

Evidence Based Medicine & Pain Management: New Challenges in a Changing Healthcare Environment

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Disclosures

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Research:

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Overview

- Recent challenges in pain medicine
- Evidence Based Medicine: Defined or Misinterpreted?
- Evolution of EBM
- Guideline Review
 - AHRQ Guidelines for Treatment of Low Back Pain
 - CDC Guidelines for Opioids in Primary Care
 - HCA HTCC Spine Injections Re-review
- Future Options for Applying EBM in Pain Management
- System-wide approach to EBM for LBP

Legislative & Healthcare System

Current State

- Unsustainable growth of health costs, poor outcomes
- HITECH Act (American Recovery and Reinvestment Act of '09
 - \$19 billion in subsidies for Meaningful Use of EHR
- Patient Protection and Affordable Care Act of 2010
- Centers of Medicare and Medical Services (CMS) creating shared-savings programs for ACOs
 - Reduce cost and improve quality
 - Penalize hospitals for avoidable readmissions
 - Base reimbursement on quality measures
- Shift from fee-for-service to greater financial and clinical accountability
- National Pain Strategy released March 2016



National Pain Strategy

A Comprehensive Population Health Level Strategy for Pain



CMS.gov

Centers for Medicare & Medicaid Services



MACRA / MIPS



Sept 28, 2015



National Pain Strategy

A Comprehensive Population Health Level Strategy for Pain

- Education, research, and treatment have focused on the pathophysiological mechanisms involved in chronic pain
- Approach inadvertently encourages a “magic bullet” approach
- Deemphasizes other factors, making treatment and rehabilitative efforts futile
- Widespread use of unnecessary diagnostic tests and procedures and relatively ineffective and potentially harmful treatments linked to high costs

2. Pain Prevention and Care

- Characterize benefits and costs of current prevention and treatment approaches
 - Need thorough benefit-to-cost analysis
 - Identify and create incentives for use of interventions with high benefit-to-cost ratios
 - **Low or little evidence**, low benefit-to-risk ration should be identified through clinical studies and **dis-incentivize** their use
- Develop nation-wide pain self-management programs
 - Good evidence, but under utilized
 - Programs should be integrated into the health care system
 - Goal setting problem solving, decision making and psychosocial aspects should be included
- **Develop standardized, consistent, and comprehensive assessments and outcome measures**

4. Service Delivery and Reimbursement

Vision:

Chief among the supporting policy approaches would be **reimbursement incentives** and **payment structures** that **support population-based care models** of proven effectiveness, especially in interdisciplinary settings, and encourage multimodal care geared toward improving a full range of patient outcomes.

4. Service Delivery and Reimbursement

- Incongruency between **high-quality evidence base** care and real world clinical practice
- Single modality treatments (meds/ injections) often fail as stand alone interventions
- Shift towards more integrated, team approach
- Current system **incentivizes specialty care**

Priorities:

Service Delivery & Reimbursement

1. To develop public policy recommendations that defines future payment, and incentives, for **evidence-based integrated** multimodal care and interdisciplinary team care of persons with chronic pain.
2. Target CMS with policy and guideline recommendations on how to achieve policy.
3. Determine impact of deliverable on quality, access and cost

4. Service Delivery and Reimbursement

Objective 2:

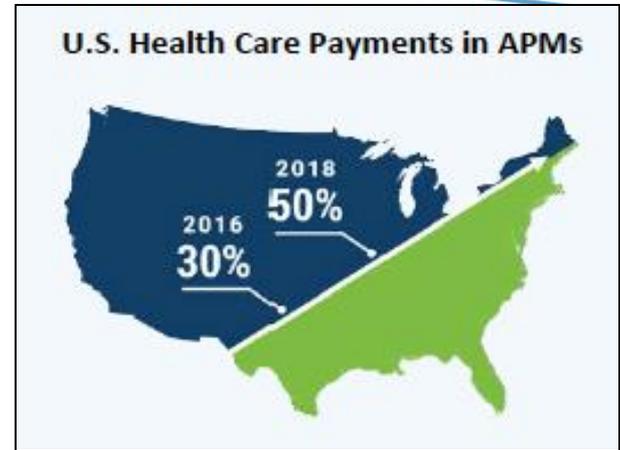
Enhance the **evidence base** for pain care and integrate it into clinical practice through defined **incentives** and **reimbursement strategies**, to ensure that the delivery of treatments is based on the **highest level of evidence**, is population-based, and represents real-world experience.

4. Service Delivery and Reimbursement

Objective 3:

Tailor reimbursement to promote and incentivize high-quality, coordinated pain care through an integrated biopsychosocial approach that is cost-effective, comprehensive, and improves outcomes for people with pain.

MACRA Proposed Rule



- Alternative Payment Models (APMs)
- Merit-Based Incentive Payment System (MIPS)
 - CMS will begin collecting measurement data January 1, 2017 as basis for adjusting payments beginning January 1, 2019
 - Performance period is one calendar year
 - Payment adjustments can be positive, neutral, or negative and will affect up to 4% of payment in 2019, phasing up to 9% of payment in 2022

Is “evidence” making a comeback?

- National Pain Strategy & MACRA
- Incentives changing for all stakeholders
- Population health vs. fee for service
- Healthcare and outcomes are more complicated



What is a guideline?

“Guidelines are recommendations intended to assist providers and recipients of health care and other stakeholders to make informed decisions. Recommendations may be related to clinical interventions, public health activities, or government policies.”

WHO 2004, 2007

Six Domains of Appraisal of Guidelines for Research & Evaluation

1. Explicit scope and purposes
2. Stakeholder involvement
3. Rigor of development
4. Clarity of presentation
5. Applicability
6. Editorial independence

IOM. Clinical practice guidelines we can trust. In: Graham R, et al. Washington, DC: National Academies Press:2011;33-4.

Growth of Clinical Practice Guidelines

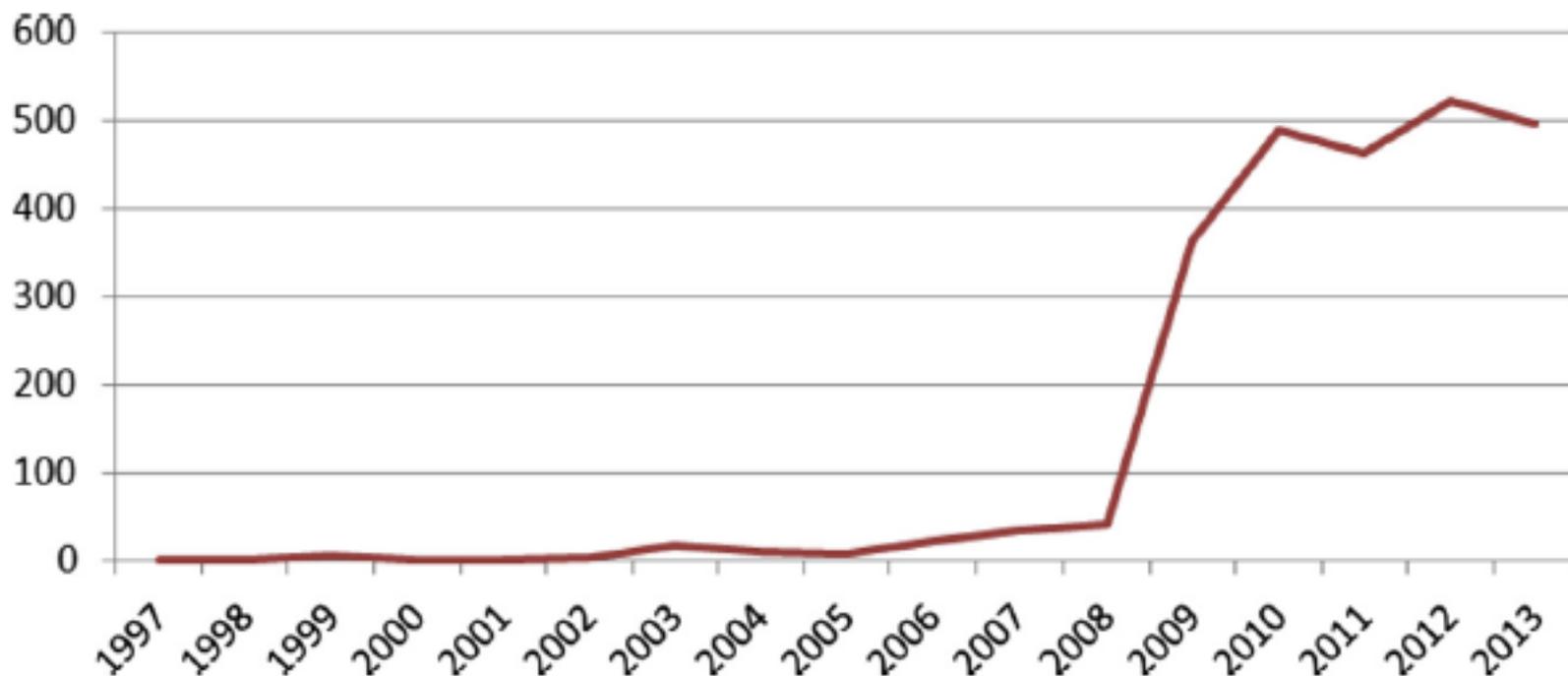


Fig. 1. Number of new guidelines published each year on the NGC. (Data from Javaher SP. National Guideline Clearinghouse. Available at: www.guideline.gov. Accessed December 13, 2014.)

IOM Standards for Practice Guidelines

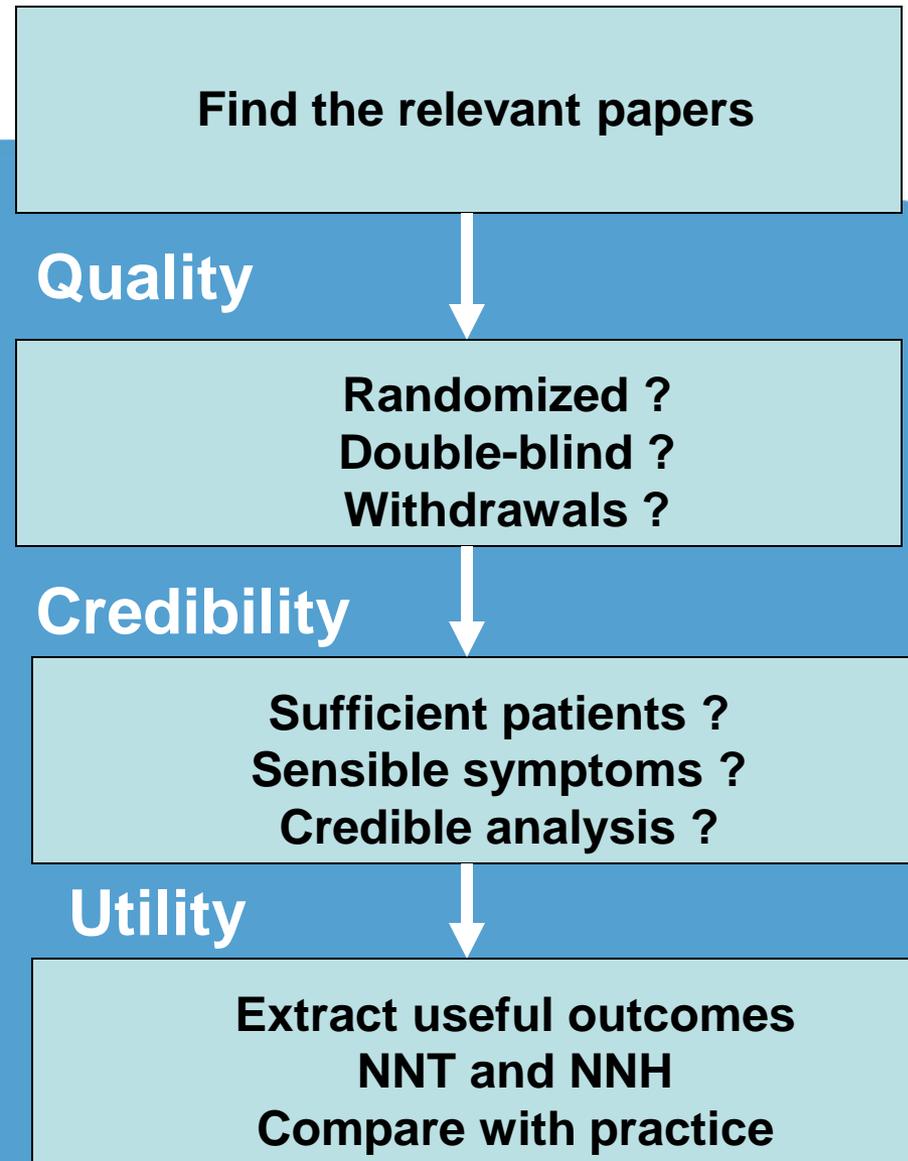
1. Establish transparency
2. Management and disclosure of conflict of interest
3. Guideline development group composition
4. Evidence based on systematic review of literature
5. **Strength of rating for the clinical recommendations**
6. **Articulation of clinical recommendations in standardized form**
7. External review
8. Keeping guidelines updated

Guidelines “Issues”

- Practice variation based on scientific uncertainty or differences in values
- Adherence to unacceptable standards and unwillingness to change based on conflicts of interest
- Inconsistency among guidelines can also arise from variations in values, tolerance of risks, preferences, and risks

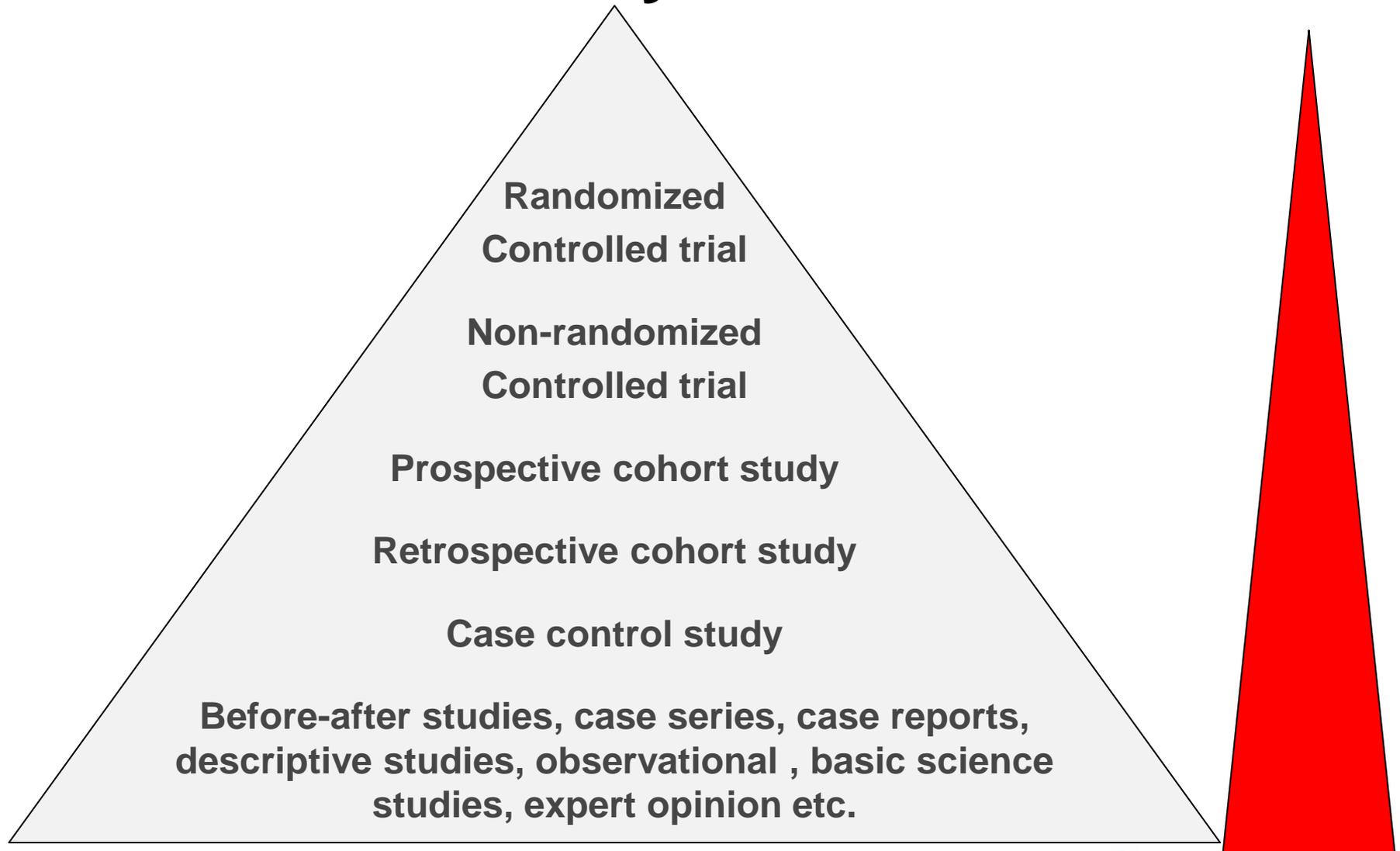
What is Evidence Based Medicine (EBM) ?

Evidence- Based Medicine (EBM)



Evidence Hierarchy

BIAS



Before-after studies, case series, case reports,
descriptive studies, observational, basic science
studies, expert opinion etc.

Criteria for Levels of Evidence and Grade of Recommendation

Level of Evidence

Level I: Large randomized trials with clear-cut results

Level II: Small randomized trials with uncertain results and moderate risk of error

Level III: Nonrandomized, contemporaneous controls

Level IV: No controls, case series only

Grade

A: Supported by at least one Level I randomized trial

B: Supported by at least one Level II

C: Supported only by Level III, IV, or V evidence

“Evidence Based Medicine”

“Method of integrating individual clinical expertise with the best available evidence from systematic research.” ¹

“The *conscientious, explicit and judicious* use of current best evidence in making decisions about the care of individual patients.” ²

1. Straus SE, et al. *Evidence-Based Medicine*. 3rd ed. Edinburgh: Churchill Livingstone, 2005.
2. Evidence-based medicine. A new approach to teaching the practice of medicine. *JAMA* 1992;268:2420-5.

Definitions

Efficacy: impact of an intervention as determined through a clinical trial

Effectiveness: impact of intervention in real work situation

Definitions

Usual Practice (standard of care): the diagnostic and treatment process that an average, prudent provider in the community should follow.

Best Practice: strives for optimal care of the patient recognizing wide variations in medical practice exist

Evidence Based Practice (EBP): centers on a specific question. The integration of best research evidence combined with clinical expertise and patient values.

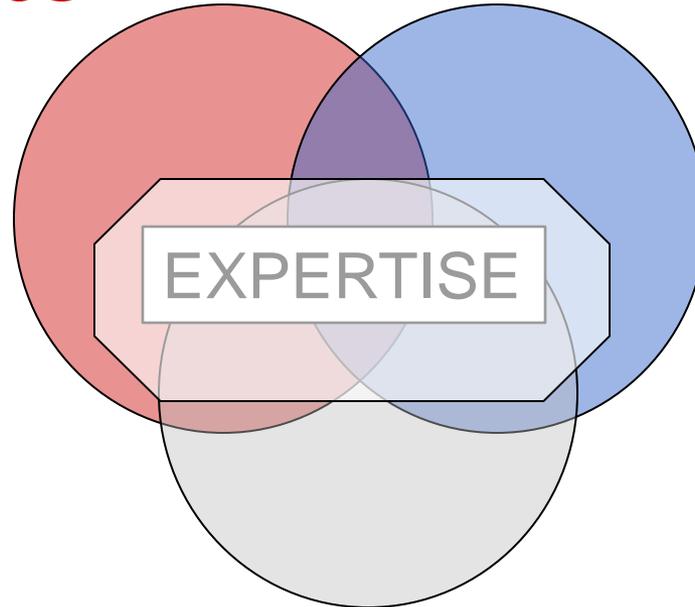
Evidence Based Practice (EBP): 5 Steps

1. Conversion of need for information into specific, structured, and answerable question
2. Identification of the best evidence to answer the question
3. Critical evaluation of the evidence for validity
4. Integration of the critical evaluation with one's clinical expertise, patient's biology, values, and circumstances
5. Re-evaluation of the previous 4 steps, emphasizing improving effectiveness and efficiency of process

Evidence Based Healthcare Decisions

**Clinical State &
Circumstances**

**Population
Values &
Preferences**



Research Evidence

Drivers of EBM

- Presence of marked variation in treatments
- Increasing cost, overutilization of services/ procedures
- Improvement in ability to measure and analyze outcomes
- Payor and federal mandates to improve quality and measure outcomes

EBM Methodologic Superstructure

- **ASK**
- **ACQUIRE**
- **APPRAISE**
- **APPLY**

Concerns

- Now ubiquitous term
- Co-opted by working groups, professional societies, and authors
- Adhere?
- Hippocratic Oath integration

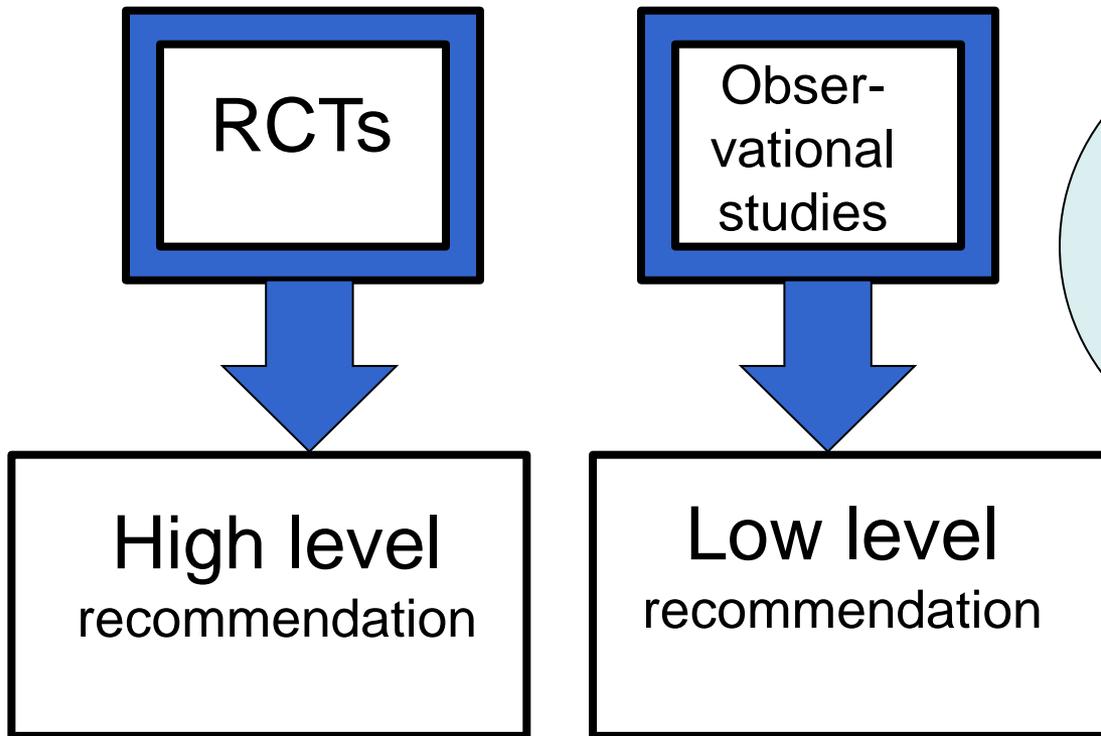
Evidence Based Medicine

Is there a gap between what is known and what is done?

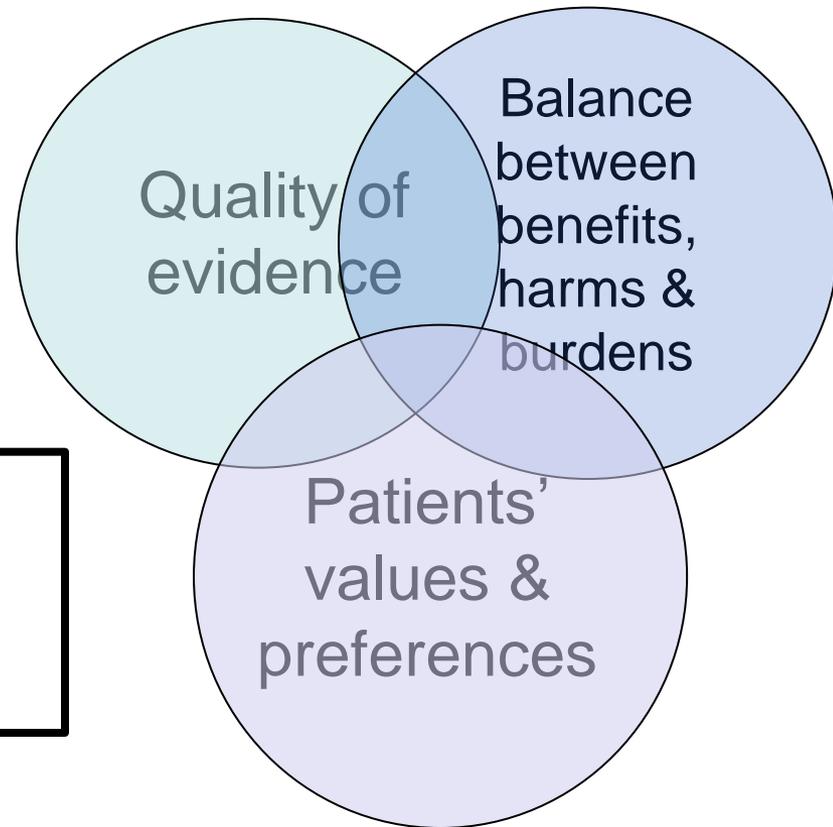
Knowledge Translation

Multidimensional, active process of ensuring new knowledge is gained through the course of research ultimately improves lives of people and involves knowledge validation and dissemination

From Evidence to Recommendations



Old System



GRADE



GRADE

Grades of Recommendation Assessment, Development and Evaluation

Aim: develop a common, transparent and sensible system of grading quality of evidence and strength of recommendations

International group of guideline developers, methodologists, and clinicians

GRADE Evidence Type or Quality

1. **Randomized clinical trials (RCTs)** or overwhelming evidence from **observational studies**
2. **RCTs** with important limitations or exceptionally strong evidence from **observational studies**
3. **Observational studies** or **RCTs** with notable limitations
4. **Observational studies** with important limitations, **RCTs** with several limitations, clinical experience and observations

Methodology for Categorizing Evidence

Study design	Initial evidence type	Criteria for moving DOWN	Criteria for moving UP	Final Evidence Type
Randomized Controlled Trial (RCT)	1	Risk of bias	Strength of Association	1
		Inconsistency	Dose-Response	2
Observational Study	3	Indirectness	Direction of all plausible residual confounding or bias	3
		Publication Bias		4

GRADE: Final Evidence Type

Evidence Type	
1	One can be very confident that true effect lies close to that of the estimate of the effect
2	True effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
3	Confidence in the effect estimate is limited and the true effect might be substantially different from the estimate of the effect
4	One has very little confidence in the effect estimate, and true effect is likely to be substantially different from estimate of effect
Insufficient evidence	No studies are present

GRADE: Final Recommendations (ACIP)

Types

Category A: Apply to all persons in a specified group and indicate most patients should receive the recommended course of action

Category B: Indicates that there should be individual decision making; different choices will be appropriate for different patients, so clinicians must help patients arrive at a decision consistent with patient values, preferences, and specific clinical situations

Category A

Recommendation:

Based on type 3 and 4 evidence when advantages of a clinical action greatly outweigh disadvantages based on 4 factors

Category B

Recommendation:

When advantages and disadvantages of a clinical action are balanced

“Active Ingredients”

- ‘active ingredient’: element within a pharmacologic intervention (PI) that is responsible for its therapeutic action
- Active ingredients reported significantly less often in titles for non-pharmacologic intervention (NPIs)
- NPIs are more complex, contain several interacting components that are all necessary for the intervention to be effective
 - Many different behaviors from HC professionals or participants
 - Many different types of outcome measurement
 - Tailored to different contexts or settings within one study

Different descriptions of 'behavioral counseling' as an intervention

Study 1	Study 2
Feedback on diaries	Assessment of readiness to change
Reinforcement	Attitude change
Recommendations for change	Goal setting
Answers to questions	Specific behavior advice
General support	

EBM: to the Test

1. AHRQ Comparative Effectiveness Review.
Noninvasive treatments for low back pain
2. CDC Guidelines for Opioid Prescribing in Primary Care
3. WA HCA Re-review of Decision on Spinal Injection
Procedures



Effective Health Care Program

Noninvasive Treatments for Low Back Pain *Executive Summary*

1.

Key Questions: Comparative benefits and harms of:

1. Different pharmacological therapies for acute or chronic nonradicular low back pain, radicular, or spinal stenosis?
2. Nonpharmacologic therapies including multidisciplinary rehabilitation, exercises, modalities, devices, psychological therapies, acupuncture, massage, yoga, magnets.

Pharmacotherapy for Acute LBP

Table B. Pharmacological therapies versus active comparators for acute low back pain

Drug	Pain: Magnitude of Effect	Pain: Evidence	Pain: SOE	Function: Magnitude of Effect	Function: Evidence	Function: SOE
Acetaminophen vs. NSAID	Unable to estimate	1 RCT	Insufficient	Unable to estimate	1 RCT	Insufficient
NSAID vs. NSAID	No difference	6 RCTs	Moderate	--	--	--
Opioid vs. NSAID	Unable to estimate (inconsistent)	3 RCTs	Insufficient	No difference	1 RCT	Insufficient
Long-acting opioid vs. long-acting opioid	No clear difference	4 RCTs	Moderate	No clear difference	4 RCTs	Moderate
Long-acting opioid vs. short-acting opioid	No clear difference*	6 RCTs	Low	--	--	--
Benzodiazepine (diazepam) vs. skeletal muscle relaxant	No difference	1 RCT	Low	--	--	--
Skeletal muscle relaxant vs. skeletal muscle relaxant	No clear difference	1 SR (2 RCTs)	Low	--	--	--

CI = confidence interval; NSAID = nonsteroidal anti-inflammatory drug; RCT = randomized controlled trial; RR = relative risk; SOE = strength of evidence; SR = systematic review; SSRI = selective serotonin reuptake inhibitor.

Findings

- Acetaminophen no more effective than placebo for acute low back pain
- Duloxetine is more effective than placebo for pain and function in patients with chronic low back pain
- New evidence for pregabalin for radicular pain is inconsistent to reliably estimate effects
- Tricyclic antidepressants not effective vs placebo for pain relief or function
- More specific types of exercises are effective
- Similar conclusions of multidisciplinary rehabilitation and psychological therapies

Limitations of the Evidence Base

- Evidence on effectiveness of interventions for radicular low back pain are sparse
- Studies frequently short term
- Many studies report mean changes in outcome measures (i.e. pain and function), not dichotomized outcomes (e.g. > 30% or > 50% pain relief or function improvement)
- Pain treatment responses are bimodal, basing on continuous outcomes could obscure treatment effects
- Additional challenges with non-pharmacologic interventions

2. CDC Opioid Guidelines for Primary Care



PROP

PHYSICIANS FOR RESPONSIBLE OPIOID PRESCRIBING

2012 JUL 25 P 1:48

July 25, 2012

Dockets Management Branch
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville MD 20852

The undersigned clinicians, researchers and health officials from fields that include Pain, Addiction,
Primary Care, Internal Medicine, Anesthesiology, Psychiatry, Neurology, Emergency Medicine,
Toxicology, Rheumatology, and Public Health submit this petition under Section 31 CFR 10.20 and 31

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1. Strike the term “moderate” from the indication for non-cancer pain
2. Add a maximum daily dose, equivalent to 100 mg of morphine for non-cancer pain
3. Add a maximum duration of 90-days for continuous daily use for non-cancer pain

Long-Acting (LA)/ Extended Release (ER) Opioids

Indication:

*“ER/LA opioids are indicated for the management of pain **severe enough** to require daily, around-the-clock, long-term opioid treatment and for which **alternative treatment options** are inadequate.”*

- Addiction, Abuse, and Misuse
- Life-threatening Respiratory Depression
- Accidental Exposure
- Neonatal Opioid Withdrawal Syndrome
- Interaction With Alcohol

Dosing and Monitoring

Doses >200 mg oral morphine equivalents/day should prompt re-evaluation and increased monitoring.

APS/AAPM Opioid Guidelines for Chronic Noncancer Pain

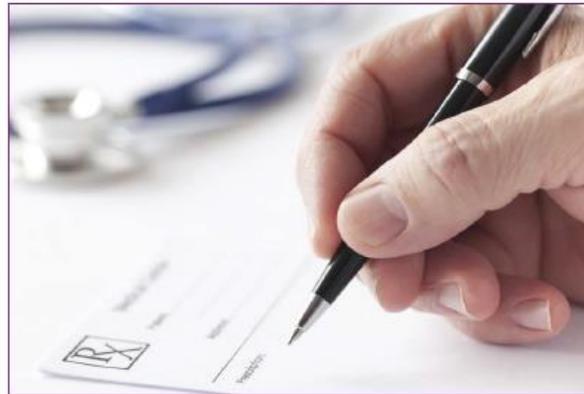
Do not exceed 120 mg of oral morphine equivalents/day without either demonstrated improvements in function and pain or first obtaining a consultation with pain management expert.

Washington State Medical Directors Guideline on Opioid Dosing

AAPM, American Academy of Pain Medicine; APS, American Pain Society.

Chou R, et al. *J Pain*. 2009;10(2):113-130; The Management of Opioid Therapy for Chronic Pain Working Group. *VA/DOD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain*. Washington, DC: Department of Veterans Affairs, Department of Defense; 2010; Washington State Agency Medical Directors' Group. *Interagency Guideline on Opioid Dosing for Chronic Non-cancer Pain: An Educational Aid to Improve Care and Safety with Opioid Treatment*. Olympia, WA: Washington State Department of Labor and Industries; 2010.

CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016



U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Intended for primary care clinicians who are treating patients with chronic pain (i.e., pain > 3 months or past the time of normal tissue healing) in outpatient settings.

CDC Guidelines for Opioids: Process

Evidence:

- APS/AAPM Opioid Guidelines 2009
- AHRQ systematic review of 2014

Process:

- Core Expert Group (CEG)
- Stakeholder Review Group (SRG)
- Draft Document, Federal Review (80 FR 77351)
Public comment through Jan 13, 2016
- National Center for Injury Prevention & Control (NCIPC) Board of Scientific Counselors
- Opioid Guideline Workgroup (OGW)

Draft CDC Guideline for Prescribing Opioids for Chronic Pain, 2016: Summary of Stakeholder Review Group Comments and CDC Response



- Transparency in process, no empathy for patients, not patient-centered, ignored Federal Advisory Committee Act
- Opposing evidence of dose limitations at 50 and 90 MME/day
- Evidence built on systematic reviews from 2009 and 2014
- Changed study criteria to 1 yr, and then “no evidence” claim

cdc.gov



GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN

DETERMINING WHEN TO INITIATE OR CONTINUE

- 1 Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate.
- 2 Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how opioid therapy will be discontinued if benefits do not outweigh risks. Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.
- 3 Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy.



CLINICAL REMINDERS

- Opioids are not first-line or routine therapy for chronic pain
- Establish and measure goals for pain and function
- Discuss benefits and risks and availability of nonopioid therapies with patient

When to initiate or continue

Selection of opioids, dosage, follow-up, and discontinuation

OPIOID SELECTION, DOSAGE, DURATION, FOLLOW-UP, AND DISCONTINUATION

CLINICAL REMINDERS

- Use immediate-release opioids when starting
- Start low and go slow
- When opioids are needed for acute pain, prescribe no more than needed
- Do not prescribe ER/LA opioids for acute pain
- Follow-up and re-evaluate risk of harm; reduce dose or taper and discontinue if needed

- 4 When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids.
- 5 When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when considering increasing dosage to ≥ 50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥ 90 MME/day or carefully justify a decision to titrate dosage to ≥ 90 MME/day.
- 6 Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, immediate-release opioids should be prescribed for the expected duration of treatment, and less will often be sufficient.
- 7 Clinicians should evaluate the benefits and risks of starting opioid therapy for chronic pain and should evaluate benefits and risks periodically during therapy. Clinicians should taper opioids to lower dosages when appropriate.



Risk Management

ASSESSING RISK AND ADDRESSING HARMS OF OPIOID USE

- 8 Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥ 50 MME/day), or concurrent benzodiazepine use, are present.
- 9 Clinicians should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months.
- 10 When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.
- 11 Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible.
- 12 Clinicians should offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder.

CLINICAL REMINDERS

- Evaluate risk factors for opioid-related harms
- Check PDMP for high dosages and prescriptions from other providers
- Use urine drug testing to identify prescribed substances and undisclosed use
- Avoid concurrent benzodiazepine and opioid prescribing
- Arrange treatment for opioid use disorder if needed

MMWR, CDC Guidelines for Prescribing Opioids. March 15, 2016, Vol. 65. 1-50.



U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

LEARN MORE | www.cdc.gov/drugoverdose/prescribing/guideline.html

1. When to initiate or continue opioids

#	Recommendation	Evidence Category/ Type
1	Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. If opioids used, should be in combination with non-opioid pharmacologic therapy.	A , 3
2	Establish treatment goals. Continue only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.	A, 4
3	Discuss with patients known risks and realistic benefits of opioid therapy and responsibilities of patient and clinician.	A, 3

2. Selection of opioids, dosage, duration, follow-up, and discontinuation

#	Recommendation	Evidence Category, type
4	When starting opioids, prescribe immediate release instead of ER/LA opioids	A, 4
5	Prescribe lowest effective dose. - Use caution at any dosage. - Carefully reassess benefits and risks when increasing ≥ 50 MME/day - Avoid increasing > 90 MME/day or carefully justify a decision to titrate ≥ 90 MME/day	A, 3
6	Long term begins with treatment of acute pain. Prescribe no greater quantity than needed for expected duration of pain - 3 days or less will often be sufficient - > 7 days is rarely needed	A, 4
7	Evaluate benefits and harms within 1-4 wks Re-evaluate every 3 months or more frequently IF benefits do not outweigh harms, taper down or discontinue	A, 4

3. Risk management: assessing risk & addressing harms

#	Recommendation	Evidence Category, type
8	Evaluate risk factors for opioid related harms. Consider offering naloxone with increase in risk for overdose, substance abuse history, higher opioid dosages > 50 MME/day, benzodiazepine use	A, 4
9	Check PDMP for high dosages and prescriptions from other providers.	A, 4
10	Use urine drug testing to identify prescribed substances and undisclosed use	B, 4
11	Avoid concurrent benzodiazepine and opioid prescribing	A, 3
12	Arrange treatment for opioid use disorder if needed, including office-based treatment in combination with behavioral therapies for patients with opioid use disorder	A, 2

"While we are largely supportive of the guidelines, we remain concerned about the evidence base informing some of the recommendations, conflicts with existing state laws and product labeling, and possible unintended consequences associated with implementation, which includes access and insurance coverage limitations for non-pharmacologic treatments, especially comprehensive care, and the potential effects of strict dosage and duration limits on patient care."

Patrice A. Harris, MD, the AMA board chair-elect

Implications for Patients

- More cautious and thoughtful approach for using controlled substances
- Greater education for patient and family members of the dangers of misuse, abuse, and diversion
- Possible undertreatment of pain for patients
- Stigmatization of “chronic pain patients”
- Providers “not treating chronic pain patients” and overwhelming pain medicine resources, access
- Increase mortality and adverse events with use of other pharmacologic agents

CDC Guidelines for Prescribing Opioids for Chronic Pain

- CDC's recommendations are made on the basis of a systematic review of best available evidence.
- Clinical decision making should be based on a relationship between the clinician and patient, and an understanding of the patient's clinical situation, functioning, and life context.
- The recommendations in the guideline are voluntary, rather than prescriptive standards.
- Clinicians should consider the circumstances and unique needs of each patient when providing care.

3. Spine Injections

Number and Coverage Topic

20110318B – Spinal Injections

HTCC Coverage Determination

Therapeutic Medial Branch Nerve Block injections, Intradiscal injections and Facet injections are **not a covered benefit**

Therapeutic Lumbar Epidural Injections; Cervical-thoracic Epidural Injections and Sacroiliac Joint Injections are a **covered benefit** for the treatment of chronic pain

HTCC Reimbursement Determination

❖ Limitations of Coverage

- Therapeutic Epidural Injections in the lumbar or cervical-thoracic spine for chronic pain are a covered benefit when all of the following conditions are met:
 - For treatment of radicular pain
 - With fluoroscopic guidance or CT guidance

WA HCA Health Technology Assessment re-review

- Increase in spinal injections '94-'01 > 200%
- Key questions (4)
- Public comment
- Spectrum Research, Inc. re-review Dec '15
- Public comment by MPW (Multispecialty Pain Workgroup)
- Public meeting March 18, 2016

Comments on Re-Review and EBM

- Assertion of nonspecific nature of back pain
- Evidence base restriction to RCTs
 - High-quality prospective studies excluded
 - Misinterpretation of Friedly et al not an efficacy but comparative effectiveness between 2 techniques
- Importance of subgroup analyses for each question
- Importance of reliance on categorical data, not continuous data



Agency for Healthcare Research and Quality
Advancing Excellence in Health Care



AHRQ-Funded Study Finds Little Benefit From Corticosteroid Injections for Common Cause of Spine- Related Pain

Electronic Newsletter, Issue 431

AHRQ's Electronic Newsletter summarizes Agency research and programmatic activities.

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812

JULY 3, 2014

VOL. 371 NO. 1

A Randomized Trial of Epidural Glucocorticoid Injections for Spinal Stenosis

CONCLUSIONS

In the treatment of lumbar spinal stenosis, epidural injection of glucocorticoids plus lidocaine offered minimal or no short-term benefit as compared with epidural injection of lidocaine alone. (Funded by the Agency for Healthcare Research and Quality; ClinicalTrials.gov number, NCT01238536.)

- “At 6 weeks, both the glucocorticoid-lidocaine-alone (GL/LI) groups had improvement in the RMDQ score compared to baseline, but there was no significant difference between for RMDQ and intensity of leg pain.”
- 67% of GL/LI ESI group vs 54% of lidocaine ESI group reported being “very or somewhat satisfied” with treatment

Can health system(s) improve clinical care and evidence-based medicine along the way?



What Is Driving Spine Care Conversations In Washington?

Group	Recommendations
Hospitals / Clinics	<ul style="list-style-type: none"> • Support or sustain a LBP quality improvement program that includes measuring patients' functional status over time using the Oswestry Disability Index • Use a validated screening tool such as the STarT Back tool or Functional Recovery Questionnaire (FRQ) no later than the 3rd visit to identify patients that are not likely to respond to routine care • Take steps to integrate evidence-based guidelines, scripts, shared decision making, and patient education materials into clinical practice and workflow • Take steps to integrate comprehensive patient education and effective messaging into clinical practice and workflow for low back pain patients
Individual Providers	<ul style="list-style-type: none"> • Establish referral relationships with physical medicine and rehabilitation physicians, also known as physiatrists • Incorporate comprehensive patient education and expectation-setting into care for low back pain patients, particularly when the patient is requesting care that is not recommended by evidence-based guidelines



What Are The Bree Requirements For The Lumbar Fusion Bundle?

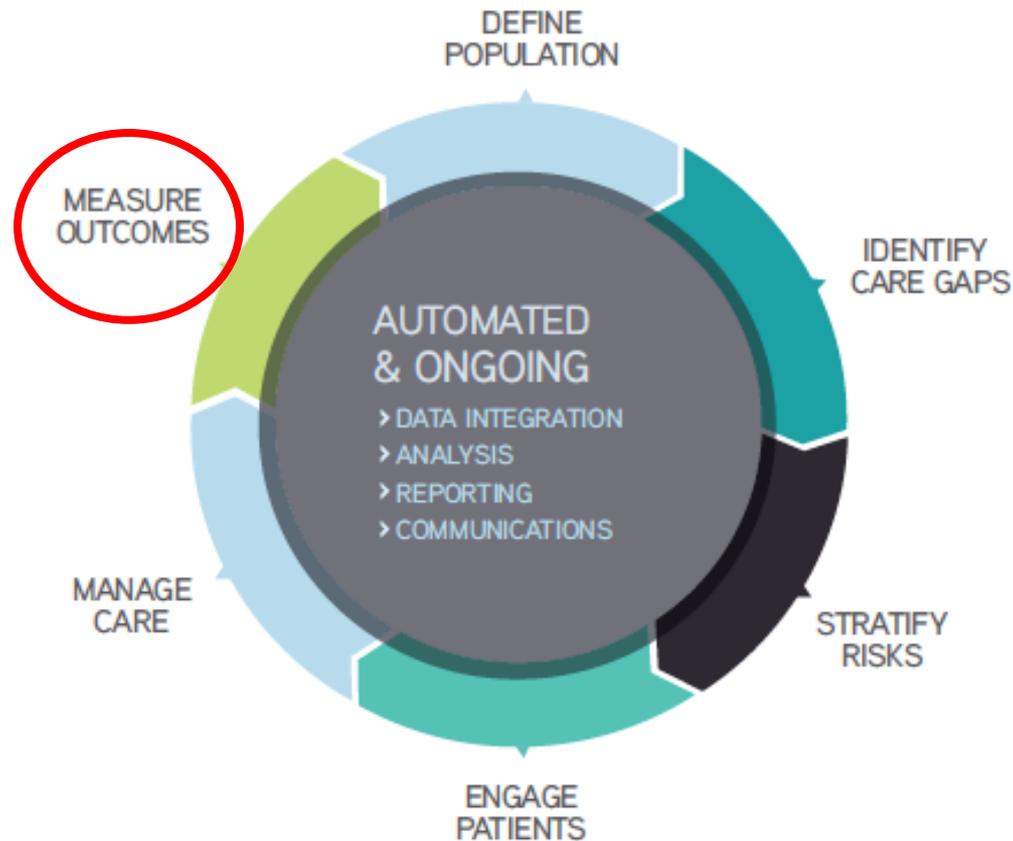
Disability Despite Non-Surgical Therapy

- Document disability (e.g. ODI)
- Document imaging findings on standard scale
- Document >3 months structured non-surgical therapy by collaborative team
- Document persistent disability despite therapy

Fitness for Surgery

- Document 13 requirements related to patient safety (e.g. BMI < 40, A1c)
- Document patient engagement (e.g. designation of personal care partner)
- Document optimal preparation for surgery (e.g. cardiac fitness, delirium)

Population Health: Automation & Data



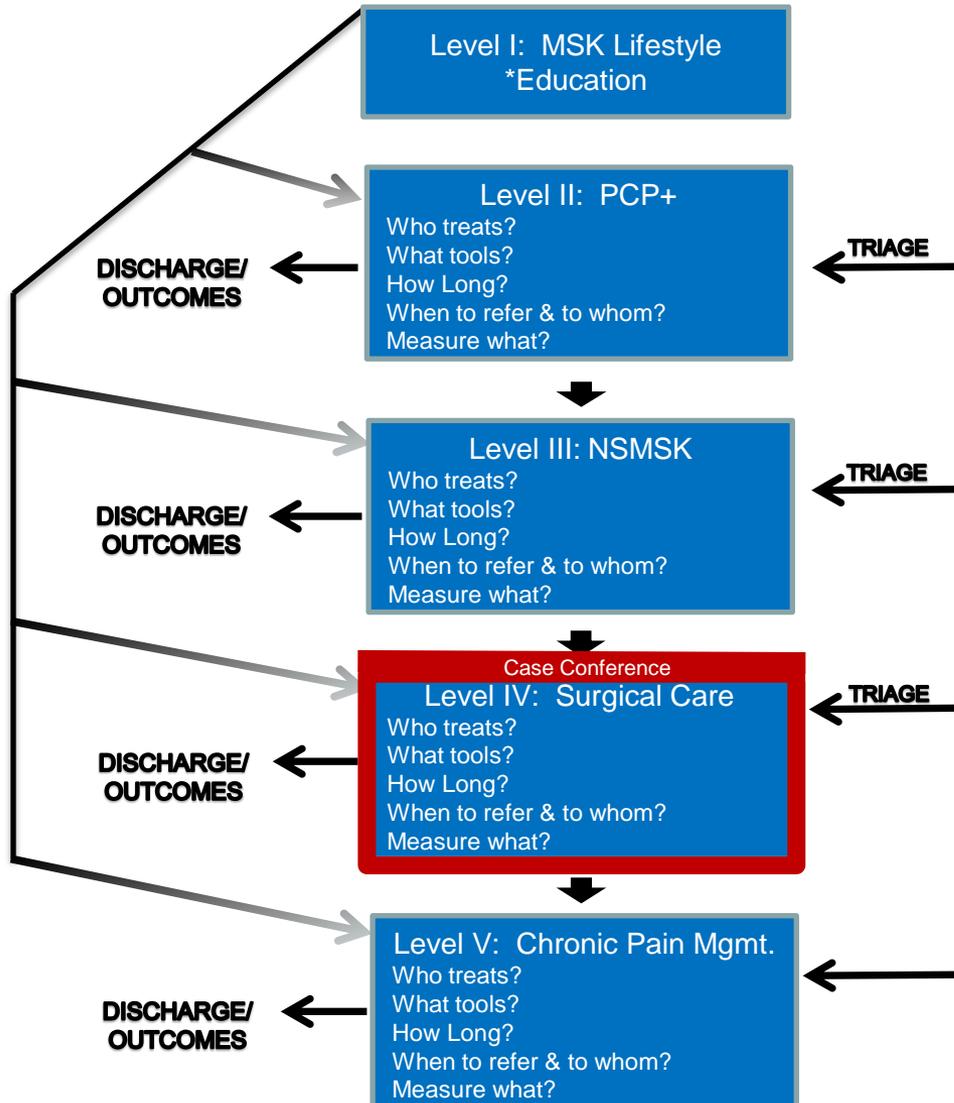


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68

EBM Care Pathways for LBP



Low Back Pain Metrics

Process Measures (IT analytics)

Patient Reported Outcome (PRO)Tools TONIC

Use of Medical Resources:
IMAGING, MEDICATIONS, PT,
INJECTIONS, SURGERY

TIMELINESS OF CARE

ADHERENCE TO PATHWAY

TIME TO RECOVER

PATHWAY ENTRY AND EXIT

Metric Set

ICHOM

PAIN

SCOAP

FUNCTION

PROMIS

QUALITY OF LIFE

CERTAIN

SATISFACTION

STRONG FOR
SURGERY

ABSENTEEISM

Swedish Eastside Integrated Spine Program

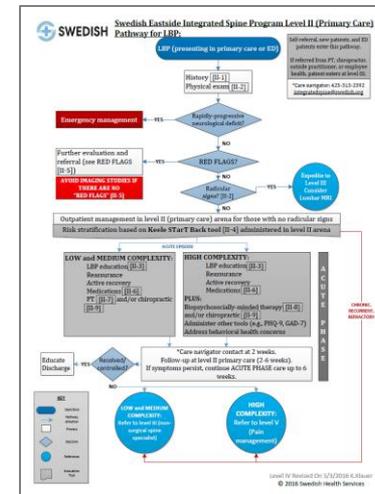
Level I *MSK Lifestyle (Under development)*

Level II *Primary Care providers and extenders*

Level III *Non-surgical MSK specialists*

Level IV *Surgical specialists*

Level V *Chronic pain management specialists*



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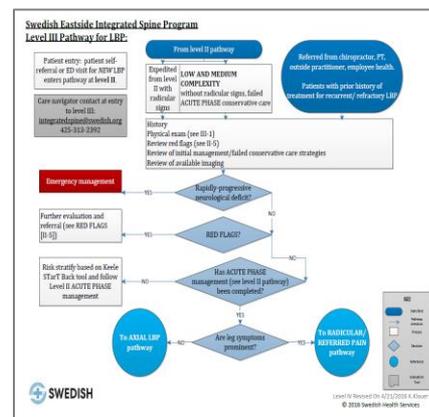
Level I *MSK Lifestyle (Under development)*

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Swedish Eastside Integrated Spine Program

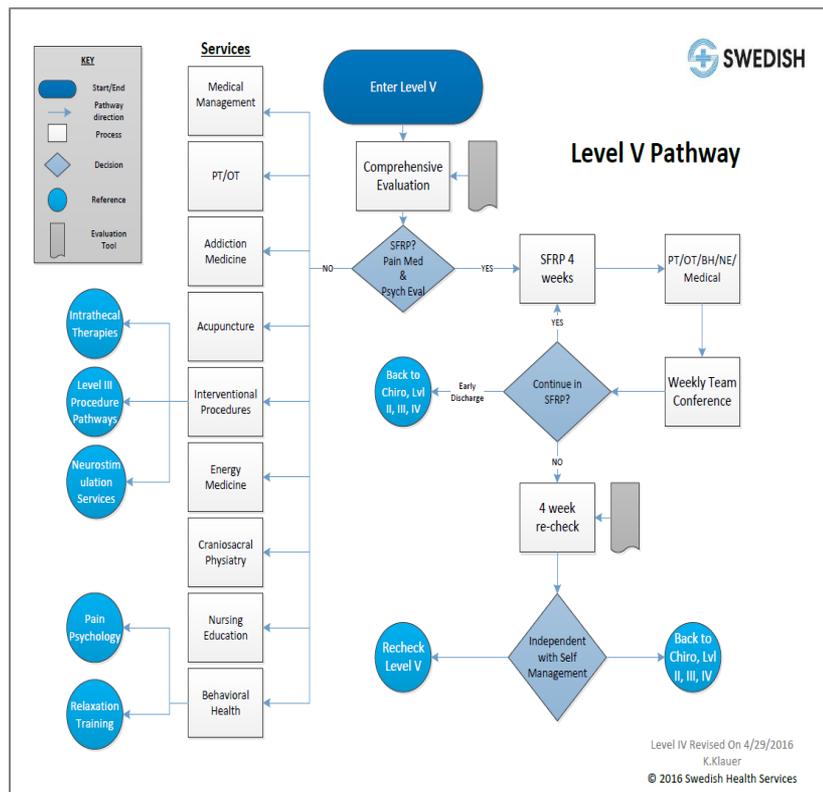
Level I *MSK Lifestyle (Under development)*

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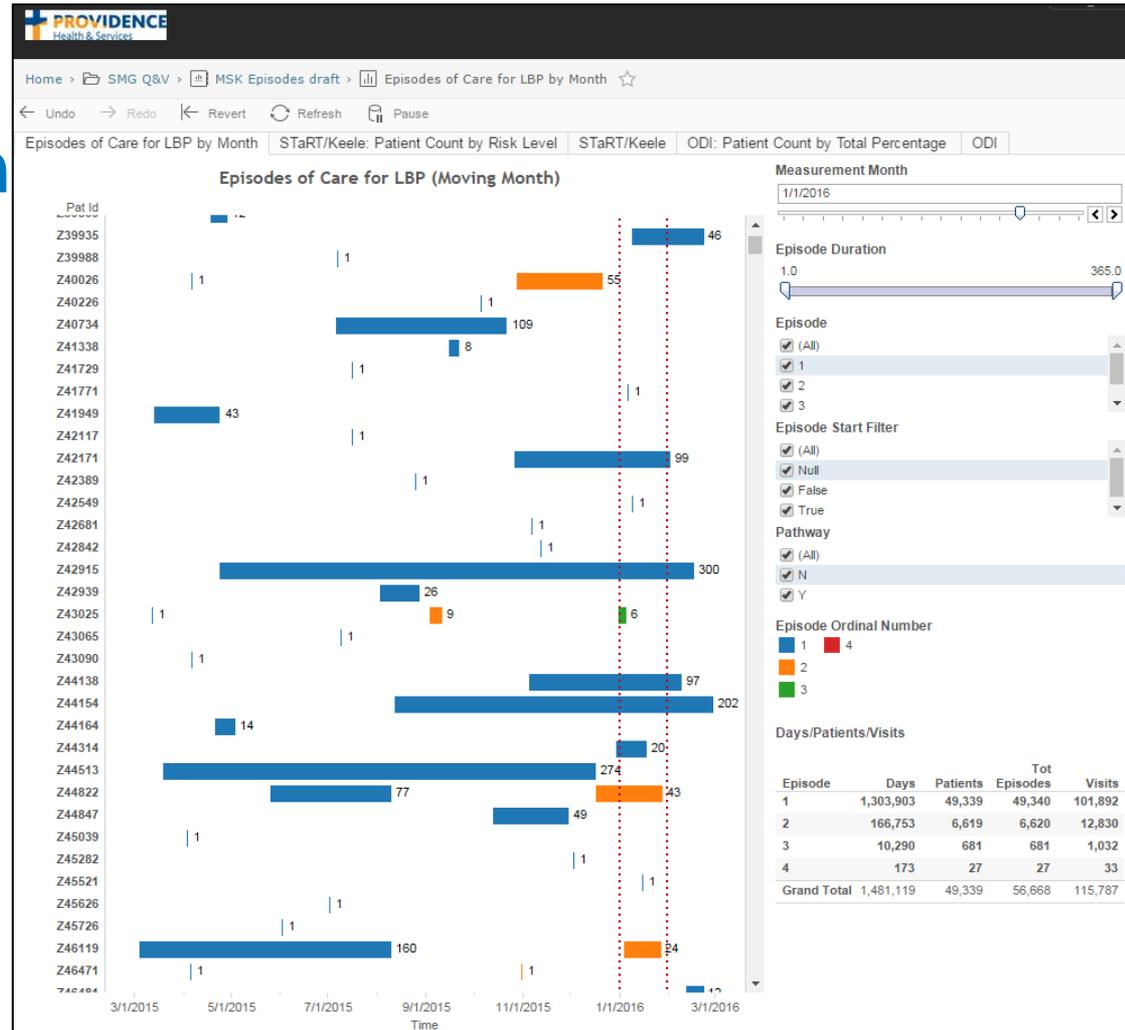


Preliminary Analysis of Swedish Low Back Pain Pathway

Quality & Value

Low Back Pain Episodes at Swedish

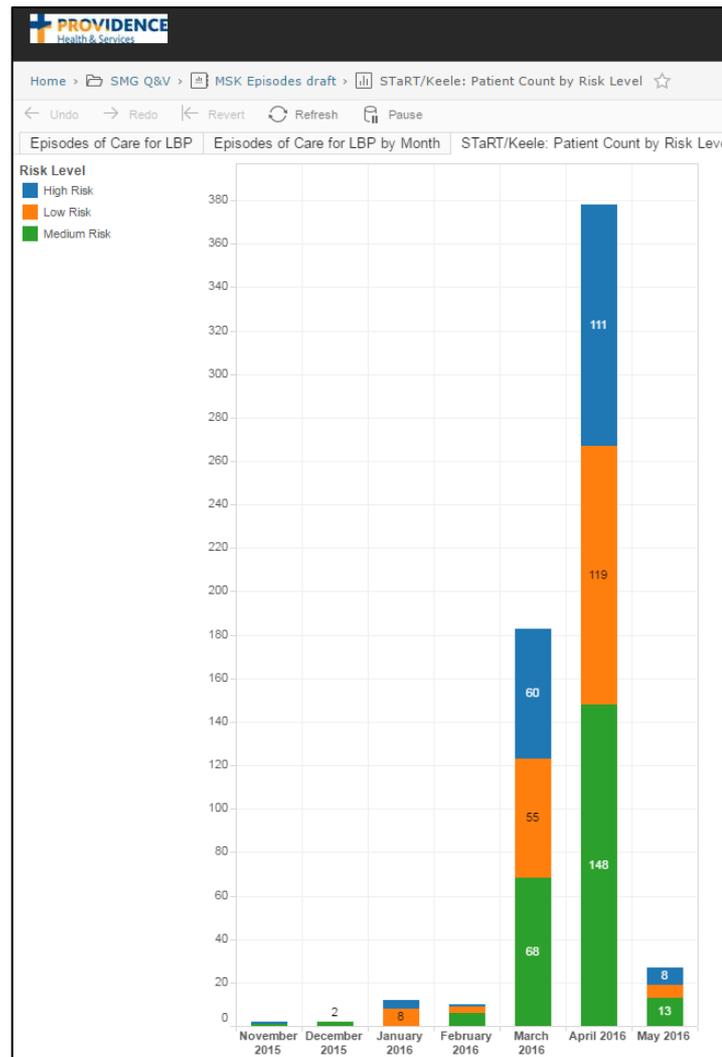
- 49,000 patients with 56,000 episodes of LBP in past year
- Approx. 4,500 LBP episodes per month
- Average length of LBP Episode: 26 days
- *LBP Episode: a consultation or series of consultations for low back pain preceded and followed by 3 months without consultation for low back pain¹*



1. de Vet HC, Heymans MW, Dunn KM, Pope DP, van der Beek AJ, Macfarlane GJ, Bouter LM, Croft PR. Spine (Phila Pa 1976). 2002 Nov 1; 27(21):2409-16.

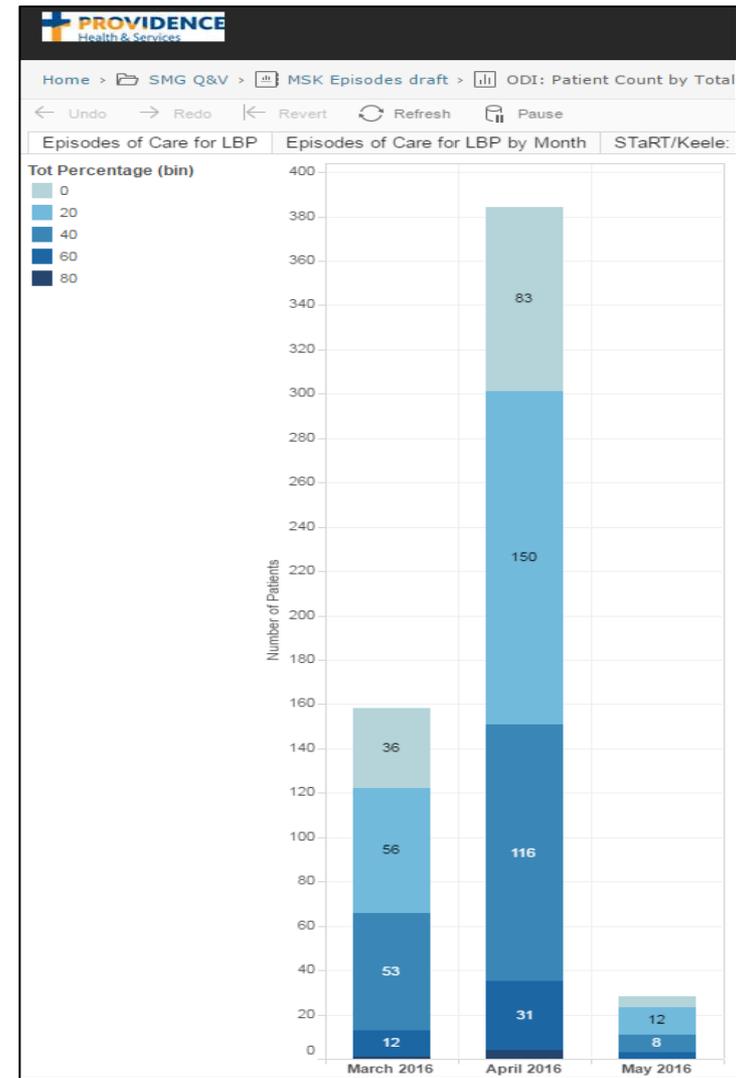
STarT Back Screening Tool for Risk Assessment

- Implementing STarT Back Screening tool for risk assessment and treatment pathway assignment
- 614 STarT Backs completed to date
 - 31% Low Risk
 - 39% Medium Risk
 - 30% High Risk



Oswestry Disability Index

- Quantifying disability with the Oswestry Disability Index (ODI)
- 570 ODIs completed:
 - 22% Minimal Disability
 - 38% Moderate Disability
 - 31% Severe Disability
 - 8% Crippling Back Pain
 - 1% Bed-bound



Providence Occupational Medicine Program

“Working together for a healthier workforce”

(Internal initiatives on behalf of employers)

Development of specific care pathways

- ED, UC, PCP, Ortho, Neuro, Outpatient Therapy
- ✓ Increases access
- ✓ Facilitates utilization of the appropriate care setting
- ✓ Efficiently coordinates care reducing over utilization of services
- ✓ Expedites return to employment process
- ✓ Enhances Outcomes

Provision of integrated services

- Combined medical specialty with onsite outpatient therapies specific to this patient population
- ✓ Promotes convenience, productivity
- ✓ Expedites

Standardization of paperwork

- Centralized management of claim initiation documents
- ✓ Enhanced patient experience
- ✓ Reduction in claim length
- ✓ Enhances outcomes

Employer Engagement

- Creation of Employer Advisory Committee
- ✓ Aligns the needs of employers with the delivery system
- Collaboration with third Party Administrators and Retro

Added Services

- In clinic impairment ratings
- Onsite exposure / inoculation response team
- Comprehensive bloodborne pathogen program

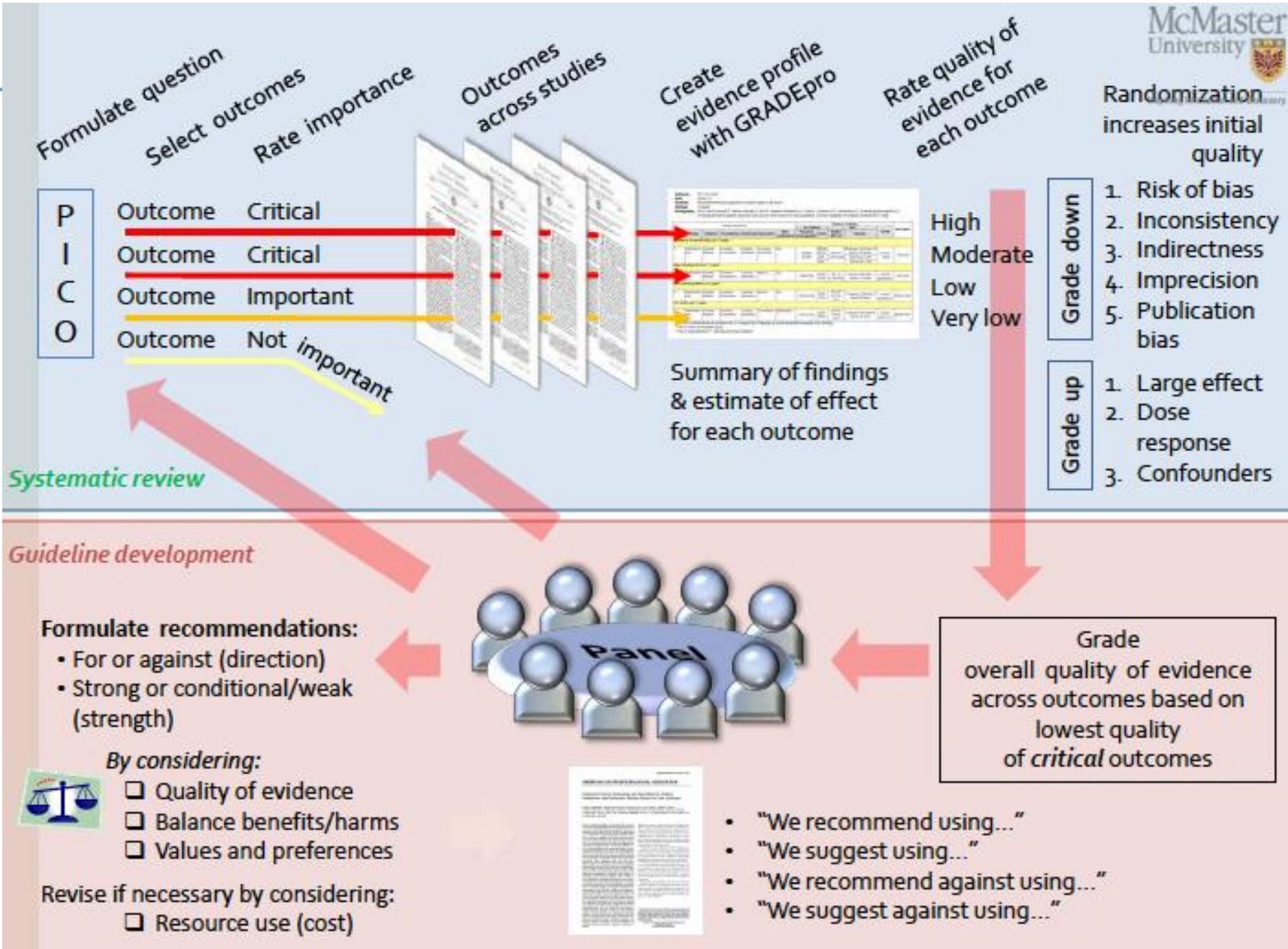
Product Development

- Customized Employer Reporting
- ✓ Utilization, Cost Prevention, Safety, Wellness
- Employer protocol data base
- ✓ Identification and adherence to specific employer processes
- System outcome tracking
- ✓ Best practice development



Summary

- EBM is at a “tipping point”
- Incentives from payors, federal, state, and hospital systems are helping to shift EBM from an academic exercise to more pragmatic “patient” vs “subject” outcomes
- National Pain Strategy and MACRA in line with focus on EBM
- Need to adjust “hierarchy” of evidence, value of observational data, “active ingredients”
- Critical need monitor for bias and “misuse” of evidence



Evidence Based Medicine

“The *conscientious, explicit and judicious* use of current best evidence in making decisions about the care of individual patients.”

1. Evidence-based medicine. A new approach to teaching the practice of medicine. *JAMA* 1992;268:2420-5.

Thanks



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Evidence-Based Resources

- Centre for Evidence Based Medicine: <http://www.cebm.net>
- Cochrane Reviews:
<http://www.thecochranelibrary.com/view/0/index.html>
- JAMA evidence: www.jamaevidence.com
- Johns Hopkins University Welch Medical Library: Evidence Based Medicine Resources: <http://www.welch.jhu.edu/internet/ebr.html>
- National Guideline Clearing House: <http://guideline.gov/>
- University of Washington Healthlinks: Evidence-Based Practice:
<http://libguides.hsl.washington.edu/ebp>