Note: Slides have been updated to reflect changes to the economic results that occurred after the October 19 Public meeting.

Cognitive and Mind-Body Therapies for Chronic Low Back and Neck Pain: Effectiveness and Value

Public Meeting – October 19, 2017

ICER
INSTITUTE FOR CLINICAL AND ECONOMIC REVIEW

WIFI: TCEGuest

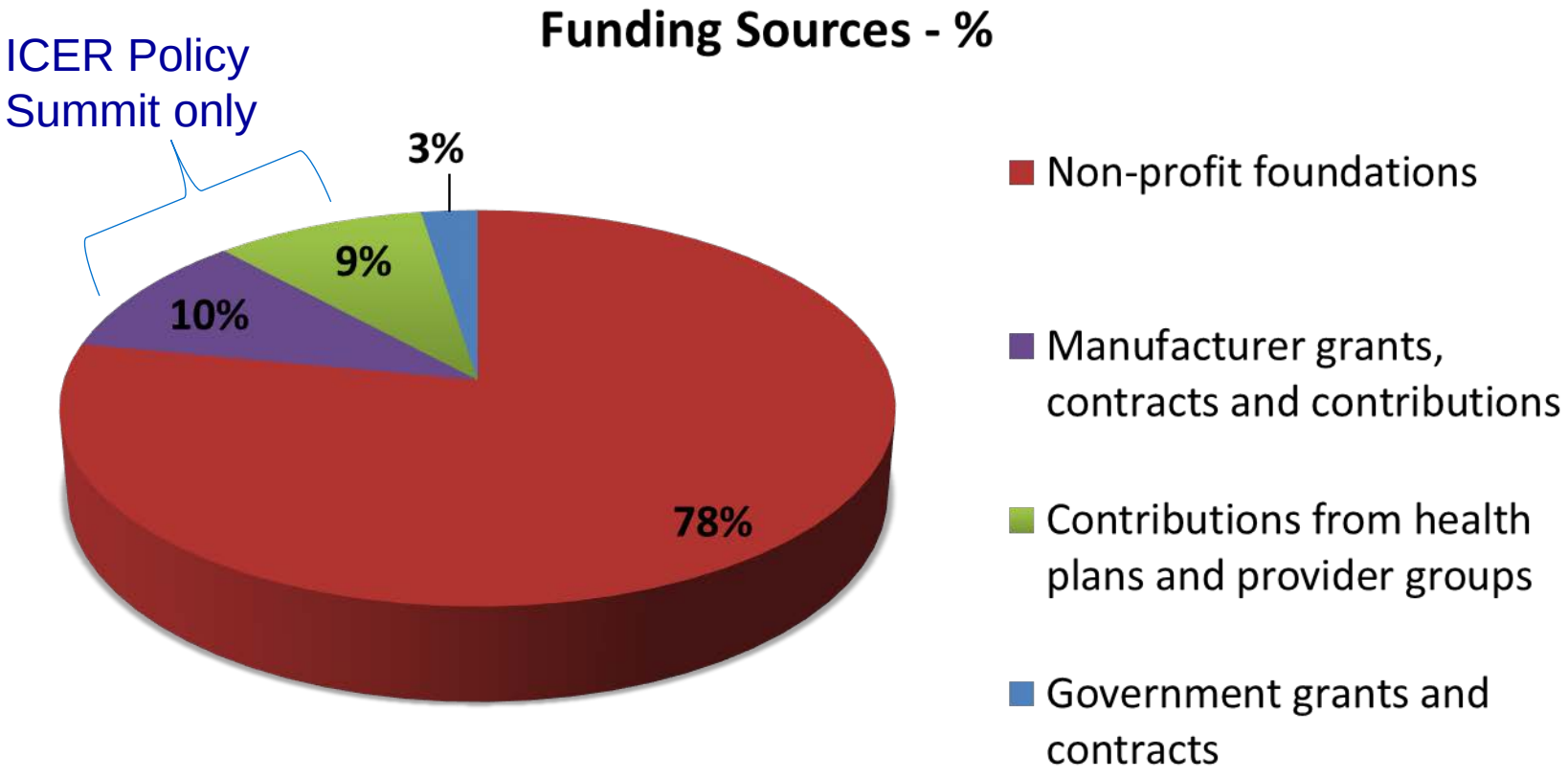
Welcome and Introduction

- California Technology Assessment Forum (CTAF)

- The Institute for Clinical and Economic Review (ICER)

Sources of Funding, 2017

ICER Policy Summit only



Welcome and Introduction

- **Why are we here today?**
  - Among the most common reasons for physician visits
  - National opioid epidemic with 4,659 overdose deaths in California in 2015
  - Interest in non-pharmacologic treatments for pain

> *Patients with chronic pain report feelings of anger, depression, and guilt related to their pain and its impact on their functioning, which can control all aspects of their life. A diagnosis of chronic pain poses similar challenges for family members who must modify their activities and expend considerable emotional energy to care for a family member in pain.*
>
> *-- From discussions with patient groups*

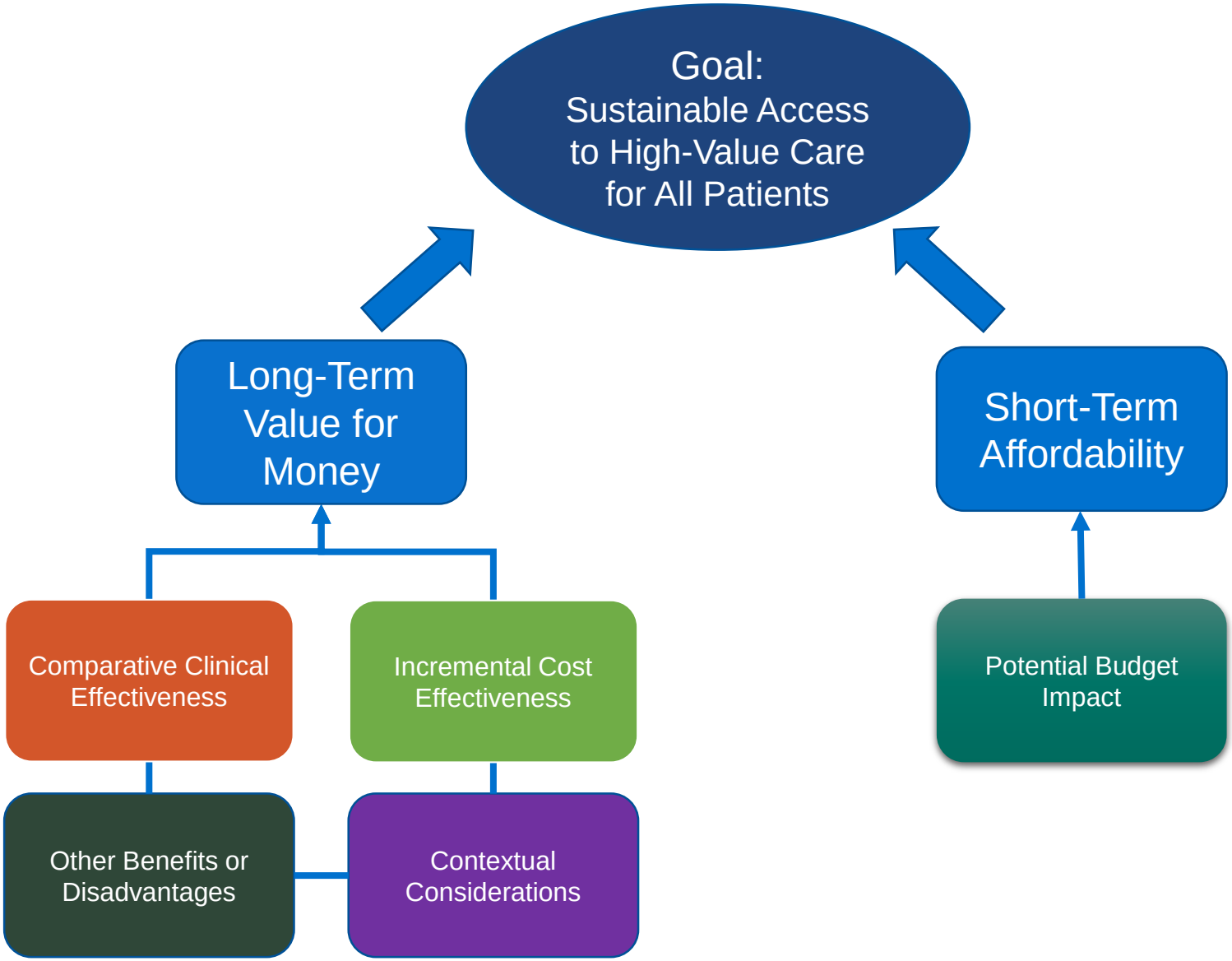
Welcome and Introduction

- **Why are we here today?**
  - Increasing health care costs affecting individuals, state and federal budgets
  - Non-traditional treatment approaches often raise questions about appropriate use, cost
  - Patients can have difficulty accessing treatments
    - Lack of insurance coverage
    - Burdensome out-of-pocket costs
  - Need for objective evaluation and public discussion of the evidence on effectiveness and value

Welcome and Introduction

How was the ICER report on treatments for chronic low back and neck pain developed?

- Scoping with guidance from patient groups, clinical experts, and other stakeholders
- Internal ICER staff evidence analysis and cost-effectiveness modeling
- Public comment and revision
- Expert report reviewers
  - Steven Atlas, MD, MPH
  - Ravi Prasad, PhD
- How is the evidence report structured to support CTAF voting and policy discussion?


Goal:
Sustainable Access to High-Value Care for All Patients
Long-Term Value for Money
Short-Term Affordability
Comparative Clinical Effectiveness
Incremental Cost Effectiveness
Potential Budget Impact
Other Benefits or Disadvantages
Contextual Considerations

Agenda

10:00am:	Welcome and Opening Remarks
10:15 am:	Presentation of the Evidence **Evidence Review**: Jeffrey Tice, MD **Cost Effectiveness**: Richard Chapman, PhD, MS
11:15 pm:	Public Comments and Discussion
11:45 am:	Lunch
12:30 pm:	CTAF Deliberation and Votes
1:45 pm:	Break
2:00 pm:	Policy Roundtable
3:00 pm:	Reflections and Wrap Up
3:30 pm:	Meeting Adjourned

Meeting materials available at: https://goo.gl/LN7FKs

Evidence Review

Jeffrey A. Tice, MD

Professor of Medicine

University of California, San Francisco

ICER

INSTITUTE FOR CLINICAL AND ECONOMIC REVIEW

Key Review Team Members

Ifeoma Otuonye, MPH

Margaret Webb, BA

Disclosures:

We have no conflicts of interest relevant to this report.

Topic in Context

- 2015 Global Burden of Disease
  - Low back and neck pain is leading cause of disability
- Cost: $88 billion in 2013
  - Growing faster than any other group of diagnoses
- Chronic pain (>12 weeks)
  - Majority of disability and cost associated with low back and neck pain
- Chronic pain differs from acute: CNS PET scans
  - Ongoing inflammation and pain center activation
  - Higher levels of emotional circuit activation and central sensitization amplifying pain perception

Effect on Lives Can Be Profound

- Limit or stop normal activities of daily living
- Feelings of anger, depression, and guilt
- Impact on family
  - Emotional and physical energy caring for person in chronic pain
  - They experience the same anger, depression and guilt, but not the pain
  - Pain controls their lives as well

Management

- Activity modification
- Pharmacologic: NSAIDS, opioids, SNRIs, tricyclic antidepressants, anti-epileptics
- Physical therapy, exercise, manipulation
- Invasive: Surgery, injections, pumps, TENS
- **Cognitive / mind-body**: acupuncture, cognitive behavioral therapy, mindfulness-based stress reduction, yoga, tai chi

Harms of Standard Therapies

- NSAIDS, anti-depressants, anti-epileptics
  - GI bleed, renal dysfunction, sedation
- Opioids
  - Sedation, constipation, sex hormone suppression
  - Pain hypersensitivity
  - Opioid dependence
- Surgery
  - Surgical complications
  - Failed back syndrome

Scope of the Review

- Population
  - Adults ≥ 18 years old with low back or neck pain for ≥ 12 weeks
- Interventions: cognitive / mind-body for pain
  - Acupuncture
  - Cognitive behavioral therapy (CBT)
  - Mindfulness-based stress reduction (MBSR)
  - Yoga
  - Tai chi
- Added to usual care (advice, PT, medications)

Key Outcomes

- Function: most important – ability to do essential activities
  - Oswestry Disability Index (ODI)
  - Roland Morris Disability Questionnaire (RMDQ)
- Pain
  - **Visual analog scale (VAS): 0-10 or 0-100**
    - Intensity
    - Bothersomeness
- Other
  - Return to work, quality of life, mood

Methods

- Follow AHRQ review methods:
  - Chou et al. Nonpharmacologic Therapies for Low Back Pain: A Systematic Review for an American College of Physicians Practice Guideline. Annals IM. 2017.
  - Qualitative update of prior systematic reviews with follow-up at least 4 weeks after completing active therapy

Insights from Discussions with Patients

- Most important outcome: function
  - Return to work
  - Able to do the things that bring joy to their life without pain overwhelming the experience
  - Relief from their sense of suffering
- Friends and family suffer almost as much as the patient
- Access to cognitive and mind-body therapies are limited by insurance and availability

Results

Chronic Low Back Pain: Acupuncture

- Significant reductions in disability and pain with acupuncture, standardized acupuncture, and sham acupuncture
- No significant difference from sham acupuncture
- Example: significant reduction in disability*
  - Individualized 60%
  - Standardized 60%
  - Sham 59%
  - Usual care 39%

* ≥ 3 point improvement on RMDQ

Chronic Low Back Pain: CBT

- Non-significant trend towards reduction in disability compared with usual care in ACP review
- Significant reduction in pain
- Differences remain clinically significant at 1 and 2 years of follow-up
- Additional benefits: reduced depression and improved quality of life in one trial

Chronic Low Back Pain: MBSR

- Significant reduction in disability and pain
- Differences remain clinically significant at 1 and 2 year follow-up
- No significant differences between MBSR and CBT

Chronic Low Back Pain: Yoga

- Small to moderate benefits on both function and pain compared with usual care
- Outcomes equivalent to physical therapy in one trial
- Benefits decrease in magnitude with longer follow-up

Chronic Low Back Pain: Tai Chi

- Substantially less evidence than for other interventions considered
- AHRQ review: tai chi had a small effect on pain and moderate effect on pain with low strength of evidence
- No new trials identified

Chronic Neck Pain: Acupuncture

- Significant reductions in disability and pain with acupuncture, standardized acupuncture, and sham acupuncture
- No significant difference from sham acupuncture
- Less evidence than for low back pain

Chronic Neck Pain: CBT

- Short trials with equivocal reductions in disability and pain beyond the active treatment phase
- Few trials

Chronic Neck Pain: MBSR

- No trials identified

Chronic Neck Pain: Yoga

- No trials identified

Chronic Neck Pain: Tai Chi

- One small trial with high potential for bias
- Very small benefit compared with usual care

Harms

- No serious adverse events reported in trials
- Adverse events
  - Pain, bleeding at needle insertion sites
  - Strains and joint aches
  - Increase in back and neck pain up to one month
- No important harms, therefore the judgements about net health benefits is driven by the clinical benefits

Comparative Clinical Effectiveness for Chronic Low Back Pain

Intervention	Net Health Benefit	Level of Certainty	ICER Evidence Rating
Acupuncture	Small	Moderate	C+: Comparable or better
CBT	Small	Moderate	C+: Comparable or better
MBSR	Small	Moderate	C+: Comparable or better
Yoga	Small	Moderate	C+: Comparable or better
Tai Chi	Small	Low	P/I: Promising, but inconclusive

CBT: cognitive behavioral therapy, MBSR: mindfulness-based stress reduction

Comparative Clinical Effectiveness for Chronic Neck Pain

Intervention	Net Health Benefit	Level of Certainty	ICER Evidence Rating
Acupuncture	Small	Low	P/I: Promising, but inconclusive
CBT	Small to none	Low	I: Insufficient
MBSR	Unknown	Low	I: Insufficient
Yoga	Unknown	Low	I: Insufficient
Tai Chi	Small to none	Low	I: Insufficient

CBT: cognitive behavioral therapy, MBSR: mindfulness-based stress reduction

Comments Received

- Objective measures of pain would be helpful in trials of therapy for pain: NIH initiative
- Patients going to acupuncturists are more satisfied with communication, office conditions, staff helpfulness, and outcomes than national benchmarks
- CBT is not generic; pain CBT is specific
- The emphasis on the potential placebo effect of acupuncture should be reconsidered.

Cost Effectiveness

Richard Chapman, PhD, MS

Director of Health Economics, ICER

ICER
INSTITUTE FOR CLINICAL
AND ECONOMIC REVIEW

Key Review Team Members

Varun Kumar, MBBS, MPH, MSc

Dan Ollendorf, PhD

Disclosures:

We have no conflicts of interest to disclose.

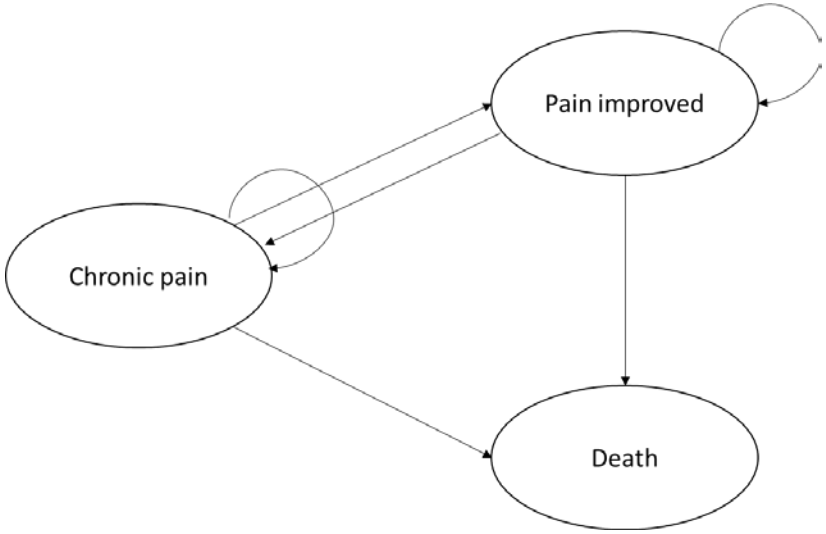
Objective

Estimate the cost effectiveness of cognitive and mind-body therapies relative to usual care for the treatment of chronic low back pain

Methods in Brief

Model Overview

- **Model Type:** Markov model
- **Population:** 47-year-old individuals with chronic low back pain
- **Perspective:** Health care system (direct medical care and drug costs)
- **Interventions:** Acupuncture, CBT, MBSR, yoga, tai chi
- **Comparators**: Usual care
- **Time Horizon:** Five years
- **Setting:** United States
- **Discount Rate:** 3% for costs and health outcomes



Model Outcomes

- **Base Case Analysis (at five years)**
  - Total costs
  - Total QALYs
  - Incremental cost-effectiveness ratio
  - Incremental cost per successful treatment (pain improvement)
- **Sensitivity Analyses**
  - One-way sensitivity analysis
  - Probabilistic sensitivity analysis
- **Scenario Analyses**
  - Shorter time-horizons (one and three years)
  - Modified societal perspective (productivity loss)

Key Assumptions

- No subsequent therapy for those who had not improved or had a relapse of pain
- Assumed same probability of treatment response for all active interventions except tai chi
- No intervention-related adverse events
- Spontaneous improvement in pain could occur following unsuccessful treatment with intervention or usual care
- Those with pain improvement and without relapse have no QoL deterioration over time
- Those with pain recurrence reverted to chronic pain state (with same cost and quality of life)

Model Inputs: Intervention Frequency

Intervention	Frequency	Source
Acupuncture	Two sessions/week for three weeks followed by one session/week for four weeks	Cherkin et al., 2009
CBT	One two-hour session/week for eight weeks	Cherkin et al., 2016*
MBSR	One session/week for eight weeks	Cherkin et al., 2016*
Yoga	One session/week for 12 weeks	Sherman et al., 2011
Tai Chi	Two sessions/week for eight weeks followed by one session/week for two weeks	Hall et al., 2011

Model Inputs: Six-Month Probability of Response

	Mean	Lower Range	Upper Range	Source
Acupuncture	0.600*	0.480‡	0.720‡	Cherkin et al., 2009
CBT	0.600*	0.492	0.676	Cherkin et al., 2016
MBSR	0.600*	0.520	0.703	Cherkin et al., 2016
Yoga	0.600*	0.560	0.780	Sherman et al., 2011
Tai Chi	0.500	0.450§	0.600‡	Hall et al., 2011
Usual Care	0.441	0.359	0.542†	Cherkin et al., 2016
Recurrence	0.259	0.126	0.346	Calculation, Norton et al., 2015

*Average of transition probabilities for acupuncture, CBT, mindfulness therapy and yoga reported in studies.

‡Assumed range of 20% around the point estimate.

§Does not represent a 20% lower-end range. Assumed to be greater than the mean estimate of effectiveness associated with usual care in the one-way sensitivity analysis.

†Assumed to be lower than the mean estimate of effectiveness in the one-way sensitivity analysis for tai chi.

Model Inputs: Health State Utilities

	Base Case	Lower Range	Upper Range	Source
Chronic Low Back Pain (Baseline)	0.66	--	--	Johnson et al., 2007
Low Back Pain Improved	0.81	0.729	0.891	Johnson et al., 2007; ranges ±10% of mean estimate
Death	0	0	0	Convention

*Alternative assumption: 0.81

Model Inputs: Costs

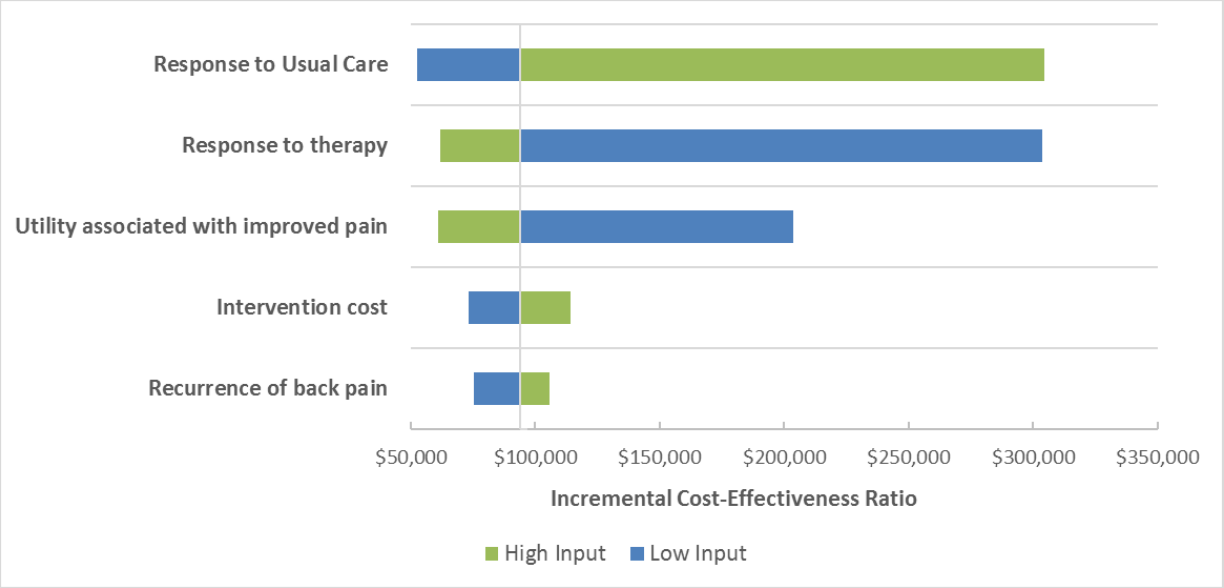
Service	Cost	Source
Acupuncture (per session)	$104	Zhang, 2014
CBT (per two-hour session)	$212	Gore et al., 2012
Yoga (per session)	$18	Assumption: same as tai chi
MBSR (per session)	$59	Innerwell Integrative Counseling Services
Tai Chi (per session)	$18	The Tai Chi Center
Office Visit for Active Intervention	$52	Centers for Medicare & Medicaid Services, 2017
Usual Care (total)	$109	Centers for Medicare & Medicaid Services, 2017
Background Health Care Costs – Chronic Pain	$701	Fritz et al., 2012; Gore et al., 2012
Background Health Care Costs – Improved Pain	$301	

Results

Base Case Results

Therapy	Costs	QALYs	Incremental Cost/QALY vs. Usual Care
Acupuncture	$5,657	3.4338	$53,933
CBT	$6,316	3.4338	$93,799
MBSR	$5,097	3.4338	$19,975
Yoga	$4,832	3.4338	$3,929
Tai Chi	$4,992	3.4234	$36,759
Usual Care	$4,767	3.4173	-

One-Way Sensitivity Analysis (CBT)



	Low Input	High Input	Low Input Result	High Input Result	Range
Intervention Cost	$169.42	$254.12	$73,282	$114,312	$41,029
Response to Therapy	0.492	0.676	$303,721	$61,740	$241,982
Response to Usual Care	0.359	0.542	$52,603	$304,697	$252,094
Recurrence of Back Pain	0.126	0.346	$75,481	$105,832	$30,350
Utility Associated with Improved Pain	0.729	0.891	$203,910	$60,908	$143,002

ICER

Probabilistic Sensitivity Analysis – Probability of Cost-effectiveness at Different Thresholds

Intervention	Percentage Cost-Effective at Willingness-To-Pay Thresholds		
	$50,000 per QALY	$100,000 per QALY	$150,000 per QALY
Acupuncture	**43.80%**	**81.78%**	**91.92%**
CBT	11.74%	**52.16%**	**74.28%**
MBSR	**87.14%**	**95.24%**	**96.74%**
Yoga	**96.34%**	**97.72%**	**98.10%**
Tai Chi	**56.58%**	**67.34%**	**71.18%**

CBT: cognitive behavioral therapy, MBSR: mindfulness-based stress reduction, QALY: Quality-adjusted life year

Scenario Analyses

Incremental Cost-Effectiveness Ratios (Cost per QALY Gained) vs. Usual Care with Varying Time Horizons

	Acupuncture	CBT	MBSR	Yoga	Tai Chi
One year	$161,530	$273,774	$65,921	$20,742	$113,177
Three years	$54,221	$94,281	$20,098	$3,974	$36,964
Five years (base case)	$53,933	$93,799	$19,975	$3,929	$36,759

CBT: Cognitive Behavioral Therapy, MBSR: Mindfulness-Based Stress Reduction

Modified Societal Perspective

Intervention	Incremental Cost Effectiveness Ratio (Cost per QALY Gained)
Acupuncture	$51,989
CBT	$91,855
MBSR	$18,031
Yoga	$1,985
Tai Chi	$34,815

CBT: Cognitive Behavioral Therapy, MBSR: Mindfulness-Based Stress Reduction, QALY: Quality-Adjusted Life Year

Limitations

- Did not model varying treatment effectiveness over time due to availability of only short-term trial data
- Effectiveness of interventions (from chronic pain to pain improvement) occurred only in the first cycle when patients receive an intervention, due to availability of only short-term data
- Assumed identical benefits for four of the five interventions
- Did not model repeat or subsequent treatments
- Assumed complete adherence to each intervention
- Costs for interventions may vary widely by region and insurance coverage

Public Comments

- Acupuncture costs may range from $50-$70 per session
  - Acupuncture cost used in the model was sourced from an observational study
  - Cost per session of acupuncture to reach $50,000/QALY threshold was ~$97
  - Varying cost between $83 and $125 resulted in cost/QALY of ~$41,000 to $66,000 relative to usual care
- Alternate method to derive utility for improved health state
  - We modeled all interventions using alternate ‘pain improvement’ utility estimates; resulted in more favorable incremental cost-effectiveness ratios

Low Back Pain Model by Herman et al., 2017

- Cost-effectiveness model (CBT/MBSR vs. usual care) using RCT data from Cherkin et al., 2016
- CBT was estimated at ~$12,000 per QALY gained vs. usual care
- MBSR dominated usual care (more effective, less costly)

Key differences compared to the ICER model:

- Lower intervention costs (if same in ICER model, cost/QALY gained equals ~$300 for both CBT and MBSR)
- Greater QALY gains relative to usual care
- Greater differences in background health care costs
- Shorter time horizon (one year)

Summary and Conclusions

- All interventions had an incremental cost per QALY gained <$100,000 relative to usual care
  - Estimated ICERs ranged from ~$4,000/QALY for yoga to ~$94,000/QALY for CBT
- Results were most sensitive to patients' response to usual care, response to therapy, and utility associated with improved pain
- Including productivity loss did not appreciably change results
- Shorter time horizons resulted in increased ICERs compared to base case

Public Comment and Discussion

Matthew Bauer, LAc
The Acupuncture Now Foundation
President

Conflicts of interest:

- Status or position as an officer, board member, trustee, owner or employee of a health care company, or an organization which receives more than 25% of its funding from health care companies

Mr. Bauer is a member of the Board of Directors for American Specialty Health Group Inc., a health care company that develops and supports managed care plans for non-pharmacological services including acupuncture, chiropractic, massage therapy, etc.

Lunch

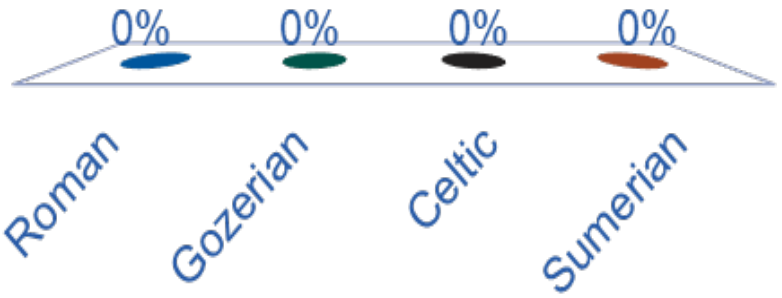
Meeting will resume at 12:30 pm

Voting Questions

WIFI: TCEGuest

0. Which ancient culture observed the holiday that is now known as Halloween?

A. Roman
B. Gozerian
C. Celtic
D. Sumerian



1. For individuals with chronic low back pain, is the evidence adequate to demonstrate that **acupuncture** provides additional net health benefit when **added to usual care**?

A. Yes

B. No

2. For individuals with chronic low back pain, is the evidence adequate to demonstrate that **cognitive behavioral therapy (CBT)** provides additional net health benefit when **added to usual care**?

A. Yes

B. No

3. For individuals with chronic low back pain, is the evidence adequate to demonstrate that **mindfulness-based stress reduction (MBSR)** provides additional net health benefit when **added to usual care**?

A. Yes

B. No

4. For individuals with chronic low back pain, is the evidence adequate to demonstrate that **yoga** provides additional net health benefit when **added to usual care**?

A. Yes

B. No

5. For individuals with chronic low back pain, is the evidence adequate to demonstrate that **tai chi** provides additional net health benefit when **added to usual care**?

A. Yes

B. No

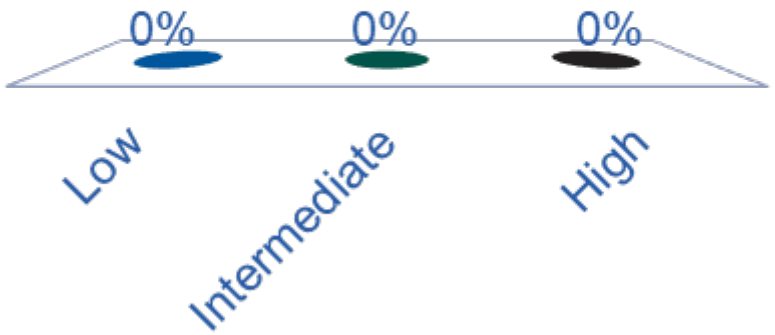
6. For individuals with chronic low back pain, is the evidence adequate to distinguish the additional net health benefits provided by **acupuncture, CBT, MBSR, yoga, and tai chi?**

A. Yes

B. No

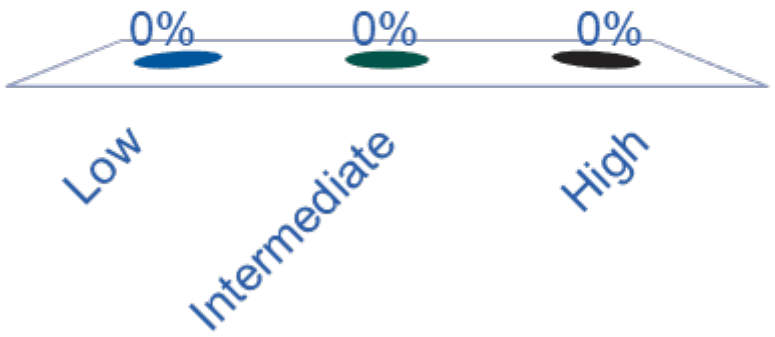
7. Given the available evidence on comparative effectiveness and incremental cost-effectiveness, and considering other benefits, disadvantages, and contextual considerations, what is the long-term value for money of treatment with **acupuncture and usual care** versus **usual care alone** for patients with chronic low back pain?

A. Low
B. Intermediate
C. High



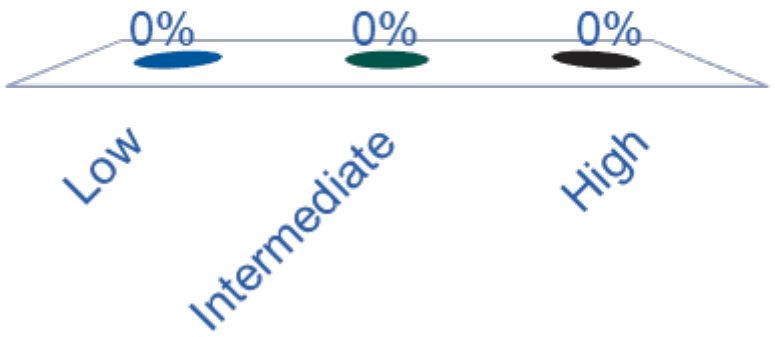
8. Given the available evidence on comparative effectiveness and incremental cost-effectiveness, and considering other benefits, disadvantages, and contextual considerations, what is the long-term value for money of treatment with **CBT and usual care** versus **usual care alone** for patients with chronic low back pain?

A. Low
B. Intermediate
C. High



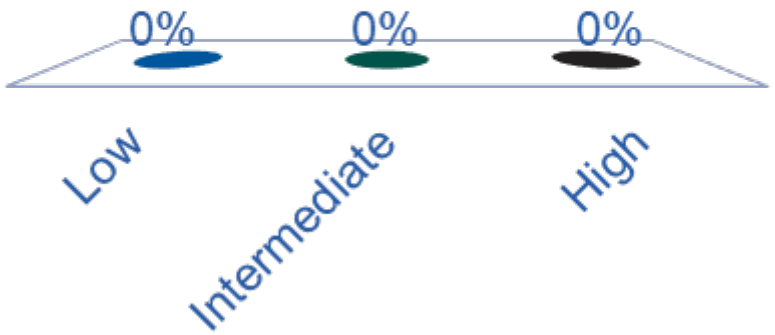
9. Given the available evidence on comparative effectiveness and incremental cost-effectiveness, and considering other benefits, disadvantages, and contextual considerations, what is the long-term value for money of treatment with **MBSR and usual care** versus **usual care alone** for patients with chronic low back pain?

A. Low
B. Intermediate
C. High



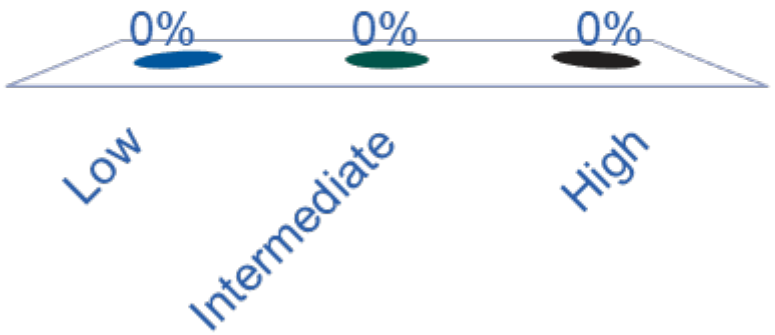
10. Given the available evidence on comparative effectiveness and incremental cost-effectiveness, and considering other benefits, disadvantages, and contextual considerations, what is the long-term value for money of treatment with **yoga and usual care** versus **usual care alone** for patients with chronic low back pain?

A. Low
B. Intermediate
C. High



11. Given the available evidence on comparative effectiveness and incremental cost-effectiveness, and considering other benefits, disadvantages, and contextual considerations, what is the long-term value for money of treatment with **tai chi and usual care** versus **usual care alone** for patients with chronic low back pain?

A. Low
B. Intermediate
C. High



12. For individuals with chronic neck pain, is the evidence adequate to demonstrate that **acupuncture** provides additional net health benefit when **added to usual care**?

A. Yes

B. No

Break
Meeting will resume at 2:00 pm

Policy Roundtable

Policy Roundtable Participants

Name	Title	COI Declaration
Penney Cowan	Founder and CEO, American Chronic Pain Association	None
Catherine Cartwright	Patient; Regional Director, American Chronic Pain Association	None
Julia Logan, MD, MPH	Chief Quality Officer, California Department of Health Care Services	Full-time employee of California DHCS
Ravi Prasad, PhD	Associate Chief, Division of Pain Medicine; Clinical Associate Professor, Anesthesiology, Perioperative and Pain Medicine; Director, Stanford Comprehensive Interdisciplinary Pain Program; Stanford University School of Medicine	None
Robert Saper, MD	Director of Integrative Medicine, Boston Medical Center	None
Tony Van Goor, MD, MMM, CPE, FACP	Senior Director, Medical Affairs and Medical Director for Policy and Health Technology Assessment, Blue Shield of California	Full-time employee of Blue Shield of California

CTAF Panel Reflections and Closing Remarks

Next Steps

- Meeting recording posted to ICER website next week
- Final Report published on November 6
  - Includes description of CTAF votes, deliberation; policy roundtable discussion
- Materials available at

  https://icer-review.org/topic/low-back-pain/

Adjourn