New England Comparative Effectiveness Public Advisory Council

Public Meeting – Burlington, Vermont
Management Options for Patients with Opioid Dependence
June 20, 2014
DRAFT: April 21, 2014

Questions for Management Options for Opioid Dependence

Introduction to CEPAC's Votes

Each public meeting of CEPAC involves deliberation and voting on key questions related to the systematic review of the evidence presented by ICER. Members of CEPAC will discuss issues regarding the application of the available evidence to guide clinical decision-making and payer policies. ICER develops the key questions with significant input from members of the CEPAC Advisory Board to ensure that the questions are framed to address the issues that are most important in applying the evidence to practice and medical policy decisions.

About the Questions

Comparative Clinical Effectiveness

The general framework within which CEPAC discusses and votes on the evidence is shown below:

Given a health care "intervention A" for "patients with condition X," we will compare its clinical effectiveness for these patients to that of a "comparator B" by voting on the following question:

Is the evidence "adequate" to demonstrate that "intervention A" is equivalent or superior to "comparator B" for "patients with condition X"?

Discussion and voting will highlight the following issues:

1. The evidence on risks and benefits to determine the *comparative* clinical effectiveness of management options for specific patient populations. In judging comparative clinical effectiveness, there are two interrelated questions: the relative magnitude of differences in risks and benefits; and the relative confidence that the body of evidence can provide in the accuracy of estimates of risks and benefits. Considering these two issues together is required in order to make a judgment of whether the evidence is "adequate" to demonstrate that one intervention is equivalent to or superior than another.
2. Issues related to individual patient preferences and values, provider training, volume, or other factors that should be considered in judging the evidence on clinical effectiveness and value.
3. Weighing the evidence on cost-effectiveness and projected budgetary impact to determine the comparative value of various management options for key patient populations.
4. Comments or recommendations related to broader considerations of public health, equity, disparities, and access.

Comparative Value

When a majority of CEPAC votes that the evidence is adequate to demonstrate that an intervention produces patient outcomes equivalent or superior to a comparator, the Council will also vote on whether or not the intervention, care management program, or other health system innovation represents a "high," "reasonable," or "low" value. For those Council members who vote that the evidence is inadequate to demonstrate that one intervention produced patient outcomes equivalent or superior to another, ICER will automatically designate these as a "low" value vote. Typically, the value "perspective" that CEPAC will be asked to assume is that of a state Medicaid program or a provider group that must make resource decisions within a fixed budget for care. While information about hypothetical budget tradeoffs are provided, CEPAC will not be given prescribed boundaries or thresholds for budget impact or incremental cost-effectiveness ratios to guide its judgment of high, reasonable, or low value. When voting on value, CEPAC will grade their votes according to the different categories on the following page to explain their rationale for determining one intervention to have "high", "reasonable", or "low" comparative value to another.

Table 1. Value Voting Categories

Low Value	Reasonable/Comparable Value	High Value
1. Worse outcomes; Higher or equivalent cost	5. Worse outcomes; Lower cost	9. Comparable outcomes; Lower cost
2. Comparable outcomes; Higher costs	6. Comparable outcomes; Comparable cost	10. Promising but inconclusive evidence of better outcomes; Lower cost
3. Promising but inconclusive evidence of better outcomes; Higher cost	7. Promising but inconclusive evidence of better outcomes; Comparable cost	11. Better outcomes; Lower or comparable cost
4. Better outcomes; Too high a cost	8. Better outcomes; Reasonable higher cost	12. Better outcomes; Slightly higher cost

Voting Questions – Management options for opioid dependence

Comparative Clinical Effectiveness

Medication-assisted therapy vs. detoxification

1. Is the evidence adequate to demonstrate that starting long-term medication-assisted therapy with any treatment option is superior to short-term detoxification for most patients with opioid dependence?

Comment: Does the evidence suggest that there are any special considerations for adolescents or other specific types of individuals?

Vivitrol® vs. Suboxone® or methadone

2. Is the evidence adequate to demonstrate that use of Vivitrol is as good as medication-assisted therapy with either methadone or Suboxone for patients with opioid dependence?

Methadone vs. Suboxone

3. Is the evidence adequate to demonstrate that maintenance therapy with methadone is at least functionally equivalent to maintenance with Suboxone in treating patients with opioid dependence?

Comment: Are there any special considerations for adolescents?

Comparative value

Medication-assisted therapy vs. detoxification

1. From the perspective of a state Medicaid program, based on the information provided in this report, would you judge the value of long-term medication-assisted therapy with any treatment option compared to detoxification to be:

   1) high; 2) reasonable; or 3) low?

2. From the perspective of a state Medicaid program, based on the information provided in this report, would you judge the value of expanded access to medication-assisted therapy to be:

   1) high; 2) reasonable; or 3) low?

Methadone vs. Suboxone

3. From the perspective of a state Medicaid program, based on the information provided in this report, would you judge the value of methadone treatment compared to Suboxone treatment to be:

   1) high; 2) reasonable/comparable; or 3) low?

Definitions

1) **Medication-assisted therapy:** long-term treatment of opioid dependence, typically for 6 months or longer, utilizing any type of opioid addiction therapy including methadone, buprenorphine, or naltrexone

2) **Detoxification**: Assisted opioid withdrawal for maximum of 30 days

3) **Opioid Dependence:** According to DSM-IV criteria, a condition characterized by significant impairment or distress caused by addiction to opioids, as manifested by three or more of the following psychological or behavioral effects in a 12-month period:

    - Tolerance or markedly increased amounts of the substance to achieve intoxication or desired effect or markedly diminished effect with continued use of the same amount of substance
    - Withdrawal symptoms or the use of certain substances to avoid withdrawal symptoms
    - Use of a substance in larger amounts or over a longer period than was intended
    - Persistent desire or unsuccessful efforts to cut down or control substance use
    - Involvement in chronic behavior to obtain the substance, use the substance, or recover from its effects
    - Reduction or abandonment of social, occupational or recreational activities because of substance use
    - Use of substances even though there is a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance

4) **Adolescent:** Individual who is age 18 years or younger.

References

1. Centers for Disease Control and Prevention. *Policy impact: Prescription painkiller overdoses*. July 2013. http://www.cdc.gov/homeandrecreationalsafety/rxbrief/ (Accessed February 2014).

2. Jones CM, Mack K, and Paulozzi L. Pharmaceutical Overdose deaths, United States, 2010. *JAMA*. 2013;309(7):657-659.

3. Substance Abuse and Mental Health Services Organization. *Results from the 2012 National Survey on Drug Use and Health: Summary of National Findings and Detailed Tables*. October 2013.

4. Centers for Disease Control and Prevention. *Drug overdose in the United States: Factsheet.* July 2013. http://www.cdc.gov/homeandrecreationalsafety/overdose/facts.html. (Accessed March 2014).

5. U.S. Department of Justice National Drug Intelligence Center. Economic Costs of Drug Abuse in the United States, 1992 – 2002. April 2011.

6. National Institute on Drug Abuse. *Topics in brief: Medication-assisted therapy for opioid addiction*. April 2012. http://www.drugabuse.gov/publications/topics-in-brief/medication-assisted-treatment-opioid-addiction (Accessed April 2014).