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

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Disclosures

Consulting:
Collegium
Daiichi Sankyo
Endo
MyMatrixx
Pfizer
Scilex
Teva

Research:
Grunenthal
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
• 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
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 changed 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)

Find the relevant papers

Quality
- Randomized?
- Double-blind?
- Withdrawals?

Credibility
- Sufficient patients?
- Sensible symptoms?
- Credible analysis?

Utility
- Extract useful outcomes
  - NNT and NNH
- Compare with practice

Moore A, McQuay H. *Bandolier’s Little Book of Making Sense of Medical Evidence.*
Evidence Hierarchy

Randomized Controlled trial
Non-randomized Controlled trial
Prospective cohort study
Retrospective cohort study
Case control study

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

BIAS
### Criteria for Levels of Evidence and Grade of Recommendation

<table>
<thead>
<tr>
<th>Level of Evidence</th>
<th>Grade</th>
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<tbody>
<tr>
<td><strong>Level I</strong>: Large randomized trials with clear-cut results</td>
<td><strong>A</strong>: Supported by at least one Level I randomized trial</td>
</tr>
<tr>
<td><strong>Level II</strong>: Small randomized trials with uncertain results and moderate risk of error</td>
<td><strong>B</strong>: Supported by at least one Level II</td>
</tr>
<tr>
<td><strong>Level III</strong>: Nonrandomized, contemporaneous controls</td>
<td><strong>C</strong>: Supported only by Level III, IV, or V evidence</td>
</tr>
<tr>
<td><strong>Level IV</strong>: No controls, case series only</td>
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</tbody>
</table>

Sackett, 1989.
“Evidence Based Medicine”

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

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

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

- RCTs
  - High level recommendation

- Observational studies
  - Low level recommendation

Grade

- Quality of evidence
- Balance between benefits, harms & burdens
- Patients’ values & preferences
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

http://www.gradeworkinggroup.org
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

<table>
<thead>
<tr>
<th>Study design</th>
<th>Initial evidence type</th>
<th>Criteria for moving DOWN</th>
<th>Criteria for moving UP</th>
<th>Final Evidence Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Randomized Controlled Trial (RCT)</td>
<td>1</td>
<td>Risk of bias</td>
<td>Strength of Association</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Inconsistency</td>
<td>Dose-Response</td>
<td>2</td>
</tr>
<tr>
<td>Observational Study</td>
<td>3</td>
<td>Indirectness</td>
<td>Direction of all plausible residual confounding or bias</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Publication Bias</td>
<td></td>
<td>4</td>
</tr>
<tr>
<td>Evidence Type</td>
<td>Description</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>---------------</td>
<td>-------------</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>One can be very confident that true effect lies close to that of the estimate of the effect</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>True effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>3</td>
<td>Confidence in the effect estimate is limited and the true effect might be substantially different from the estimate of the effect</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>One has very little confidence in the effect estimate, and true effect is likely to substantially different from estimate of effect</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Insufficient evidence</td>
<td>No studies are present</td>
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</table>
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

<table>
<thead>
<tr>
<th>Study 1</th>
<th>Study 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feedback on diaries</td>
<td>Assessment of readiness to change</td>
</tr>
<tr>
<td>Reinforcement</td>
<td>Attitude change</td>
</tr>
<tr>
<td>Recommendations for change</td>
<td>Goal setting</td>
</tr>
<tr>
<td>Answers to questions</td>
<td>Specific behavior advice</td>
</tr>
<tr>
<td>General support</td>
<td></td>
</tr>
</tbody>
</table>

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
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

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<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>Acetaminophen vs. NSAID</td>
<td>Unable to estimate</td>
<td>1 RCT</td>
<td>Insufficient</td>
<td>Unable to estimate</td>
<td>1 RCT</td>
<td>Insufficient</td>
</tr>
<tr>
<td>NSAID vs. NSAID</td>
<td>No difference</td>
<td>6 RCTs</td>
<td>Moderate</td>
<td>--</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Opioid vs. NSAID</td>
<td>Unable to estimate (inconsistent)</td>
<td>3 RCTs</td>
<td>Insufficient</td>
<td>No difference</td>
<td>1 RCT</td>
<td>Insufficient</td>
</tr>
<tr>
<td>Long-acting opioid vs. long-acting opioid</td>
<td>No clear difference</td>
<td>4 RCTs</td>
<td>Moderate</td>
<td>No clear difference</td>
<td>4 RCTs</td>
<td>Moderate</td>
</tr>
<tr>
<td>Long-acting opioid vs. short-acting opioid</td>
<td>No clear difference*</td>
<td>6 RCTs</td>
<td>Low</td>
<td>--</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Benzodiazepine (diazepam) vs. skeletal muscle relaxant</td>
<td>No difference</td>
<td>1 RCT</td>
<td>Low</td>
<td>--</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Skeletal muscle relaxant vs. skeletal muscle relaxant</td>
<td>No clear difference</td>
<td>1 SR (2 RCTs)</td>
<td>Low</td>
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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
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.
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, March 15, 2016.
CDC Guidelines for Opioids: Process

Evidence:
• APS/AAPM Opioid Guidelines 2009
• AHRQ systematic review of 2014

Process:
• Core Exert 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)
• 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
When to initiate or continue

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

Risk Management

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
- 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

ASSESSING RISK AND ADDRESSING HARMs OF OPIOID USE
- Evaluate risk factors for opioid-related harms
- Check POMP 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

**1. When to initiate or continue opioids**

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

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

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

<table>
<thead>
<tr>
<th>Number and Coverage Topic</th>
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</thead>
<tbody>
<tr>
<td>20110318B – Spinal Injections</td>
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**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 at 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

Multispecialty Pain Workgroup (MPW), 2015
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.
“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?

<table>
<thead>
<tr>
<th>Group</th>
<th>Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospitals / Clinics</td>
<td>• Support or sustain a LBP quality improvement program that includes measuring patients’ functional status over time using the Oswestry Disability Index</td>
</tr>
<tr>
<td></td>
<td>• 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</td>
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<tr>
<td></td>
<td>• Take steps to integrate evidence-based guidelines, scripts, shared decision making, and patient education materials into clinical practice and workflow</td>
</tr>
<tr>
<td></td>
<td>• Take steps to integrate comprehensive patient education and effective messaging into clinical practice and workflow for low back pain patients</td>
</tr>
<tr>
<td>Individual Providers</td>
<td>• Establish referral relationships with physical medicine and rehabilitation physicians, also known as physiatrists</td>
</tr>
<tr>
<td></td>
<td>• 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</td>
</tr>
</tbody>
</table>
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

- Define Population
- Identify Care Gaps
- Stratify Risks
- Manage Care
- Engage Patients
- Automated & Ongoing
  - Data Integration
  - Analysis
  - Reporting
  - Communications
- Measure Outcomes
Swedish Eastside Integrated Spine Program
EBM Care Pathways for LBP

Level I: MSK Lifestyle
  *Education

Level II: PCP+
  Who treats?
  What tools?
  How Long?
  When to refer & to whom?
  Measure what?

Level III: NSMSK
  Who treats?
  What tools?
  How Long?
  When to refer & to whom?
  Measure what?

Level IV: Surgical Care
  Who treats?
  What tools?
  How Long?
  When to refer & to whom?
  Measure what?

Level V: Chronic Pain Mgmt.
  Who treats?
  What tools?
  How Long?
  When to refer & to whom?
  Measure what?
## Low Back Pain Metrics

### Metric Set

<table>
<thead>
<tr>
<th>Metric Set</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICHOM</td>
</tr>
<tr>
<td>SCOAP</td>
</tr>
<tr>
<td>PROMIS</td>
</tr>
<tr>
<td>CERTAIN</td>
</tr>
<tr>
<td>STRONG FOR SURGERY</td>
</tr>
</tbody>
</table>

### Patient Reported Outcome (PRO)Tools TONIC

<table>
<thead>
<tr>
<th>Dimension</th>
</tr>
</thead>
<tbody>
<tr>
<td>PAIN</td>
</tr>
<tr>
<td>FUNCTION</td>
</tr>
<tr>
<td>QUALITY OF LIFE</td>
</tr>
<tr>
<td>SATISFACTION</td>
</tr>
<tr>
<td>ABSENTEEISM</td>
</tr>
</tbody>
</table>

### Process Measures (IT analytics)

- **Use of Medical Resources:** IMAGING, MEDICATIONS, PT, INJECTIONS, SURGERY
- **Timeliness of Care**
- **Adherence to Pathway**
- **Time to Recover**
- **Pathway Entry and Exit**
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**
Swedish Eastside Integrated Spine Program

Level I  **MSK Lifestyle (Under development)**

Level II  **Primary Care providers and extenders**

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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 pain

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
  - Expedites

## Employer Engagement
- Creation of Employer Advisory Committee
  - Aligns the needs of employers with the delivery system
  - Enhanced patient experience
  - Reduction in claim length
  - Enhances outcomes

## 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
Guideline development

Formulate recommendations:
- For or against (direction)
- Strong or conditional/weak (strength)

By considering:
- Quality of evidence
- Balance benefits/harms
- Values and preferences

Revise if necessary by considering:
- Resource use (cost)

Grade overall quality of evidence across outcomes based on lowest quality of critical outcomes

- “We recommend using…”
- “We suggest using…”
- “We recommend against using…”
- “We suggest against using…”

Systematic review

Randomization increases initial quality
1. Risk of bias
2. Inconsistency
3. Indirectness
4. Imprecision
5. Publication bias

Grade down
1. Large effect
2. Dose response
3. Confounders

Grade up
High
Moderate
Low
Very low

Summary of findings & estimate of effect for each outcome

PICO
- Outcome Critical
- Outcome Critical
- Outcome Important
- Outcome Not important

Create evidence profile with GRADEpro

Outcomes across studies

Rate quality of evidence for each outcome
Evidence Based Medicine

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

Thanks

steven.stanos@swedish.org
Evidence-Based Resources

- Centre for Evidence Based Medicine: http://www.cebm.net
- JAMA evidence: www.jamaevidence.com
- Johns Hopkins University Welch Medical Library: Evidence Based Medicine Resources: http://www.welch.jhu.edu/internet/ebr.html
- University of Washington Healthlinks: Evidence-Based Practice: http://libguides.hsl.washington.edu/ebp