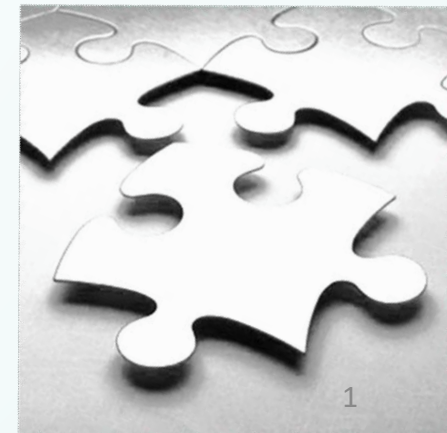


HERC Proposed Chronic Pain Policy Evidence Appraisal

Presentation to
Oregon Health Authority
Health Evidence Review Commission
Value-based Benefits Subcommittee

Andrea C. Skelly, PhD, MPH
May 16, 2019

Report prepared by:
Andrea C. Skelly, PhD, MPH
Erika D. Brodt, BS



Background

Chronic pain (CP):

- Leading cause of disability; impacts physical and mental functioning, productivity, quality of life, and relationships
- Complex, multifaceted and often refractory to treatment
- Biological factors and psychosocial contributors to pain
- Multimodal approach to management recommended

HERC proposal

- Explores expansion of coverage of specific pharmacologic and nonpharmacologic treatments to five CP conditions not currently covered under the Prioritized List of Services
- Deliberations and decision-making was paused so that an external review of cited evidence for the proposal could be completed

Purpose and Exclusions to Scope

Purpose

- To provide a rapid turnaround, independent external review of the evidence base cited in HERC's proposal and how it aligns with proposed changes for coverage of specific treatments for the five conditions specified
- To briefly review public and expert comments submitted to the HERC to capture evidence sources cited

EXCLUSIONS:

- Additional literature search for relevant evidence
- Review of Oregon's opioid prescribing guidelines
- Evaluation of potential impact of proposed changes, logistics or costs
- Recommendation for or against implementation of the proposed policy
- Formal critical appraisal or assessment of evidence suggested by commenters or evaluation of its applicability
- Recommendations regarding back and neck pain
- Evaluation of 2016 CDC Guideline or its evidence base
- Assessment of the policy development process

Methods

Evidence cited in the March 2019 “Reprioritization of Certain Chronic Pain Conditions”

- Use of validated critical appraisal instruments based on study design
- Comparison of Patients, Interventions, Outcomes, Timing and Settings (PICOTS) of included studies with those in the proposed policy
- Noted strength of evidence, potential evidence gaps

Citations from public and expert comment

- Evidence: formal clinical research studies or syntheses of such studies published in the peer-reviewed medical literature
- Listed for HERC consideration; no formal appraisal

Individual studies contained within systematic reviews or rapid reviews were not critically appraised for this report

Proposal Conditions (Populations) and Interventions

Conditions/Populations specified in the proposal:

- Fibromyalgia (FM)
- Chronic pain syndrome
- Chronic pain due to trauma
- Other chronic post-procedural pain
- Other chronic pain

Note: These are broad, heterogeneous and poorly defined (exception, FM); pain type may influence treatment response

Interventions considered (see full proposal)

- Opioid therapy (short-, long-term, tapering)
- Non-opioid pharmacologic therapy
- Non-pharmacologic therapy (Tai Chi, Yoga, exercise, acupuncture, interdisciplinary rehabilitation, mindfulness, massage/physical therapy, CBT, and pain education)

Summary

The literature on chronic pain is vast and complex; the HERC staff summarized an immense amount of research represented in the 12 systematic reviews (SRs)/rapid reviews (RR)

- Quality of the SRs/RRs was good; however overall quality of studies included in reviews and SOE for outcomes varied
- HERC search strategies, inclusion/exclusion criteria and process were not delineated; extent of missing evidence or selection objectivity cannot be evaluated
- Areas for expanded search are suggested in results tables
- Explicit links between evidence and proposed policy populations, interventions and components often unclear

Summary: Patients

- Focus appears to be on adults (clarification suggested)
- Cited evidence included patients with pain conditions other than those in the proposed policy
 - SOE was low or very low (insufficient) for many interventions; for some interventions no cited evidence pertaining to one or more of the proposed conditions
 - E.g. sparse evidence for FM for most non-pharma treatments; limited or no evidence cited for other conditions
 - **The HERC will need to carefully consider the extent to which findings for treatments for included study populations, particularly for treatments with sparse or no evidence, can be logically extrapolated to the broad range of conditions in the proposal**

Summary: Interventions

Non-pharmacologic treatments (part of multimodal care)

- SOE generally low or very low (insufficient)
- Limited/no evidence for proposed conditions other than FM; additional search suggested

Non-opioid pharmacologic treatments

- SOE Low for specific agents for FM; Evidence comparing opioid vs. non-opioid treatments for other conditions in 1 SR is low to moderate. Search for additional evidence on conditions other than FM and for use of adjunctive treatments suggested

Opioid therapy

- Cited evidence does not explicitly address exclusion of FM for the use of opioids either in the short or long term
- Overall (across time frames): Evidence primarily for MMED <90 mg, conditions other than those proposed; SOE high for improved pain, physical functioning, social functioning and sleep quality w/opioids vs. placebo but clinically important differences (CID) were not met; SOE moderate to high for ↑vomiting, constipation, other events w/opioid vs. placebo
- Short term (to 3 months); limited subanalysis suggests SOE high for improved pain (marginally meeting 1.0 cm CID and, sleep quality (CID not met) w/opioids vs. placebo;



Summary: Interventions

Long-term opioid therapy

- Definitions of long-term varied; most trials addressed mean or median MMED of <90 mg, included patients with other conditions; follow-up usually <6 months
- Effect sizes for pain relief, sleep quality in long vs. short-term were smaller; CIDs not met
- Recommendations for doses, co-prescription of naloxone for doses >50 MED, combining opioid therapy with non-pharmacologic and non-opioid pharmacologic therapies come from the 2016 CDC guidelines; additional evidence not cited

Tapering:

- Quality of available evidence very low (insufficient) with no clear evidence-based strategies for tapering
- Benefits and harms of tapering, particularly when doses are high, are not well described in the available research

Summary: Interventions

Tapering (continued):

- The evidence cited does not support the proposed policy; included studies did not compare benefits and harms for
 - Different tapering strategies e.g. how quickly to taper or change doses or over what time frame
 - Impact of tapering completely vs. to another target dose
 - Taper to a “hard” dose vs. other strategies (e.g. shared decision-making considering benefits/harms); voluntary vs. forced
- Most trials evaluated adjunctive treatments. A more direct link and context for use of these and support for tapering should be considered
- 2016 CDC guidelines form the basis for many recommendations
 - Recent publications clarify that CDC guidelines are not intended to result in abrupt cessation of opioids, forced taper or tapering to specific hard targets
 - The HERC should consider if the proposed policy is consistent with the intent of CDC guidelines, clarify and as needed revise the proposed policy’s intent, scope and support if tapering is considered

Summary : Additional observations, suggestions

Comparators:

- Usual care, placebo, other non-active comparators were most common; limited evidence for interventions vs. active comparators, for opioid vs. non-opioids or vs. nonpharmacologic treatments; comparisons between interventions is indirect, precluding firm conclusions

Other:

- Justification for specific improvement levels not provided; CIDs maybe subjective and vary across patient populations
- Comment review suggests that there has been confusion regarding the intent, scope, implementation and limitations of the proposed policy.

Summary: Some additional sources

Evidence citations from public and expert comments and others we are aware of are in the report Appendix; the HERC may wish to evaluate the applicability of these to the proposal if not already done.

Related work in process: Three concurrent AHRQ-funded comparative effectiveness reviews (protocols available online <https://effectivehealthcare.ahrq.gov/>)

- Systematic Review Update: Noninvasive Nonpharmacologic Treatments for Chronic Pain
- Nonopioid Pharmacologic Treatments for Chronic Pain
- Opioid Treatments for Chronic Pain

Questions?

