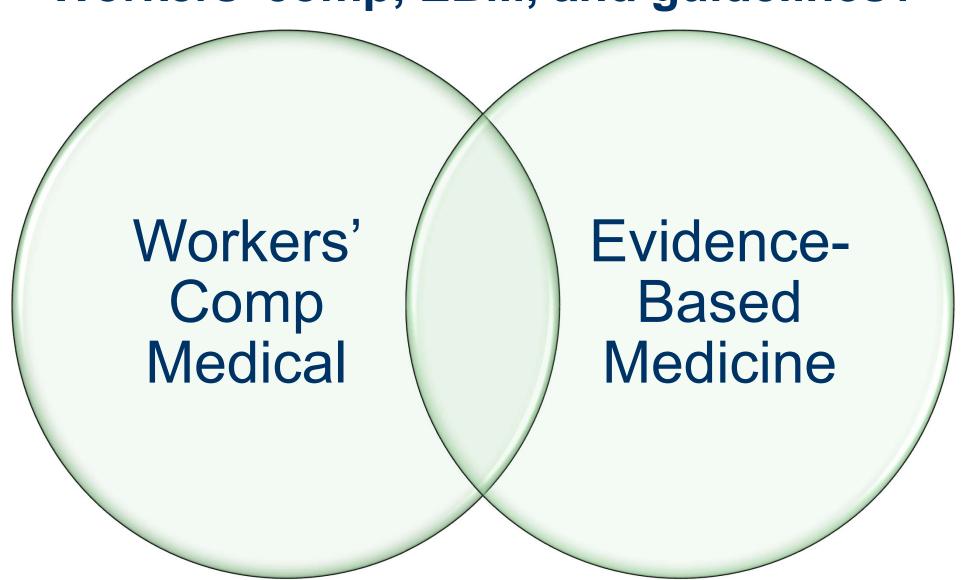
- Stephen Norwood, MD Austin, TX
- Editor-in-chief Official Disability Guidelines
- ODG is the most widely used worker's comp guideline in the world
- Acquired by MCG/Hearst Health Network
 January 2017—guidelines for over 200M lives
- Never any personal financial ownership; only paid to write, edit, and advise policy





- WC is the only area of medicine where health encounters aren't completely scripted
 - In group health, insurance companies set health policy
 - Because of the "grand bargain", workers' comp payers cannot set their own health policy
 - Also no copayments, deductibles, coinsurance
 - Result is both excessive utilization, and too much UR
- Solution: Regulators set health policy at the state level using evidence-based treatment guidelines

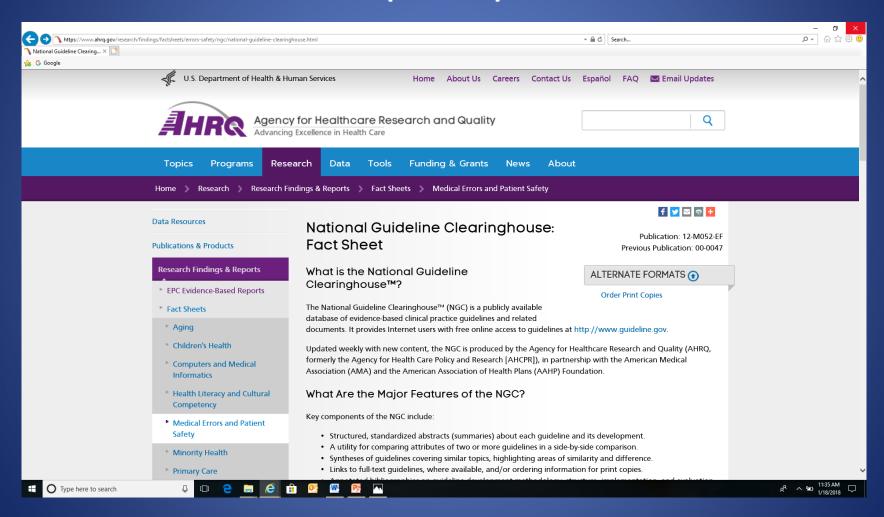
What is the relationship between Workers' comp, EBM, and guidelines?



Evidence-Based Medicine

- EBM is "healthcare based on clinical studies of what works best and what does not"
 - Systematic reviews, meta-analyses, RCT's, cohort studies trump others
 - Requires (1) transparent literature review (2) evidence-ranking
 - EBM does not vary from state-to-state
- EBM is not healthcare based on opinion, consensus, personal observation, or tradition
- 3 guidelines types: evidence- based, consensus- based, hybrid
 - Not interchangeable; not all created equal
 - Device lobby and special interests perpetually push (\$\$\$) for state and specialty specific guidelines, influencing the process by stealth from EBM towards consensus

National Guideline Clearinghouse (NGC)



National Guidelines Clearinghouse

- Most major EBM guidelines for worker's comp do not or no longer participate in NGC
- Free online access—sounds great but get what you pay for
- Guidelines must have been reviewed or revised within the past 5 years
- Must initially submit most current version, but AHRQ has not been equipped to keep up with continual updates of individual guidelines
- Unfortunately, routine use simply does not meet most jurisdictional requirements to remain current
- Content is simply summarized and abbreviated, often without source reference links

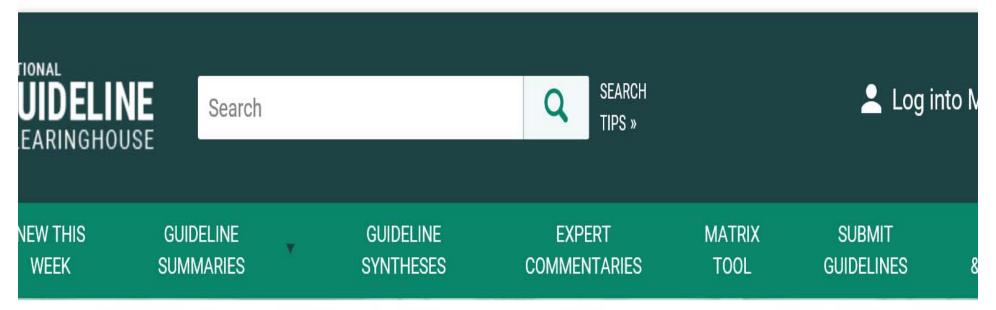
National Guideline Clearinghouse

- NGC was never intended to be an indicator of trustworthy guidelines, nor have they claimed such. NGC inclusion has recently become a marketing message touted by some guideline vendors.
- Under previous ownership, ODG was submitted and accepted for inclusion in NGC for over a decade. With altered inclusion criteria, there were several problems including providing newly required evidence-tables for NGC, since they were proprietary and over 10,000 pages.
- NGC has never been part of any strategic direction for MCG because few if any of the 15k NGC entries are used for care decisions by paying customers – health plans, governments, or hospitals.

National Guidelines Clearinghouse (NGC)

- 1,486 Guideline Summaries—many international and obscure
- Includes comp related specialty societies (American): Family practice (4), Orthopaedics (17), PM&R (2), Neurosurgery (39), General Surgery (1), Radiology (166), Pain (2), OT (9), PT (6), Podiatry (1), Psychiatry (3), Anesthesiology (8), Spine (4)
- Incomplete Colorado DWC (4) Lower extremity, Shoulder, Cervical Spine, and Low back MTGs
- Washington State L&I (8) Conservative care for epicondylosis and shoulder; cauda equina syndrome, carpal tunnel syndrome, opioid prescription
- ACOEM (only 2) Cervical and thoracic spine, Low back disorders





TAKE NOTICE: This Web site, AHRQ's National Guideline Clearinghouse, will not be available after July 16, 2018.

eral funding through AHRQ will no longer be available to support the NGC as of that date. For additional information, read our table announcement.

continue to post summaries of new and updated evidence-based clinical practice guidelines until July 2, 2018. For any ques

Institute of Medicine Study

- NAM/IOM publication *Clinical Practice Guidelines We Can Trust* raised very serious concerns regarding the use of specialty guidelines.
- "The authors concluded that despite evidence of moderate progress, the quality of practice guidelines developed by specialty societies remained unsatisfactory (Grilli et al., 2000)" (pg. 64).
- "The authors concluded that differences in group composition may lead to contrasting recommendations; more specifically, members of a clinical specialty are more likely to promote interventions in which their specialty plays a part" (pg. 84).
- Clinical Practice Guidelines We Can Trust. Institute of Medicine (US) Committee on Standards for Developing Trustworthy Clinical Practice Guidelines; Editors: Robin Graham, Michelle Mancher, Dianne Miller Wolman, Sheldon Greenfield, and Earl Steinberg. Washington (DC): National Academies Press (US); 2011. ISBN-13: 978-0-309-16422-1.

EBM as a Regulatory Tool

• Treatment guidelines <u>must</u> serve *DUAL MANDATE*

Safeguard and expedite access to quality care



Limit excessive or inappropriate utilization

If treatment guidelines are like speed limits then...



SPEED LIMIT 75

SPEED LIMIT 200 SPEED LIMIT 20



SPEED LIMIT 60



SPEED LIMIT



SPEED LIMIT 35



SPEED LIMIT

SPEED LIMIT 70



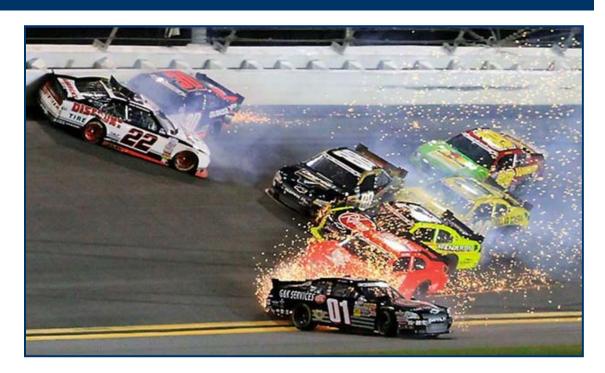
Set them too low...



Guidelines that are too restrictive cause unnecessary delays, disputes, denials, and friction, preventing workers from getting needed medical care, driving good doctors out of the system.



Set them too high...



Bad guidelines are worse than having no guidelines. If you set speed limits at 150-200 mph, there will be a lot of road kill.



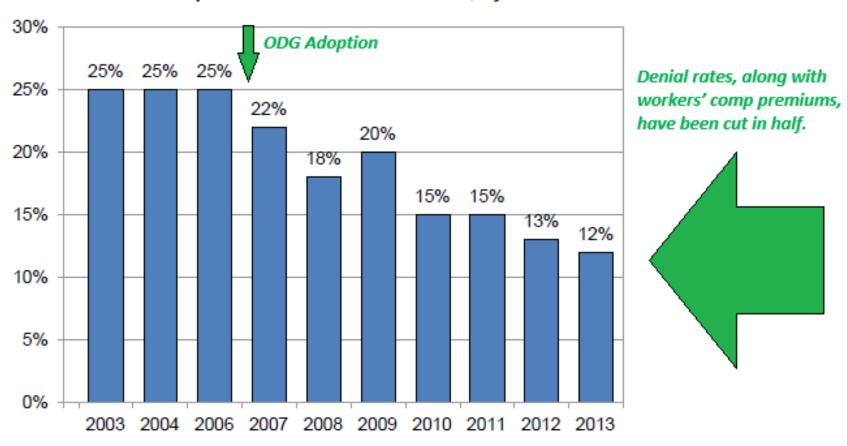
Set them just right...



Guidelines should use UR judiciously, auto-approving care while limiting excessive/inappropriate utilization. Expertise in guideline development/delivery always comes with a track record.

TDI Medical Denial Rates post-ODG

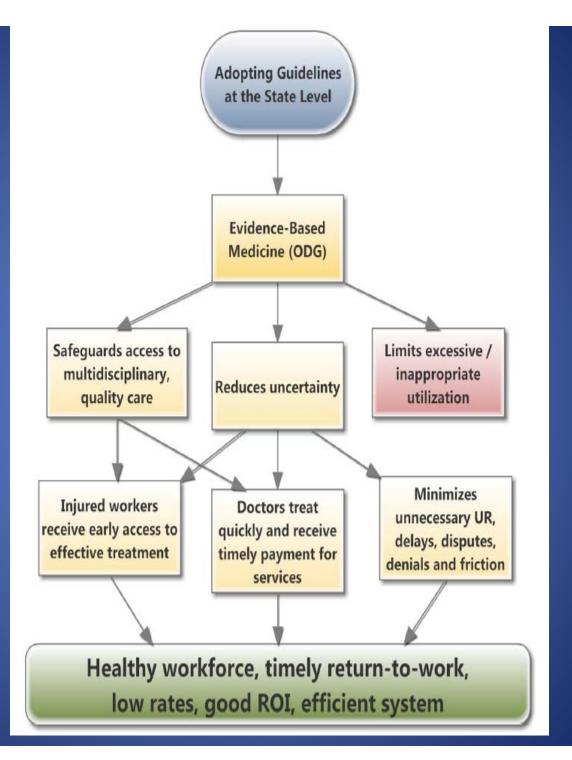
Figure 5.11: Percentage of Professional Medical Services Denied for the Top 25 Workers' Compensation Insurance Carriers, by Service Year



Note: Denial rates for 2005 were excluded due to missing data. Source: Texas Department of Insurance, Workers' Compensation Research and Evaluation Group, 2014.

Choice is

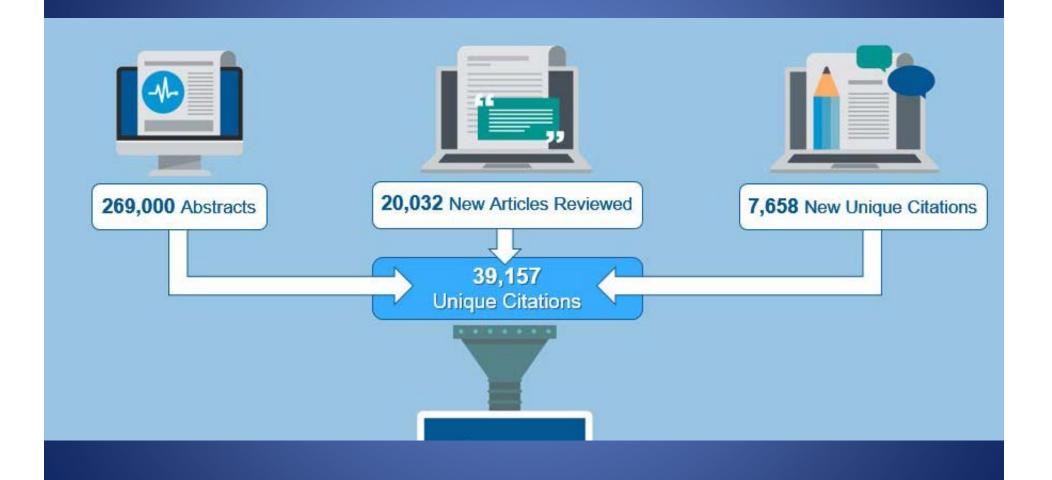




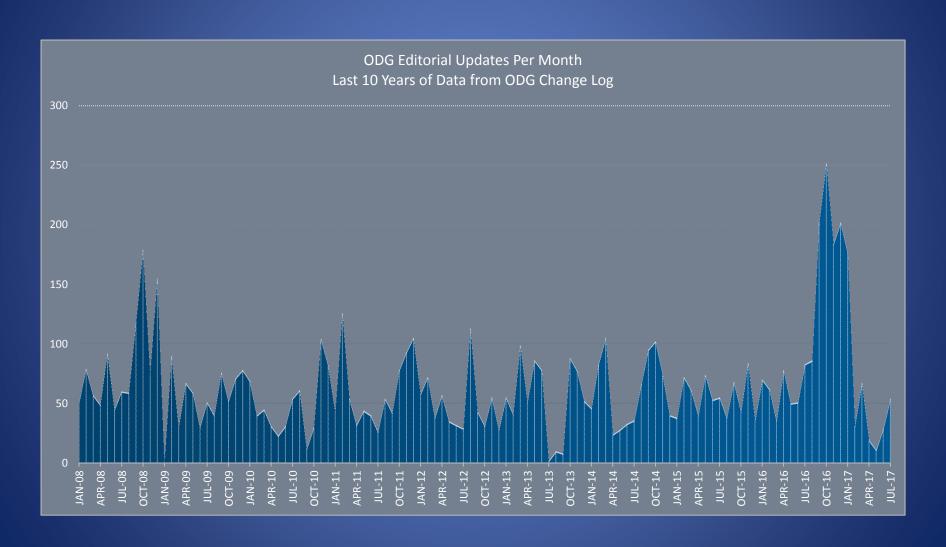
Living, breathing guidelines

- So how are guidelines kept up to date, using the latest and highest quality medical evidence?
- It starts with a quality team of physicians, pharmacologists, statisticians, data processors, among many others.
- Advisory support from a broad-base of experienced clinical clinicians representing multiple specialties is critical for recommending new updates and to review summaries before publishing.

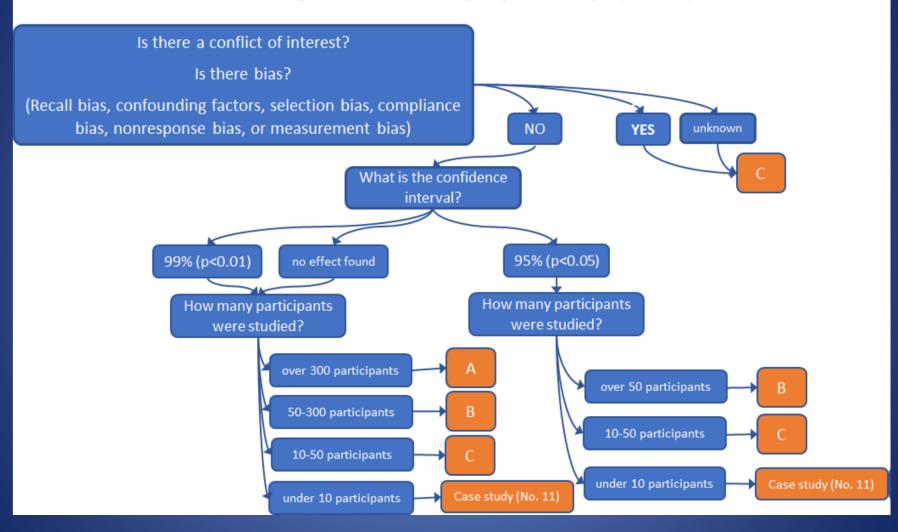
Guideline Summary Research



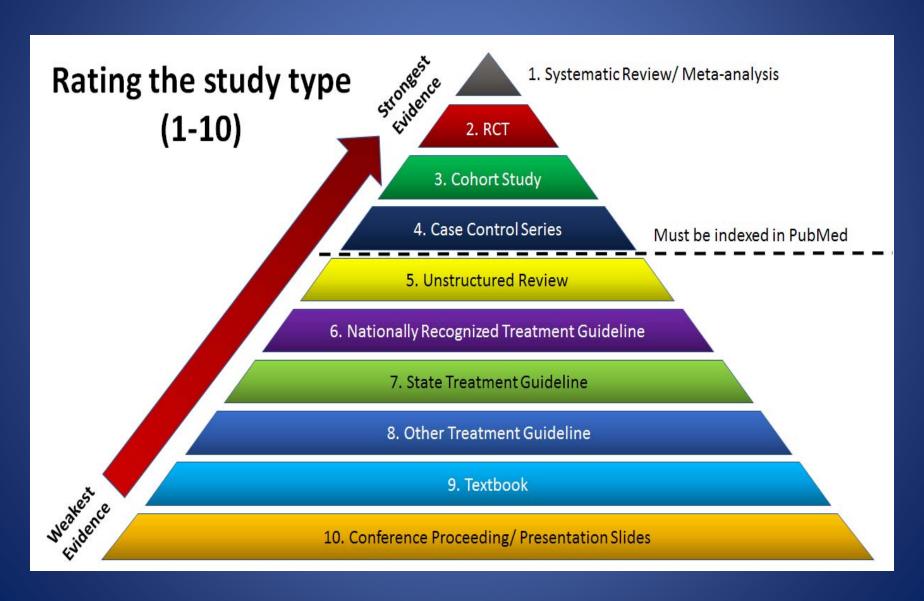
Never ending updates



Rating the study quality (A-C)



a) High b) Medium c) Low Quality



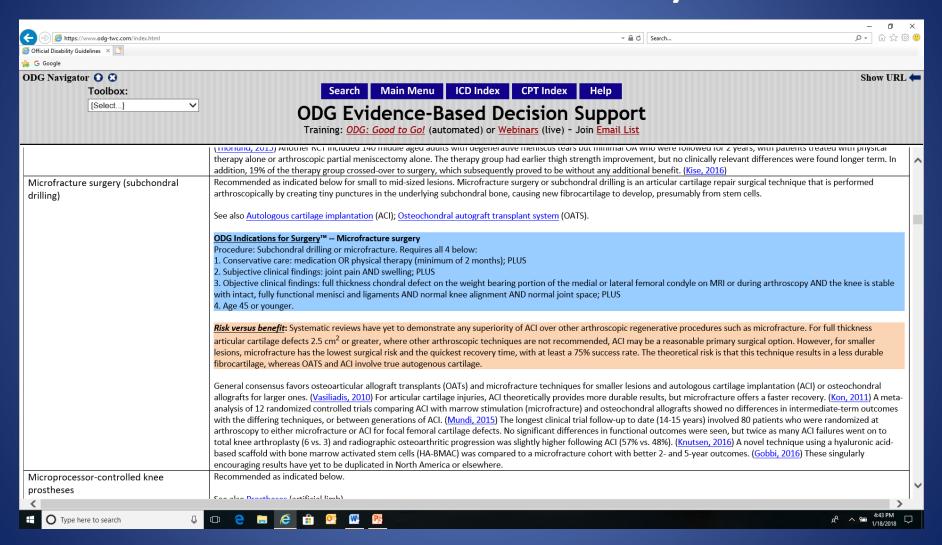
Best studies available

- Searching beyond RCTs is quite important since the biggest problem with EBM is that there are never enough quality studies. Many treatments have only lower-level evidence. Systematic reviews and meta-analyses of RCTs are the gold standard, but often do not exist for many routine, low-cost treatments, or for invasive therapies where having a control group is not practical or ethical.
- Guidelines that use only RCTs frequently uncover limited results, so many are forced to conclude "Insufficient Evidence". Then users are forced to resort to a consensus of authors, who naturally recommend procedures they are most familiar and comfortable with. "Confirmation bias," is the tendency to interpret information to confirm preexisting beliefs, and is the "fatal flaw" of specialty societies guidelines.

Guideline Anatomy

- A. Recommendation Type
- R (Rec), CR, NR (Not Rec), US
- B. Recommendation Statement
- C. See also (related topics)
- D. ODG Criteria
- Patient selection, number of visits
- E. Clinical Evidence Summary
- F. Links into the References/Studies

Guideline anatomy



Search for additional conditions

Knee and Leg Microtracture surgery (subchondral drilling) x

Junation Treatment

Treatment Treatment Treatment

Microfracture surgery (subchondral drilling)

Body system: Knee and Leg Treatment type: Surgery

Related Topics: See also Autologous cartilage implantation (ACI), Osteochondral autograft transplant system (OATS).

Conditionally Recommended

Recommended as indicated below for small to mid-sized lesions. Microfracture surgery or subchondral drilling is an articular cartilage repair surgical technique that is performed arthroscopically by creating tiny punctures in the underlying subchondral bone, causing new fibrocartilage to develop, presumably from stem cells.

ODG Criteria

ODG Indications for Surgery™ -- Microfracture surgery

Procedure: Subchondral drilling or microfracture. Requires all 4 below:

- 1. Conservative care: medication OR physical therapy (minimum of 2 months); PLUS
- 2. Subjective clinical findings: joint pain AND swelling; PLUS
- 3. Objective clinical findings; full thickness chondral defect on the weight bearing portion of the medial or lateral femoral condyle on MRI or during arthroscopy AND the knee is stable with intact, fully functional menisci and ligaments AND normal knee alignment AND normal joint space; PLUS
- 4. Age 45 or younger.

Risk vs. Benefit

Systematic reviews have yet to demonstrate any superiority of ACI over other arthroscopic regenerative procedures such as microfracture. For full thickness articular cartilage defects 2.5 cm² or greater, where other arthroscopic techniques are not recommended, ACI may be a reasonable primary surgical option. However, for smaller lesions, microfracture has the lowest surgical risk and the quickest recovery time, with at least a 75% success rate. The theoretical risk is that this technique results in a less durable fibrocartilage, whereas OATS and ACI involve true autogenous cartilage.

Evidence Summary

General consensus favors osteoarticular allograft transplants (OATs) and microfracture techniques for smaller lesions and autologous cartilage implantation (ACI) or osteochondral allografts for larger ones. (Vasiliadis, 2010) For articular cartilage injuries, ACI theoretically provides more durable results, but microfracture offers a faster recovery. (Kon, 2011) A meta-analysis of 12 randomized controlled trials comparing ACI with marrow stimulation (microfracture) and osteochondral allografts showed no differences in intermediate-term outcomes with the differing techniques, or between generations of ACI. (Mundi, 2015) The longest clinical trial follow-up to date (14-15 years) involved 80 patients who were randomized at anthroscopy to either microfracture or ACI for focal femoral cartilage defects. No significant differences in functional outcomes were seen, but twice as many ACI failures went on to total knee arthroplasty (6 vs. 3) and radiographic osteoarthritic progression was slightly higher following ACI (57% vs. 48%). (Knutsen, 2016) A novel technique using a hyaluronic acid-based scaffold with bone marrow activated stem cells (HA-BMAC) was compared to a microfracture cohort with better 2- and 5-year outcomes. (Gobbi, 2016) These singularly encouraging results have yet to be duplicated in North America or elsewhere.

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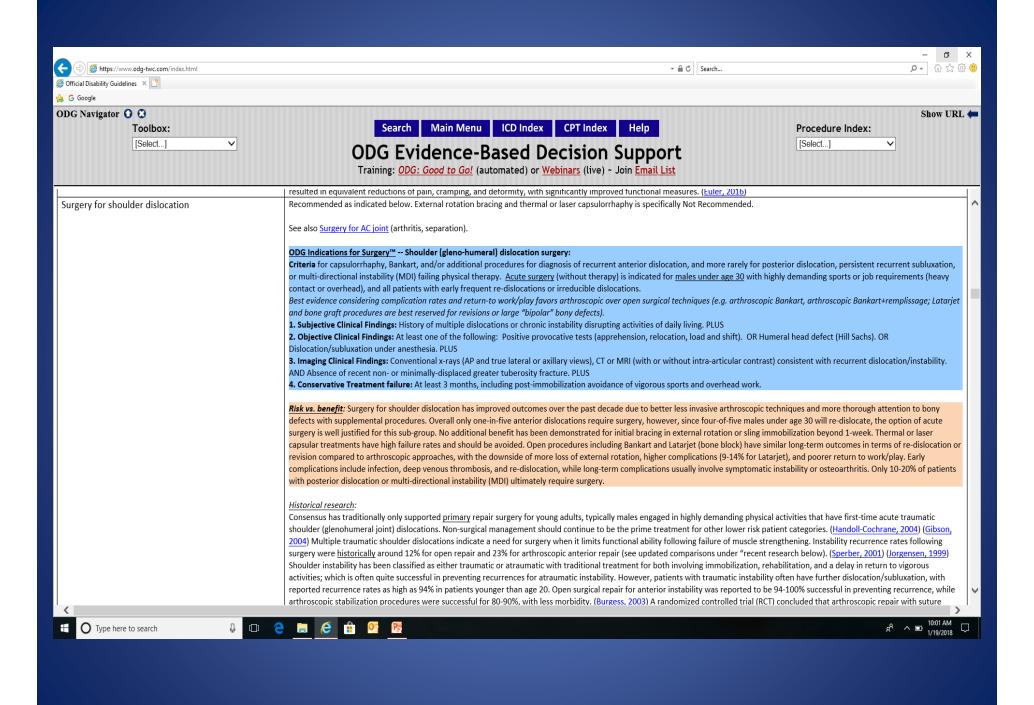
Evidence is the backbone

2 problems with EBM

- Not enough good research
- Very manual, labor intensive

Implementation should not burden healthcare delivery

Increasing expectations that guidelines be up to date



Exceptions to guidelines

- Appendix D—Documenting Exceptions to the Guidelines
- 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."

Yes, guidelines get grades

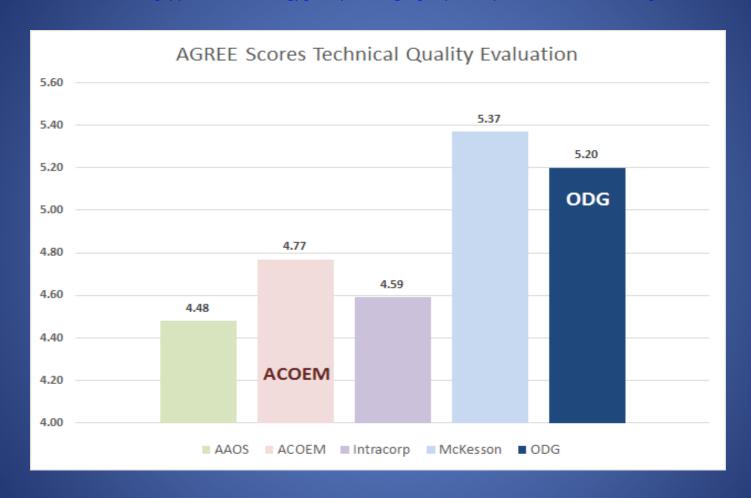
Evaluating Medical Treatment Guideline Sets for Injured Workers in California

Table S.2
Technical Quality Evaluation—AGREE Instrument Results
(Standardized Domain Scores)

Domain	AAOS	ACOEM	Intracorp	McKesson	ODG
Scope and purpose	1.00	0.89	0.89	1.00	1.00
Stakeholder involvement	0.54	0.79	0.79	0.88	0.79
Rigor of development	0.81	0.88	0.83	0.88	0.81
Clarity and presentation	0.96	0.88	1.00	1.00	0.96
Applicability	0.17	0.33	0.33	0.61	0.72
Editorial independence	1.00	1.00	0.75	1.00	0.92

Nuckols TK et al. Evaluating Medical Treatment Guideline Sets for Injured Workers in California. Published 2005 by the RAND Corporation, 1776 Main Street, P.O. Box 2138, Santa Monica, CA 90407-2138. Table 5.2, page

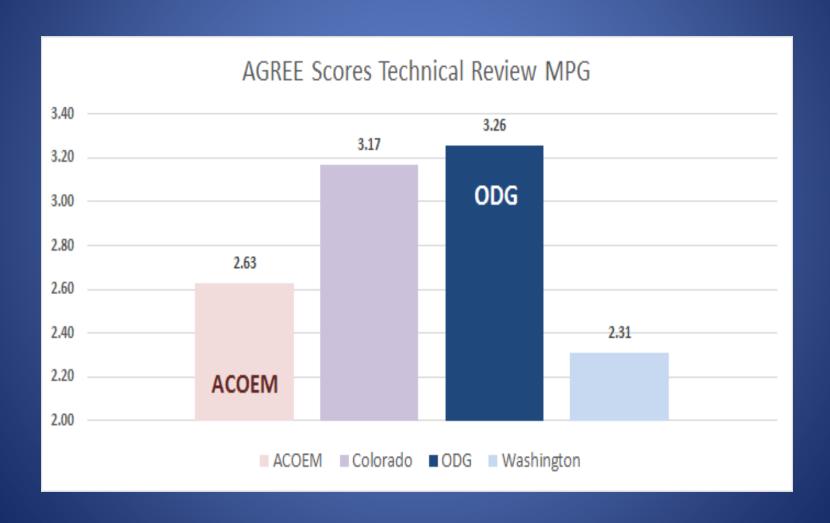
32. http://www.rand.org/pubs/monographs/2005/RAND_MG400.sum.pdf



Ju H, Liufu Z, Newton S, Merlin T (2008). Systematic review of clinical practice guidelines on the management of acute/subacute soft tissue injuries to the low back. tracSA, Adelaide, SA.

AGREE Domain	ODG Score
Scope and Purpose	83%
Stakeholder Involvement	88%
Rigour of Development	83%
Clarity of Presentation	92%
Applicability	83%
*** The state of t	03/2
Editorial Independence	92%
Eutorial macpenaence	3270
Avianaga Saaya Aayaas ACREE Damaina	970/
Average Score Across AGREE Domains	87%
ODG recommended for use (yes or no)?	Yes

2010 Montana L&I



Technical Quality and Clinical Acceptability of a Utilization Review Guideline for Occupational Conditions

ODG® Treatment Guidelines by the Work Loss Data Institute. Rand, 2017 (Nuckols, Shetty, Raaen, Khodyakov).

AGREE Domain	Score
Scope and Purpose	64%
Stakeholder Involvement	67%
Rigor of Development	55%
Clarity of Presentation	75%
Applicability	74%
Editorial Independence	69%
Average Score Across AGREE Domains	67%
Recommended for Use (yes or no):	Yes

Formularies

Many out there with multiple variations

Commercial—full adoptions, customization, list-only

State-specific

What is a Drug Formulary?

ODG STATUS







ODG STATUS



for·mu·lar·y

noun

1. an official list giving details of medicines that may be prescribed.

Other formularies

EXAMPLES

California MTUS—Exempt, non-exempt

New York WBC—Preferred, non-preferred

Washington L&I—Allowed, prior authorization required, denied

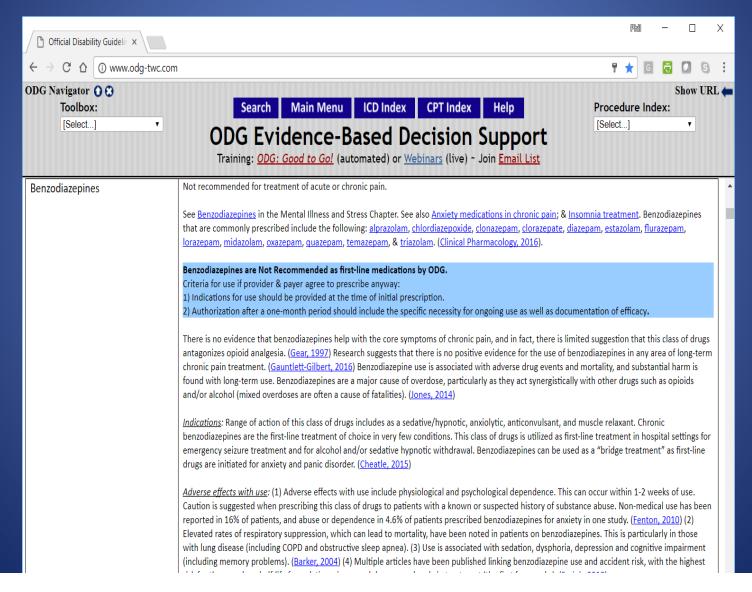
	Drug Ingredient	Reference Brand Name	Preferred / Non- Preferred* Exempt/Non-Exempt*	Special Fill**	Peri-Op***	Drug Class	Reference in Guidelines	Dosage Form	<u>Strength</u>	Unique Product Identifier(s)
1	Acetaminophen	<u>Tylenol</u>	Preferred <u>Exempt</u>			Analgesics - NonNarcotic	✓ ♦ Ankle and Foot Disorders ✓ Cervical and Thoracic Spine Disorders ✓ Chronic Pain ✓× Elbow Disorders ✓ Eye ✓× Hand, Wrist, and Forearm Disorders ✓ Hip and Groin Disorders ✓ Knee Disorders ✓ Low Back Disorders ✓ Shoulder			
2	Adalimumab	<u>Humira</u>	Non-Preferred Non-Exempt			Analgesics - Anti- Inflammatory (TNF- alpha blocker)				
3	Albuterol Sulfate	<u>Proventil</u>	Preferred Exempt			Antiasthmatic and Bronchodilator Agents	√ Work Related Asthma			
4	Alclometasone Dipropionate	<u>Aclovate</u>	Non-Preferred Non-Exempt			<u>Dermatologicals</u>	✓ Ankle and Foot Disorders			
4 <u>5</u>	Alendronate Sodium	<u>Fosamax</u>	Non Preferred Non-Exempt			(Bisphosphonate)	√× Chronic Pain √⊗ Hip and Groin Disorders ⊗ Knee Disorders × Low Back Disorders √ Shoulder			
<u>5</u> <u>6</u>	Amantadine HCL	Symmetrel	Non-Preferred Non-Exempt			Antiparkinson Agents (NMDA receptor antagonist)	× Chronic Pain × Low Back Disorders			
Z	Amcinonide_	Cyclocort	Non-Preferred Non-Exempt			<u>Dermatologicals</u>	✓ Ankle and Foot Disorders			
6 <u>8</u>	Amitriptyline HCL	<u>Elavil</u>	Non Preferred Non-Exempt			Antidepressants (TCAs)	√× Cervical and Thoracic Spine Disorders √ Chronic Pain ×⊗ Hip and Groin Disorders √×⊗ Knee Disorders √⊗ Low Back Disorders √× Shoulder			
7 9	Amlodipine Besylate	<u>Norvasc</u>	Non-Preferred Non-Exempt			Calcium Channel Blockers	√ Hand, Wrist, and Forearm Disorders			
8 10	Amoxicillin/Clavulanate P	Augmentin	Preferred Exempt			Antibiotics (Penicillins)	✓ <u>O Ankle and Foot Disorders</u> ✓ Hand, Wrist, and Forearm Disorders ✓ Low Back Disorders			
<u>11</u>	<u>Anakinra</u>	<u>Kineret</u>	Non-Preferred Non-Exempt			Analgesics - Anti- inflammatory	X Knee Disorders			
9 12	Apixaban	<u>Eliquis</u>	Non-Preferred- Non-Exempt		14 Days 4 Days	Anticoagulants	○ Ankle and Foot Disorders✓ Hip and Groin Disorders✓ Knee Disorders			4

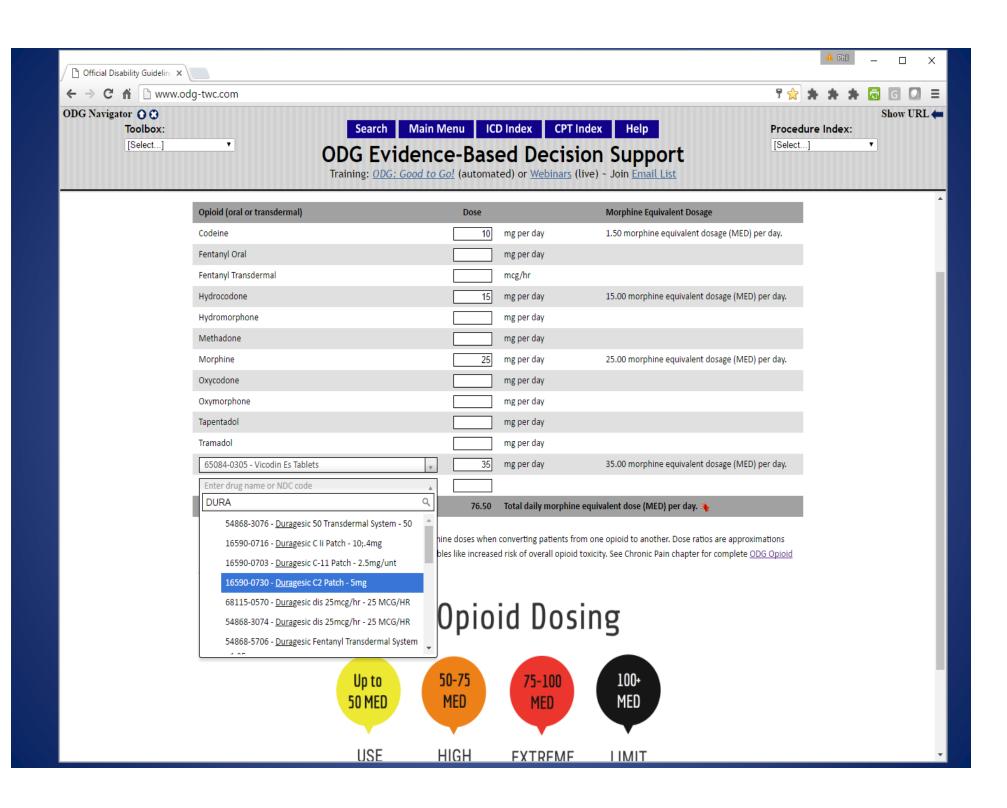
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Expanding the Formulary

Formulary directly linked to Criteria







Sorted by ODG Class:

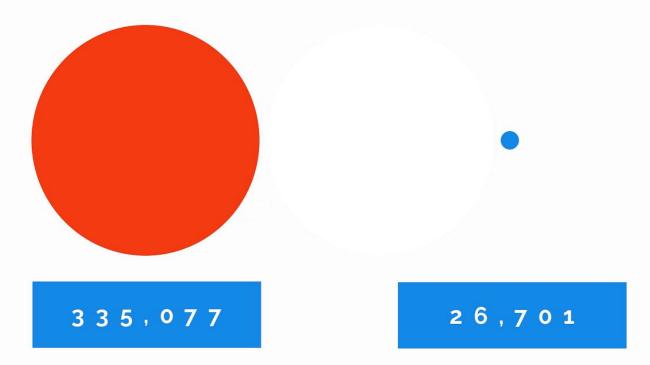
ODG Workers' Compensation Drug Formulary											
Drug Class	Generic Name	Brand Name	GE	Status	Cost						
Analgesics, narcotics	See <u>Opioids</u> .										
Analgesics, NSAIDs	See <u>NSAIDs</u> (non-steroidal anti-inflammatory drugs).										
Analgesics, OTC											
Anticonvulsants	See <u>Anti-epilepsy drugs</u> (AEDs).										
Antidepressants (for		1	<u> </u>								
pain)	Amitriptyline	Elavil®	Y	Y	\$2.72						
Antidepressants	Bupropion	Wellbutrin®	Y	N	\$86.45						
Antidepressants	Duloxetine	Cymbalta®	N	Y	\$113.70						
Antidepressants	Escitalopram	Lexapro®	N	N							
Antidepressants	Fluoxetine (for pain)	Prozac®	Y	N	\$15.00						
Antidepressants	Sertraline (for pain)	Zoloft®	Y	N	\$86.20						
Antidepressants	Venlafaxine	Effexor®	Y	Y	\$102.21						
Antidepressants	<u>Venlafaxine</u> ER	Effexor ER®	Y	Y							
Antidepressants	T T	1									
(NSRIs)	Milnacipran	Savella/Ixel®	N	N							
Antidepressants		Davella Incio									
(SNRIs)	Duloxetine	Cvmbalta®	N	Y	\$113.70						
Antidepressants			-	_							
(SNRIs)	Venlafaxine	Effexor®	Y	Y	\$102.21						
Antidepressants											
(SSRIs) (for	Fluoxetine, Sertraline (for	Prozac®,									
depression)	depression)	Zoloft®	Y	Y							
Antidepressants	Citalopram (for pain)	Celexa	Y	N							
(SSRIs) (for pain)											
Antidepressants											
(CCDI-)	P 24 /0 15	۱, ۵	3.7	*.*							

N Drug Use in Texas

Number of N-Drug Prescriptions per Year 2009 versus 2015



Post-ODG Formulary



The combined and powerful effect of the ODG treatment guidelines and ODG Drug Formulary.

Texas

Proving Ground

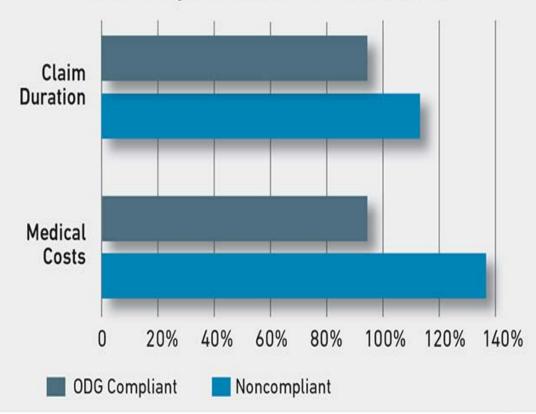
- Texas (adopts ODG guidelines in 2007, ODG Formulary in 2011)
 - Work comp premiums down 51%
 - Average lost-time down -34%, median -30%
 - RTW rates way up (acute, subacute, chronic)
 - Medical costs down 30% (N drugs down 81%)
 - Access to care up 42%
 - Jumps 26 slots in WC Premium Ranking,
 - State Report Cards from WC from F to B
 - NASI study: Texas now lowest cost state

Independent Research: JOEM Study

Impact of Treatment Guidelines on Claims Outcomes

According to the "Journal of Occupational and Environmental Medicine," evidence-based medicine has a major impact on the duration and cost of claims.

ODG Compliance on Claims Outcomes



RAND Recommendations:

- Compatibility with Medical Treatment
 Utilization Schedule
- Condition-specific requirements should be imposed sparingly.
- "A traditional formulary is a list of covered drugs with rules on how the drugs may be accessed and under which conditions".
- Formulary should be operationalized with NDC codes, would need to be created for ACOEM or MTUS, updated quarterly.
- The 'Y/N' structure of formulary preauthorization rules makes it easier to operationalize because it does not require diagnostic information.

Implementing a Drug Formulary for California's Workers' Compensation Program

Barbara O. Wynn, Christine Buttorff, Erika Meza, Erin A. Taylor, Andrew W. Mulcahy

"Living Document"

 Any EBM guideline remains alive only through frequent and diligent updating

 Real-world examples demonstrate the importance of staying relevant

"Living Document"

- Arthroscopic meniscectomy
- Bone stimulators (LIPUS)
- Stem cells
- Platelet-rich plasma (PRP)
- Corticosteroid injections-Zilretta®
- Robotics/navigation
- Functional capacity evaluation (FCE)
- BMI—joint replacement
- Outpatient joint replacement surgery
- Prolotherapy

Arthroscopic meniscectomy

 Not recommended with ANY imaging signs of OA/degenerative tear or symptoms > 1 year

 Arthroscopic surgery for OA not recommended except for locking from large loose bodies

Bone stimulators (LIPUS)

- Low-intensity pulsed ultrasound
- No longer ever recommended for fresh fractures, even with risk-factors
- Still appropriate for delayed or non-union

Stem cells

- "Not recommended"
- SC clinics under scrutiny/investigation by FDA
- Shoddy research abounds
- N. American SC clinics direct to consumer advertising for "pay to participate" studies
- NIH implicated for lack of standards on ClinicalTrials.gov

Platelet-rich plasma (PRP)

- Currently some promise but indications very limited, still controversial
- Knee OA (mild/moderate)—6 months conservative, < 50, failed CSI, once yearly
- Refractory patellar tendinosis—12 months, single injection only
- Elbow lateral epicondylitis—12 months, single injection only

Corticosteroid injections

- Concerns with time and dose-related chondrotoxic effects of steroids and local anesthetics
- Delay joint replacement following CSI (TKA 6 months, TKA 12 months)
- Diabetics beware
- Zilretta® is FDA-approved for 1-time only knee OA injection, but data preliminary

Robotics/navigation

- Not recommended lacking evidence of improved clinical outcomes
- Incidental to the primary surgical procedure and not separately billable
- Does not cause harm, but can lengthen surgery time
- Customized joint replacement components also not recommended

Functional capacity evaluation (FCE)

- Only recommended before and at conclusion of a work hardening program
- Not recommended with physical therapy, work conditioning, or for other screening purposes

BMI joint replacement

- Obesity epidemic
- Complications expected
- TKA and TSA BMI <40 following documented weight loss effort >35
- THA <35 following documented weight loss effort >30

Outpatient joint replacement surgery

- Controversial with Medicare and between hospitals and surgery centers
- Growing literature evidence to support for younger patients without co-morbidities
- More appropriate for primary UKA, TKA, THA, and TSA in descending order

Prolotherapy

- Hypertonic dextrose injections
- Resurgence in "Regenerative medicine" clinics
- Research remains very poor after 50 years
- Only recommended as 2nd-line for lateral epicondylitis meeting criteria for surgery