Discussion: Evidence-Informed Clinical Practice, Outcome Measures and Core Competencies that Advance Value-Based, Person-Centered Pain Management

MODERATOR
Ravi Prasad, PhD
Pain Psychologist
University of California-Davis School of Medicine

Shari Ling, MD
Deputy Chief Medical Officer
Centers for Medicare and Medicaid Services

Adam Seidner, MD, MPH
Chief Medical Officer
The Hartford

Christine Goertz, PhD, DC
Professor of Musculoskeletal Research
Duke Clinical Research Institute
Chair
PCORI Board of Governors

Belinda Anderson, PhD, MA(Ed), LAc
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Alliance to Advance Comprehensive Integrative Pain Management

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Evidence-Informed Clinical Practice, Outcome Measures and Core Competencies that Advance Value-Based, Person-Centered Pain Management - Considering the impact of coverage determinations on patient experience

Shari M. Ling, MD

Acting Chief Medical Officer

Centers for Medicare & Medicaid Services

Alliance to Advance Comprehensive Integrative Pain Management Symposium on May 13-14, 2020

Disclaimer & Financial Disclosure

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This presentation is a general summary that explains certain aspects of the Medicare Program, but is not a legal document. The official Medicare Program provisions are contained in the relevant laws, regulations, and rulings. Medicare policy changes frequently, and links to the source documents have been provided within the document for your reference

The Centers for Medicare & Medicaid Services (CMS) employees, agents, and staff make no representation, warranty, or guarantee that this compilation of Medicare information is error-free and will bear no responsibility or liability for the results or consequences of the use of this guide.

No financial conflicts to disclose

HHS Department-Level Strategy

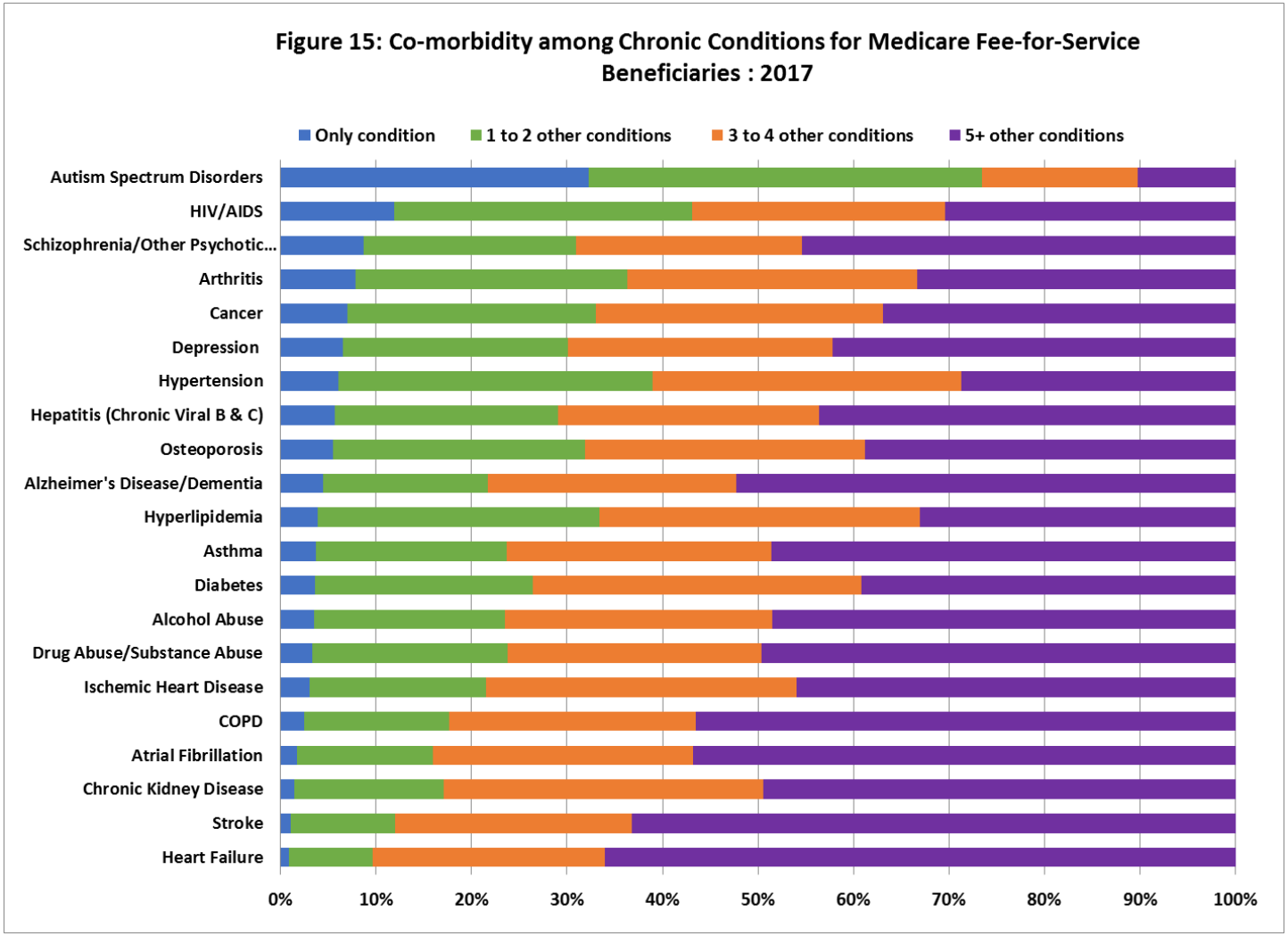
a health care system that results in better accessibility, quality, affordability, empowerment, and innovation

CMS has started a national conversation about **improving the health care delivery system**, how Medicare can contribute to making the delivery system less bureaucratic and complex, and how we can **reduce burden for clinicians, providers and beneficiaries** in a way that **increases quality of care** and decreases costs – **making the health care system more effective,** simple, and accessible, while maintaining program integrity and preventing fraud

Size and Scope of CMS Responsibilities

- CMS is the largest purchaser of health care in the world
- Combined, Medicare and Medicaid pay approximately one-third of national health expenditures (approx $800B)
- CMS covers 140 million people through Medicare, Medicaid, the Children's Health Insurance Program; or roughly 1 in every 3 Americans
- The Medicare program alone pays out over $1.5 billion in benefit payments per day
- Through various contractors, CMS processes over 1.2 billion fee-for-service claims and answers about 75 million inquiries annually

Co-morbidity among Chronic Conditions



Medicare Coverage of Acupuncture for Chronic Low Back Pain

- Effective January 1, 2020, CMS will cover acupuncture for chronic low back pain under section 1862(a)(1)(A) of the Social Security Act.
- Up to 12 visits in 90 days are covered for Medicare beneficiaries under the following circumstances:
- For the purpose of this decision, chronic low back pain (cLBP) is defined as:
  - Lasting 12 weeks or longer;
  - nonspecific, in that it has no identifiable systemic cause (i.e., not associated with metastatic, inflammatory, infectious, etc. disease);
  - not associated with surgery; and
  - not associated with pregnancy.
- An additional eight sessions will be covered for those patients demonstrating an improvement.
- No more than 20 acupuncture treatments may be administered annually.
- Treatment must be discontinued if the patient is not improving or is regressing.

Medicare Coverage of Acupuncture for Chronic Low Back Pain

- Physicians (as defined in 1861(r)(1))* may furnish acupuncture in accordance with applicable state requirements.
- Physician assistants, nurse practitioners/clinical nurse specialists (as identified in 1861(aa)(5)), and auxiliary personnel may furnish acupuncture if they meet all applicable state requirements and have:
  - A masters or doctoral level degree in acupuncture or Oriental Medicine from a school accredited by the Accreditation Commission on Acupuncture and Oriental Medicine (ACAOM); and
  - current, full, active, and unrestricted license to practice acupuncture in a State, Territory, or Commonwealth (i.e. Puerto Rico) of the United States, or District of Columbia.
- Auxiliary personnel furnishing acupuncture must be under the appropriate level of supervision of a physician, physician assistant, or nurse practitioner/clinical nurse specialist required by our regulations at 42 CFR §§ 410.26 and 410.27.
- All types of acupuncture, including dry needling, for any condition other than chronic low back pain are non-covered by Medicare.

*(r) The term “physician”, when used in connection with the performance of any function or action, means (1) a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he performs such function or action (including a physician within the meaning of section 1101(a)(7))

Medicare Coverage Construct: Social Security Act 1862(a)(1)

- **Reasonable and Necessary**

  Notwithstanding any other provision of this title, **no payment may be made** under part A or part B for any expenses incurred for items or services -

  - (A) which, … are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, …
  - (E) in the case of research conducted pursuant to §1142, which is not reasonable and necessary to carry out the purposes of that section, …

- **Defined Benefit Program**
  - Beneficiaries
    - Age ≥ 65 years
    - Disabled individuals
    - End stage renal disease
  - Providers
  - Settings

National and Local Coverage Determinations

The evidence:

- **Sufficient** evidence to conclude that the item or service **improves clinically meaningful health outcomes** for the **Medicare population**
- Based on a comprehensive review of published evidence

National

Definition: Determination by the Secretary with respect to whether or not a particular item or service is covered nationally under § 1862(a)(1)(A) .

CED: § 1862(a)(1)(E) in the case of research conducted pursuant to § 1142, which is not reasonable and necessary. .

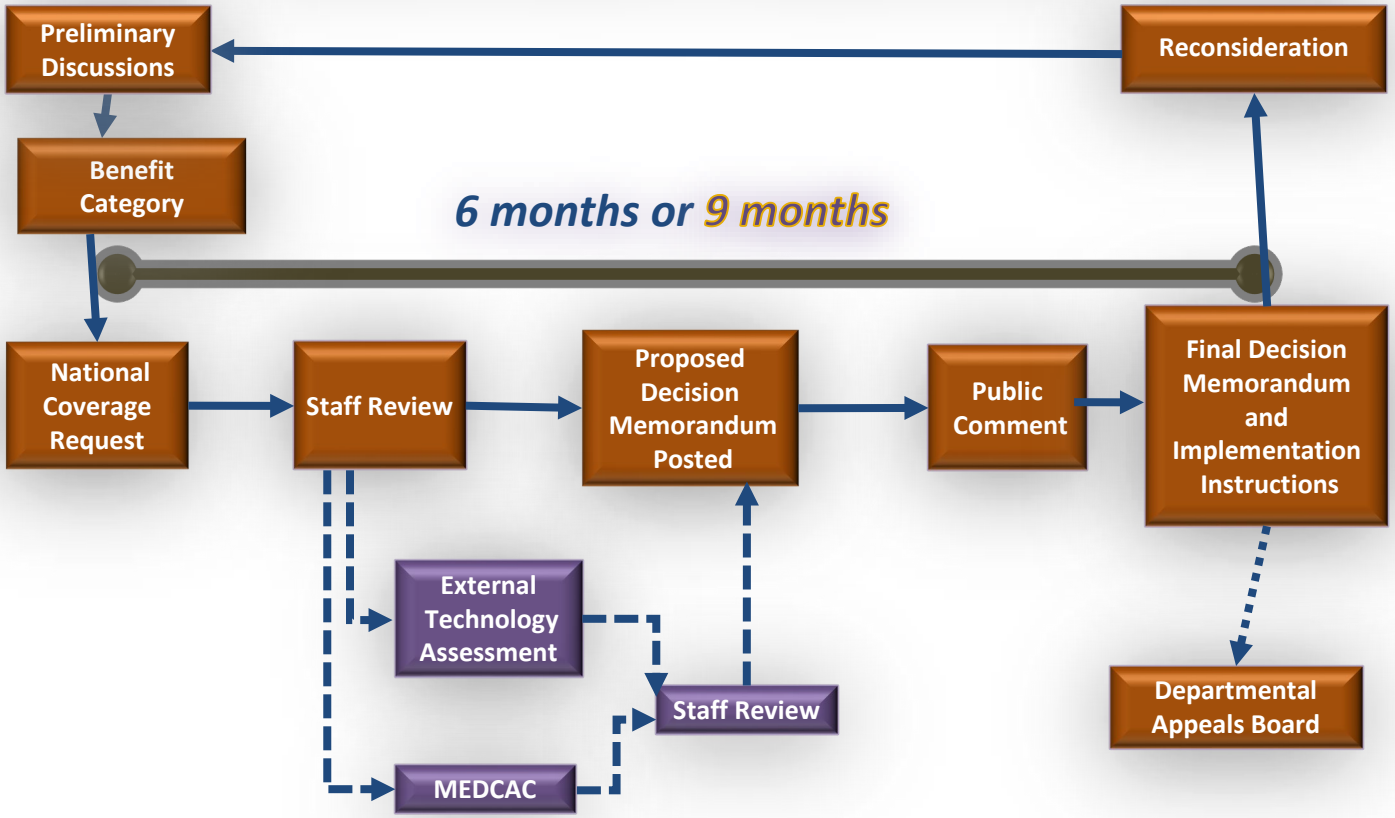
Prevention/Screening: Reasonable and necessary for the prevention or early detection of illness or disability under § 1861(d).

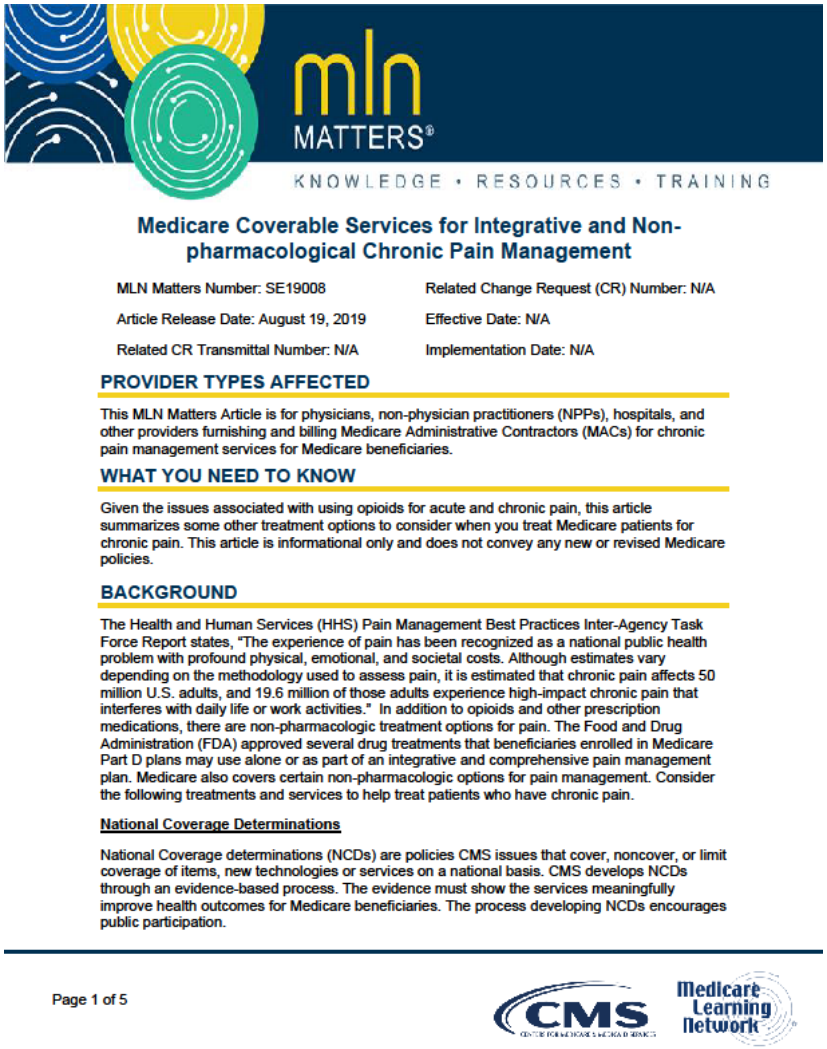
Local

Definition: Determination by a Medicare Administrative Contractor (MAC) with respect to whether or not a particular item or service is covered in the MAC jurisdictions under §1862(a)(1)(A).

EVIDENCE GAPS REMAIN - OLDER ADULTS ARE NEEDED IN CLINICAL TRIALS

MEDICARE NATIONAL COVERAGE PROCESS





mln MATTERS®

KNOWLEDGE • RESOURCES • TRAINING

Medicare Coverable Services for Integrative and Non-pharmacological Chronic Pain Management

MLN Matters Number: SE19008 | Related Change Request (CR) Number: N/A

Article Release Date: August 19, 2019 | Effective Date: N/A

Related CR Transmittal Number: N/A | Implementation Date: N/A

PROVIDER TYPES AFFECTED

This MLN Matters Article is for physicians, non-physician practitioners (NPPs), hospitals, and other providers furnishing and billing Medicare Administrative Contractors (MACs) for chronic pain management services for Medicare beneficiaries.

WHAT YOU NEED TO KNOW

Given the issues associated with using opioids for acute and chronic pain, this article summarizes some other treatment options to consider when you treat Medicare patients for chronic pain. This article is informational only and does not convey any new or revised Medicare policies.

BACKGROUND

The Health and Human Services (HHS) Pain Management Best Practices Inter-Agency Task Force Report states, "The experience of pain has been recognized as a national public health problem with profound physical, emotional, and societal costs. Although estimates vary depending on the methodology used to assess pain, it is estimated that chronic pain affects 50 million U.S. adults, and 19.6 million of those adults experience high-impact chronic pain that interferes with daily life or work activities." In addition to opioids and other prescription medications, there are non-pharmacologic treatment options for pain. The Food and Drug Administration (FDA) approved several drug treatments that beneficiaries enrolled in Medicare Part D plans may use alone or as part of an integrative and comprehensive pain management plan. Medicare also covers certain non-pharmacologic options for pain management. Consider the following treatments and services to help treat patients who have chronic pain.

National Coverage Determinations

National Coverage determinations (NCDs) are policies CMS issues that cover, noncover, or limit coverage of items, new technologies or services on a national basis. CMS develops NCDs through an evidence-based process. The evidence must show the services meaningfully improve health outcomes for Medicare beneficiaries. The process developing NCDs encourages public participation.

Page 1 of 5

CMS | Medicare Learning Network®

- **Additional National Policies to Care for Medicare Beneficiaries with Chronic Pain**
- Beneficiaries with multiple (two or more) chronic conditions that you expect will last at least 12 months or until the death of the patient, and that place the patient at significant risk of death, acute exacerbation, decompensation, or functional decline can get Chronic Care Management (CCM) services, or Complex CCM services. An MLN Matters article is available at https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnproducts/downloads/chroniccaremanagement.pdf.
- Medicare also covers Behavioral Health Integration Services for treatment of behavioral health, or psychiatric conditions, including substance use disorders. These services use a care team approach to facilitate and coordinate behavioral health treatment regardless of if the diagnosis or diagnoses are pre-existing or newly diagnosed. These services may benefit some beneficiaries who have a co-occurring behavioral health condition(s). Please see https://www.cms.hgov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/BehavioralHealthIntegration.pdf for more information.
- These and other care management services can give your patients the medical care and coordination services they need to help manage their pain, and other chronic conditions. You can bill these services for 30-day or one month periods and may include activities you or your clinical staff perform. You can get more information at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Care-Management.html.
- Medicare's Initial Preventive Physical Exam (IPPE) and subsequent Annual Wellness Visits (AWV) to help detect illnesses in the earliest stages to evaluate your patients' pain severity, and to review the current treatment plan

CMS, Pain, and the SUPPORT for Patients and Communities Act

- Section 6032 of the SUPPORT Act requires an Action Plan to address payment and coverage for therapies and devices that manage acute and chronic pain, recommend demonstration models, examine access to care in underserved communities, and submit a Report to Congress that summarizes the plan and describes next steps. CMS Consulted with the Pain Best Practices Task force and took public comment throughout the process of developing the draft Action Plan
- Section 6086 of the Act is the Dr. Todd Graham Pain Management Study, which requires a Report to Congress on how to improve Medicare coverage and payment for non-opioid treatments, including those that could augment opioids; support integrated care; minimize the risk of substance use disorders (SUD), address the needs of beneficiaries with mental disorders and suicide; examine health disparities, outline strategies for beneficiaries with OUD and SUD; furnish education on drugs co-prescribed with opioids that increase risk; create a beneficiary education tool. The Study includes an impact analysis on the anticipated costs to Medicare in implementing new services or treatments to manage acute and chronic pain

Thank you!

Contact

Shari Ling, MD

Acting CMS Chief Medical Officer

Shari.ling@cms.hhs.gov

Discussion: Evidence-Informed Clinical Practice, Outcome Measures and Core Competencies that Advance Value-Based, Person-Centered Pain Management

Christine Goertz, PhD, DC

Professor of Musculoskeletal Research
Duke Clinical Research Institute
Chair
PCORI Board of Governors

Alliance to Advance Comprehensive Integrative Pain Management

AACIPM
Innovation & Progress in Person-Centered Pain Management

A Virtual Symposium | May 14, 2020

Christine Goertz, DC, PhD,
Duke University, Department of Orthopaedic Surgery
The Spine Institute for Quality - University of Iowa, Department of Epidemiology

Duke Orthopaedic Surgery

Duke Clinical Research Institute | MUSCULOSKELETAL

Outcomes in Integrated Pain Management

Examples

- **Patient Reported Outcomes (PROs)**
  - Pain Intensity
  - Pain Interference
  - Physical Function
- **Patient Satisfaction**
- **Adverse Events**
- **Costs**
- **Healthcare Utilization**
- **Medication Usuage**

Who Decides What Outcomes Matter?

Examples of Outcomes Data Sources

- Electronic Health Records (EHR)
- Insurer Claims Data
- Clinical Data Registries
- Public Records
- Research Studies
- Wearables/Smart phones

Research Studies

Spine

SPINE Volume 39, Number 14, pp 1128-1143

EPIDEMIOLOGY

Report of the NIH Task Force on Research Standards for Chronic Low Back Pain

Richard A. Deyo,* Samuel F. Dworkin,† Dagmar Amtmann,† Gunnar Andersson,‡ David Borenstein,§ Eugene Carragee,¶ John Carrino,‖ Roger Chou,* Karon Cook,** Anthony DeLitto,†† Christine Goertz,‡‡ Partap Khalsa,§§ John Loeser,† Sean Mackey,¶ James Panagis,¶¶ James Rainville,‖‖ Tor Tosteson,*** Dennis Turk,† Michael Von Korff,††† and Debra K. Weiner††

Despite rapidly increasing intervention, functional disability due to chronic low back pain (cLBP) has increased in recent decades. We often cannot identify mechanisms to explain the major negative impact cLBP has on patients' lives. Such cLBP is often termed nonspecific and may be due to multiple biologic and behavioral etiologies. Researchers use varied inclusion criteria, definitions, baseline assessments, and outcome measures, which impede comparisons and consensus. Therefore, NIH Pain Consortium charged a research task force to draft standards for research on cLBP. The resulting multidisciplinary panel recommended using 2 questions to define cLBP; classifying cLBP by its impact (defined by pain intensity, pain interference, and physical function); use of a minimum data set to describe research participants (drawing heavily on the Patient Reported Outcomes Measurement and facilitate future research addressing the genomic, neurological, and other mechanistic substrates of cLBP. We expect that the research task force recommendations will become a dynamic document and undergo continual improvement.

Perspective: A task force was convened by the NIH Pain Consortium with the goal of developing research standards for cLBP. The results included recommendations for definitions, a minimum data set, reporting outcomes, and future research. Greater consistency in reporting should facilitate comparisons among studies and the development of phenotypes.

Key words: low back pain, chronic low back pain, research standards, minimum data set, NIH Task Force.

Level of Evidence: N/A

Spine 2014;39:1128–1143

Spine

SPINE Volume 39, Number 14, pp 1128-1143

EPIDEMIOLOGY

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(drawing heavily on the Patient Reported Outcomes Measurement

Spine 2014;39:1128–1143

Clinical Data Registries

Clinical Data Registries

Identify	Identify best practices
Enhance	Enhance healthcare quality through feedback/benchmarking mechanisms
Open	Open dialogue between clinicians and payers/purchasers/policy-makers/stakeholders
Build	Build a community of chiropractors who are committed to data-driven healthcare delivery

Minimum Recommended Data Set for Spine-Related Registries

- Patient Characteristics
- Diagnosis and Co-morbidities
- Clinical Response
- Patient Reported Outcomes
- Medication Usage
- Adverse Events
- Utilization Data
- Cost
- Patient Satisfaction

Centers for Medicare and Medicaid (CMS)

CMS Quality Payment Program (QPP)

CMS QPP rewards value and outcomes in one of two ways:

1. Merit-based Incentive Payment System (MIPS)
2. Advanced Alternative Payment Models (APMs)

Examples of 2020 Performance Measures for Pain Management

- Functional Status After Lumbar Discectomy/Laminectomy
- Functional Status After Lumbar Fusion
- Functional Status Change for Patients with Hip Impairments
- Functional Status Change for Patients with Elbow, Wrist or Hand Impairments
- Functional Status Change for Patients with Knee Impairments
- Functional Status Change for Patients with Low Back Impairments
- Functional Status Change for Patients with Neck Impairments
- Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments
- Functional Status Change for Patients with Shoulder Impairments

Why are Outcomes Important?

Changing the way we pay for healthcare...

FROM VOLUME TO VALUE

What is Volume?

- Pay regardless of quality, outcomes
- Pay for every test & procedure, regardless of necessity
- Doesn't pay for important aspects of care, such as coordination

Why Payment Reform Matters

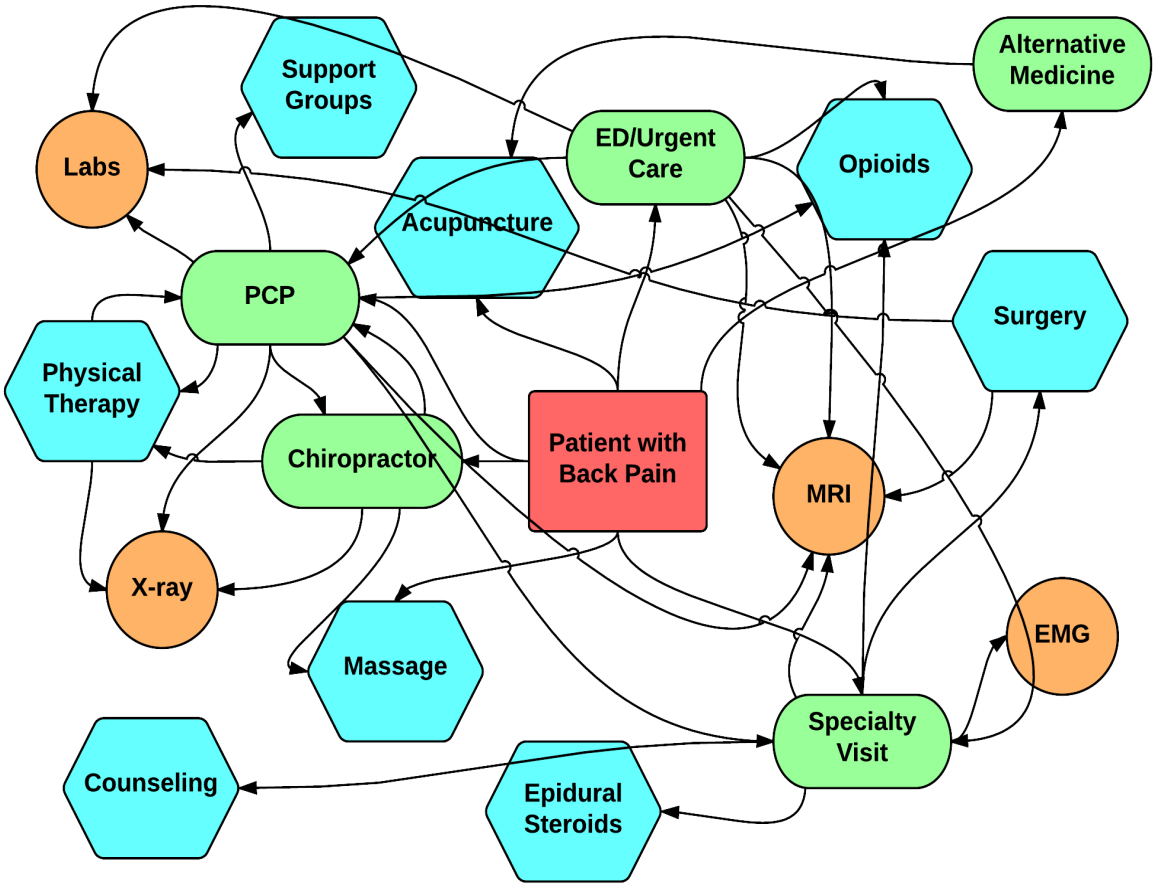
- Pay for care we want, including better prevention, coordination & disease management
- Don't pay for unnecessary care, such as duplicative tests
- Incentivize & reward providers for high-quality, efficient care
- Remove financial barriers to improving delivery of care

What is Value?

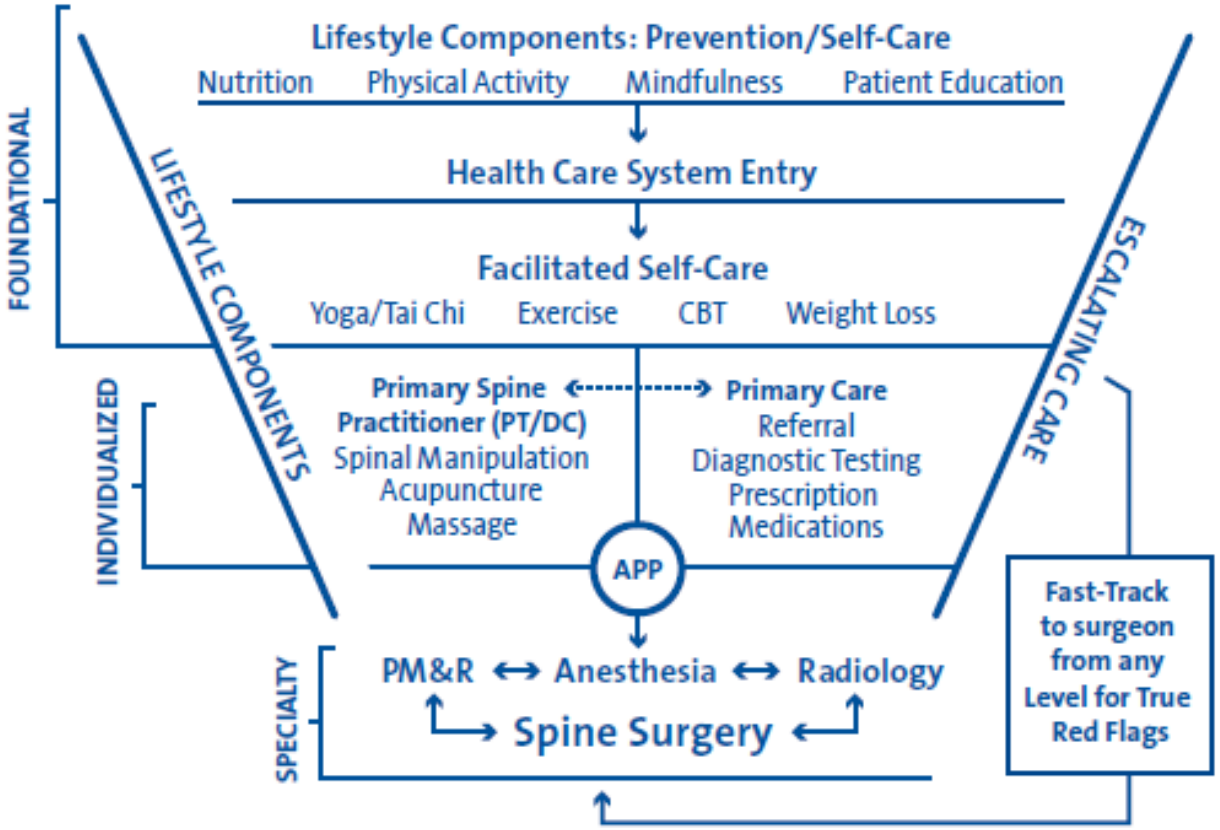
- Pay that reflects provider performance, such as quality & safety of care
- Payment methods designed to spur efficiency & reduce unnecessary spending
- Payment methods must address efficiency & quality

Outcomes Can Influence Patient Care

- **Cost**
- **Risk**
- **Best Practices – Diagnosis**
  - Consistency within and across providers
  - Correlation with treatment outcomes
- **Best Practices – Treatment**



Shared with permission from Dr. Brian Justice.


Lifestyle Components: Prevention/Self-Care
Nutrition
Physical Activity
Mindfulness
Patient Education
Health Care System Entry
Facilitated Self-Care
Yoga/Tai Chi
Exercise
CBT
Weight Loss
FOUNDATIONAL
LIFESTYLE COMPONENTS
ESCALATING CARE
INDIVIDUALIZED
Primary Spine Practitioner (PT/DC)
Spinal Manipulation
Acupuncture
Massage
Primary Care
Referral
Diagnostic Testing
Prescription
Medications
APP
SPECIALTY
PM&R ↔ Anesthesia ↔ Radiology
Spine Surgery
Fast-Track to surgeon from any Level for True Red Flags

CLINICAL GUIDELINES | 4 APRIL 2017

Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain: A Clinical Practice Guideline From the American College of Physicians FREE

*Amir Qaseem, MD, PhD, MHA; Timothy J. Wilt, MD, MPH; Robert M. McLean, MD; Mary Ann Forciea, MD; for the Clinical Guidelines Committee of the American College of Physicians **

Article, Author, and Disclosure Information

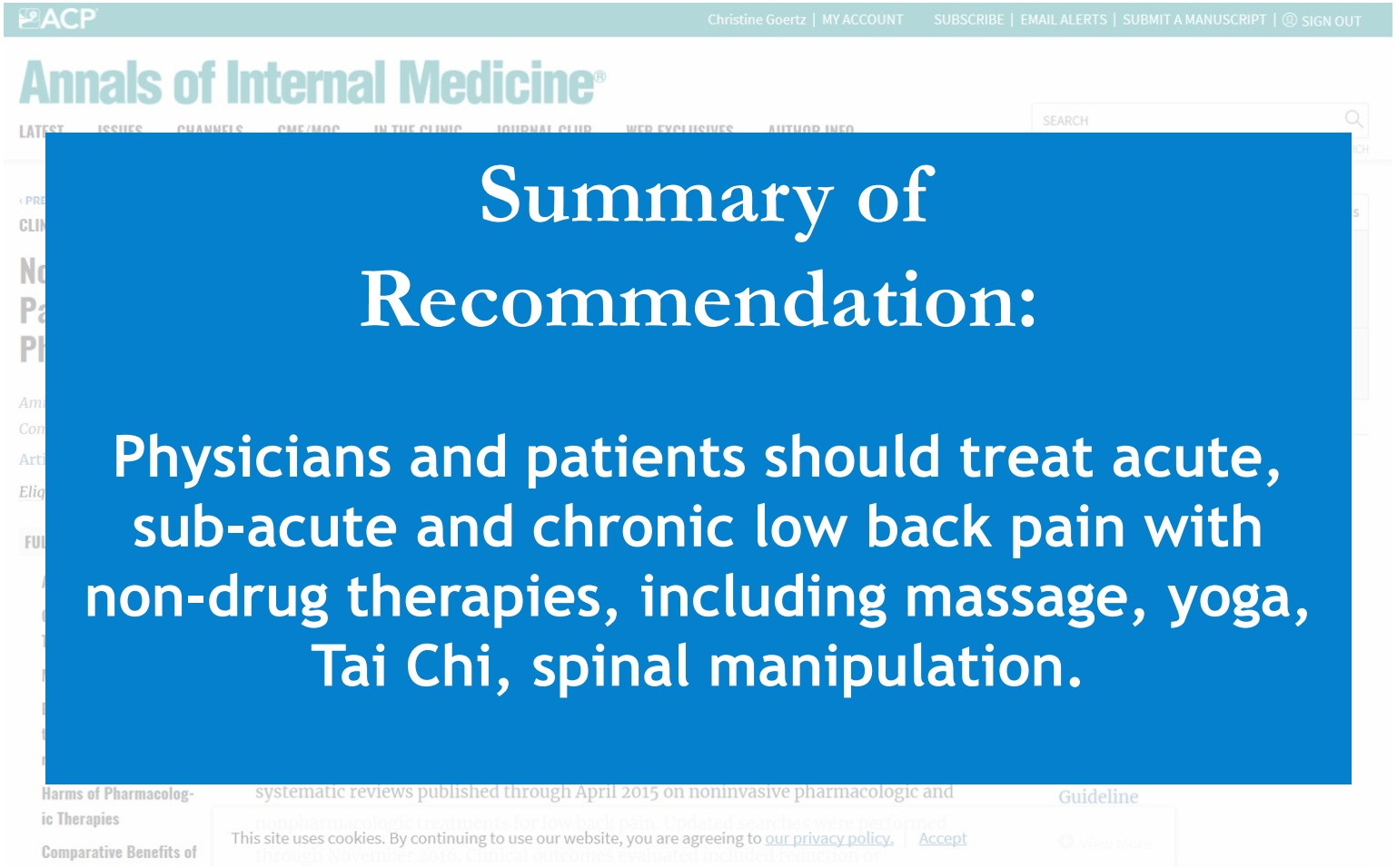
Eligible for CME Point of Care *Learn More*

Published: *Ann Intern Med.* 2017;166(7):514-530.
DOI: 10.7326/M16-2367
Published at *www.annals.org* on 14 February 2017

Abstract

Description: The American College of Physicians (ACP) developed this guideline to present the evidence and provide clinical recommendations on noninvasive treatment of low back pain.

Methods: Using the ACP grading system, the committee based these recommendations on a systematic review of randomized, controlled trials and systematic reviews published through April 2015 on noninvasive pharmacologic and nonpharmacologic treatments for low back pain. Updated searches were performed through November 2016. Clinical outcomes evaluated included reduction or



Summary of Recommendation:

Physicians and patients should treat acute, sub-acute and chronic low back pain with non-drug therapies, including massage, yoga, Tai Chi, spinal manipulation.

Problem

Quality? Consistency? Transparency?

Solution

Quality! Consistency! Transparency!

Thank you

Twitter: @ChristineGoertz

Discussion: Evidence-Informed Clinical Practice, Outcome Measures and Core Competencies that Advance Value-Based, Person-Centered Pain Management

Adam Seidner, MD, MPH
Chief Medical Officer
The Hartford

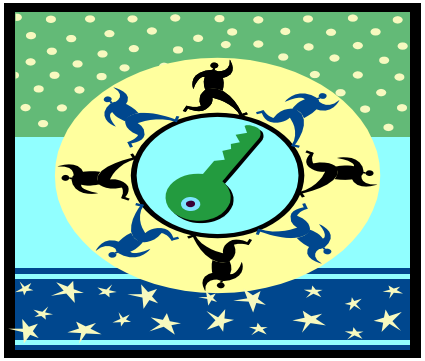
Alliance to Advance Comprehensive Integrative Pain Management

Payer Perspective: Evidence-Informed Clinical Practice, Outcome Measures and Core Competencies that Advance Value-Based, Person-Centered Pain Management - Considering the impact of coverage determinations on patient experience.

Adam Seidner MD MPH CIC
Chief Medical Officer
The Hartford
May 14, 2020

Outline

- Evidence Quality
- Payer perspective
- Value proposition
  - Patient preference
  - Shared decision making



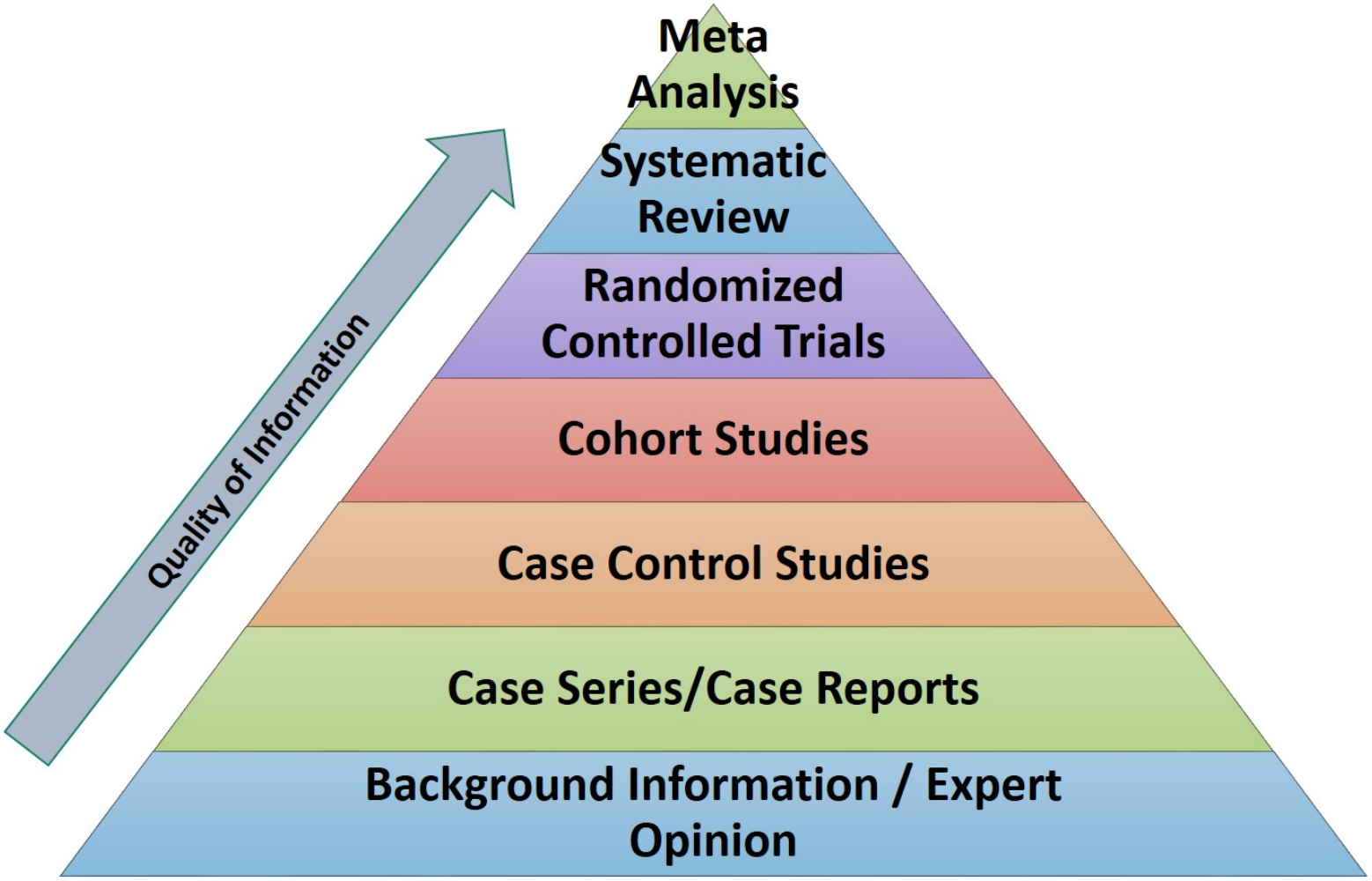
Evidence Quality

Medical Science:
Different Types of Studies
Experimental vs. Observational
Quality of Evidence = Strength of Recommendation

Consensus statement

- A comprehensive analysis by a panel of experts of a scientific or medical issue.
- The terms ‘recommendation’, ‘evidence-based’ and ‘guideline’ should not be used in the context of consensus statements.
- Findings of a consensus panel should be stated as ‘opinions’ or ‘suggestions’.

Evidence Pyramid



Payer perspective

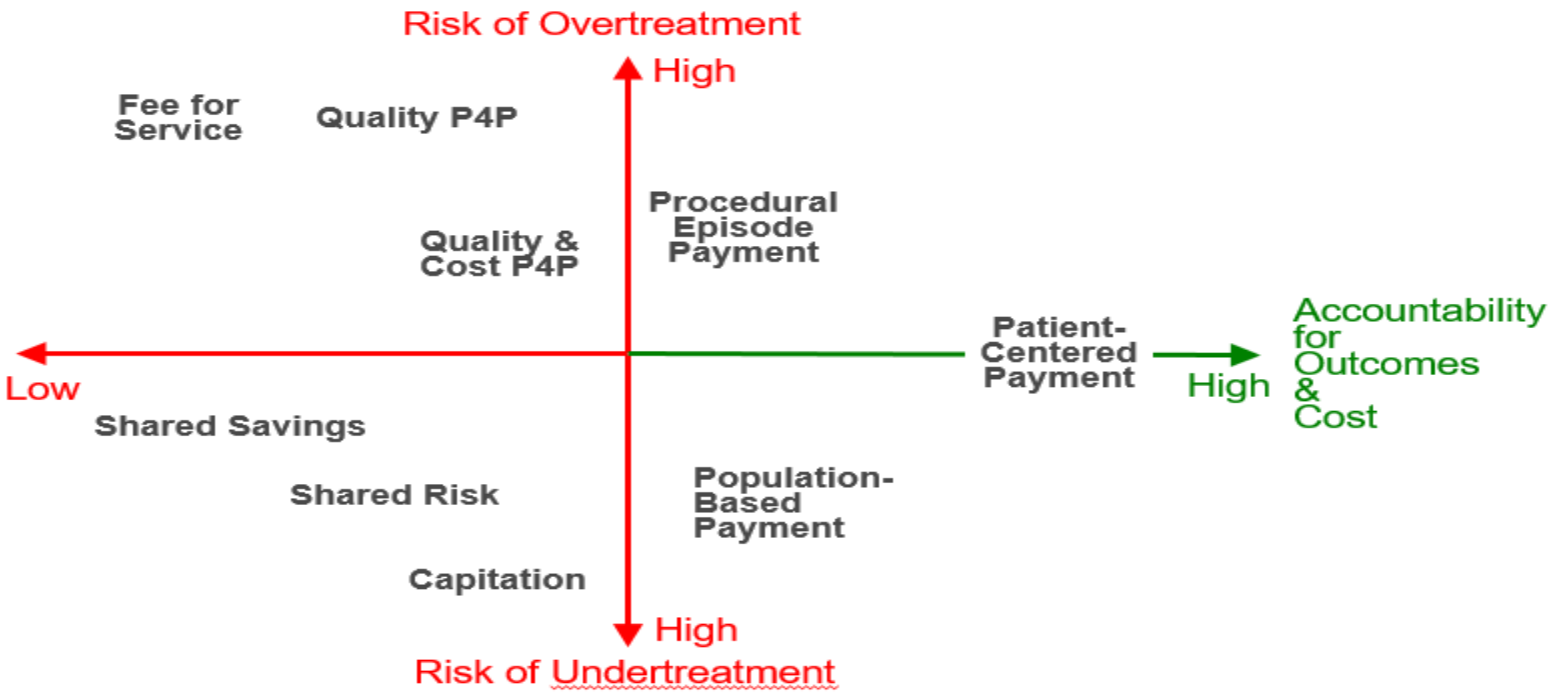
A complex process to increase the likelihood of making good decisions

- transparency
- consistency
- accountability

[Harold Miller: CHQPR]

Value proposition: Patient Centric

Pairing clinical outcomes with claims and cost data and collaboratively conducting well-designed pragmatic clinical or observational studies, all stakeholders can learn from more meaningful and relevant outcomes.



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THANK YOU

Discussion: Evidence-Informed Clinical Practice, Outcome Measures and Core Competencies that Advance Value-Based, Person-Centered Pain Management

Belinda Anderson, PhD, MA(Ed)., LAc
Director of the Institute for Health and Wellness
Monmouth University

Alliance to Advance Comprehensive Integrative Pain Management

Alliance to Advance Comprehensive Integrative Pain Management - Symposium on May 13-14, 2020

Panel: Evidence-Informed Clinical Practice, Outcome Measures and Core Competencies that Advance Value-Based, Person-Centered Pain Management

Considering the impact of coverage determinations on patient experience

Belinda (Beau) Anderson PhD, LAc
Director, Institute for Health and Wellness, Monmouth University
Associate Clinical Professor, Albert Einstein College of Medicine
Research Professor, Pacific College of Health and Science

Implications of Medicare Coverage of Acupuncture for cLBP

- Set a precedent
- Evidence-based

- Education – competencies, accreditation, training

- Implementation
  - Research → best practice guidelines → real world practice and settings
  - Complexity
  - ‘Comprehensive and integrative’

Implications - Precedent

- Legitimized - strength and quality of the research evidence
- Facilitate
  - Coverage by other payers
  - Coverage for other conditions (AACIPM repository)

- Implications for other complementary and integrative therapies
  - Build evidence base

  - Build education and licensing infrastructure

Implications - Education

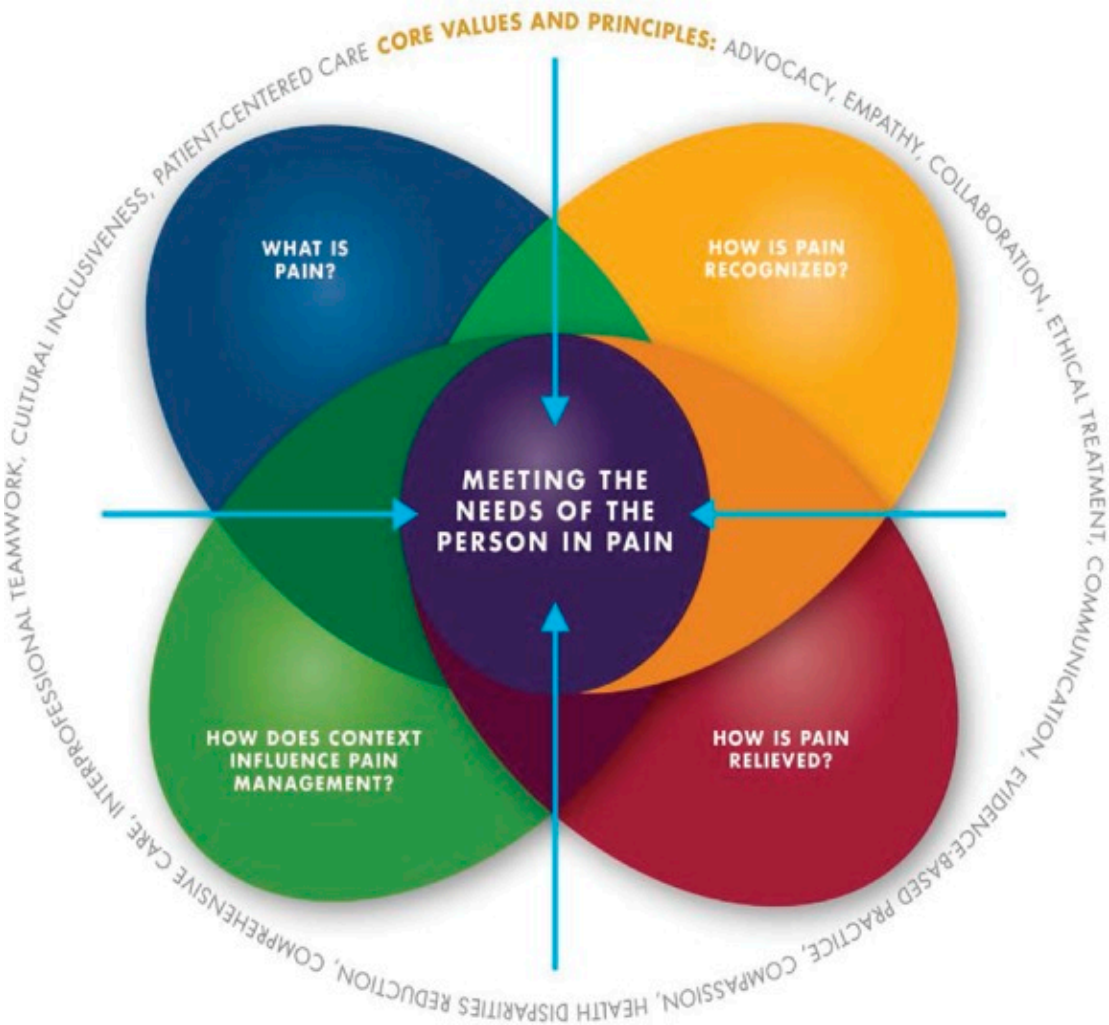
- Utilize established pain management competencies (Fishman et al)

Others

- Increased demand → impact on profession
- Greater provision in biomedical settings – specialized training
- Increased importance of interprofessional education
- Changes in accreditation curriculum requirements (Masters/Doctoral)

Fishman et al.
Pain Med 2013;14:971-81

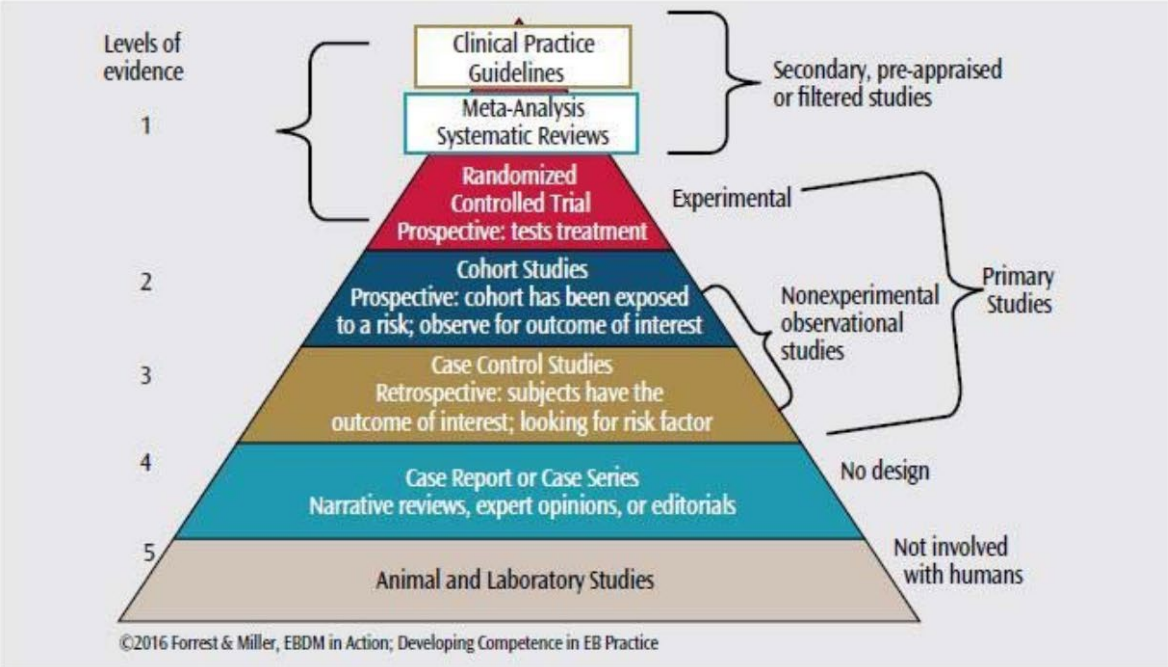
- Multidimensionality
- Assessment and measurement
- Management
- Context



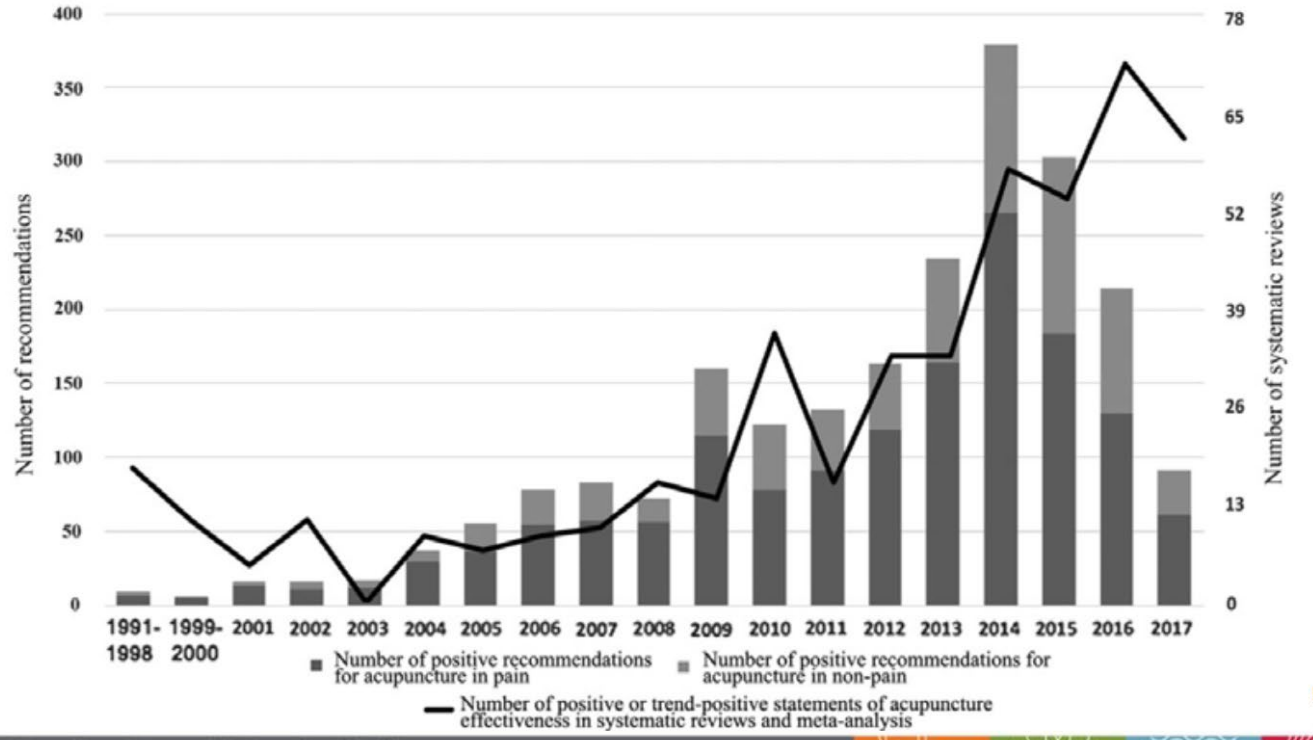
Implications - Implementation

- Research → best practice guidelines → real world practice and settings
  - Efficacy/effectiveness/pragmatic
- Implementation is a complex process
  - Settings, stakeholders, education, process etc.
- ‘comprehensive, integrative’?
  - Integrative or pluralistic
  - Different cultures and paradigms
  - Patient - messaging, choice, transparency

When is an intervention ready for implementation?



Treatment Guidelines for Acupuncture



Birch et al, 2018

Contact Information

Belinda Anderson, PhD, LAc

banderso@Monmouth.edu

Thank you