CEPAC Voting and Policy Implications Summary
Attention Deficit Hyperactivity Disorder: Effectiveness of Treatment in At-risk Preschoolers and Long-term Effectiveness in All Ages
June 1, 2012

The New England Comparative Effectiveness Public Advisory Council (CEPAC) is an independent forum in which clinical and public policy experts publicly deliberate on evidence reviews of the clinical effectiveness and value of health care services. Through these deliberations, and summary votes held on key evidence questions, CEPAC provides guidance on how the existing evidence can best be applied to improve the quality and value of health care services across New England. CEPAC is comprised of 17 members, a mix of clinicians and public representatives from each New England state. Representatives of state Medicaid programs and of regional private payers are included as ex-officio members of CEPAC. CEPAC members are recruited through an open public nomination process, and are selected on the basis of their experience and training in the interpretation and application of medical evidence in health care delivery.

This public meeting of CEPAC discussed management options for Attention Deficit Hyperactivity Disorder (ADHD). Staff from the Institute for Clinical and Economic Review (ICER) provided CEPAC with a supplementary evidence report that included the evidence review developed by the Agency for Healthcare Research and Quality (AHRQ), with additional material and analyses including: 1) updated information on patient management options for ADHD published since the AHRQ review; 2) regional and national data on prevalence, utilization, and existing clinical guidelines and payer coverage policies; and 3) the results of budgetary impact and cost-effectiveness analyses developed to support discussion of the comparative value of different management options. Prior to the in-person CEPAC meeting, a conference call was held with two clinical experts in the treatment of ADHD, Laurence Greenhill, MD of Columbia University and Peter Jensen, MD of the REACH Institute and Mayo Clinic. These experts discussed treatment options available for ADHD and responded to CEPAC member questions.

This summary includes the results of the votes of CEPAC on key evidence questions. In addition, we present policy considerations highlighted by CEPAC and by the roundtable of regional clinical experts, patient advocates, and regional payers that discussed the implications of CEPAC votes for clinical practice, and payer policies. The meeting agenda and full attendance list, including roundtable panelists, are shown in Appendix A.

Summary of Votes and Recommendations

Following the outline of the AHRQ review, CEPAC members voted on questions concerning the comparative clinical effectiveness and comparative value of management options for preschoolers and school-aged children with ADHD. CEPAC members noted throughout the voting process the challenge of making relative comparisons between treatments with no uniform definition of 'usual care' used in the various studies.

Comparative clinical effectiveness: ADHD treatment for preschoolers

Based on the findings of the AHRQ review and time limitations of the CEPAC meeting, members of CEPAC were asked for their consent to the following stipulations.

- **Due to limitations of the available evidence, the evidence is not adequate to demonstrate that any other medication is as good as or better than methylphenidate (MPH) as a first-line treatment for preschoolers with either ADHD or DBD.**

  CEPAC Vote: 13 Yes 0 No

- **Due to limitations of the available evidence, the evidence is not adequate to demonstrate that any branded parent behavior training program is better than any other in preschoolers with ADHD or DBD.**

  CEPAC Vote: 13 Yes 0 No

Voting Questions

1. **Is the evidence on risks and benefits adequate to demonstrate that medication is as good as or better than usual care for treating preschoolers with ADHD or DBD?**

   CEPAC Vote: 10 Yes 3 No

a. If yes, does the evidence suggest that:
   - Medication is as good as (equivalent to) usual care without medication?
     CEPAC Vote: 1 Yes
   - Medication is better than usual care without medication?
     CEPAC Vote: 9 Yes

Comments: Members of CEPAC who voted that the evidence is adequate to demonstrate that medication is as good as or better than usual care stated that this does not imply that all preschoolers should receive medication as a first-line treatment for ADHD or that medication is an effective treatment option for all preschoolers.

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2. **Is the evidence on risks and benefits adequate to demonstrate that parent behavior training is as good as or better than usual care for treating preschoolers with ADHD or DBD?**

   CEPAC Vote: 13 Yes 0 No

a. If yes, does the evidence suggest that:
   - Parent behavior training is as good as (equivalent to) usual care?
     CEPAC Vote: 0 Yes
   - Parent behavior training is better than usual care?
     CEPAC Vote: 13 Yes

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3. **Is the evidence on risks and benefits adequate to demonstrate that medication combined with behavioral/psychosocial interventions (including parent behavior training) is as good as or better than using medication alone to treat preschoolers with ADHD or DBD?**

   CEPAC Vote: 3 Yes 10 No

When over half of CEPAC votes "no", indicating that they believe the evidence is not adequate to demonstrate that an intervention is as good as or better than a comparator, CEPAC members who vote "no" are asked to choose from a set of reasons (Appendix B) to explain the rationale of their vote.

Of the 10 CEPAC members who voted "no", all 10 ranked insufficient quantity of evidence (i. e. too few studies) as the most important factor in their reasoning that the evidence is inadequate.

Comparative clinical effectiveness: Long-term effectiveness of ADHD treatment for children 6 years and older

Based on the findings of the AHRQ review and time limitations of the CEPAC meeting, members of CEPAC were asked for their consent to the following stipulations.

- **There is sufficient evidence to demonstrate that medications are better than usual care for treating patients with ADHD over the age of 6.**

  CEPAC Vote: 11 Yes 0 No 2 Abstain

Voting Questions

1. **Is the evidence on risks and benefits adequate to demonstrate that any other medication is as good as or better than methylphenidate (MPH) in treating ADHD patients over the age of 6?**

   CEPAC Vote: 7 Yes 6 No

a. If yes, does the evidence suggest that:
   - Other medication(s) are as good as (equivalent to) MPH beyond 1 year?
     CEPAC Vote: 7 Yes
   - Other medication(s) are better than MPH beyond 1 year?
     CEPAC Vote: 0 Yes

Comments: Members of CEPAC who voted that the evidence is inadequate to demonstrate that any other medication is as good as or better than MPH in treating ADHD patients over the age of 6 emphasized that other medications may be as good or better than MPH for certain subpopulations, including children with anxiety disorders and tics.

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2. **Is the evidence on risks and benefits adequate to demonstrate that parent behavior training is as good as or better than usual care in treating ADHD patients over the age of 6?**

   CEPAC Vote: 4 Yes 9 No

When over half of CEPAC votes "no", indicating that they believe the evidence is not adequate to demonstrate that an intervention is as good as or better than a comparator, CEPAC members who voted "no" are asked to choose from a set of reasons (Appendix G) to explain the rationale of their vote.

All CEPAC members ranked insufficient quantity of evidence (i. e. too few studies) as the most important factor in their reasoning that the evidence is inadequate.

Only two CEPAC members chose a second most important factor in their reasoning that the evidence was inadequate, selecting the following:

- Uncertainty over the rates or magnitude of clinical benefit
- Limited generalizability of the evidence to "real world" patients or clinicians.

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3. **Is the evidence on risks and benefits adequate to demonstrate that medication combined with behavioral/psychosocial interventions is as good as or better than medication alone?**

   CEPAC Vote: 10 Yes 2 No 1 Abstain

a. If yes, does the evidence suggest that:
   - Medication combined with behavioral/psychosocial interventions is as good as (equivalent to) medication alone beyond 1 year?
     CEPAC Vote: 2 Yes
   - Medication combined with behavioral/psychosocial interventions is better than medication alone beyond 1 year?
     CEPAC Vote: 7 Yes

   One CEPAC member abstained from voting on whether medication combined with behavioral/psychosocial interventions is as good as (equivalent to) or better than medication alone beyond 1 year.

Votes on 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 reference option, the Council members are also asked to vote on whether the intervention represents a "high", "reasonable", or "low" value. The value perspective that members of CEPAC are asked to assume is that of a state Medicaid program that must make resource decisions within a fixed budget for care. While information about hypothetical budget tradeoffs are provided, CEPAC is not given prescribed boundaries or thresholds for budget impact, PMPM changes, or incremental cost-effectiveness ratios to guide its judgment of high, reasonable, or low value. Only those CEPAC members who vote that the evidence is adequate to demonstrate equivalent or superior clinical effectiveness are asked to vote on comparative value.

ADHD treatment for preschoolers

1. **Based on reimbursement levels provided with this report, would you judge the comparative value of medication compared to usual care to be of 1) high value; 2) reasonable value; or 3) low value compared to usual care?**

   CEPAC Vote: 6 High 3 Reasonable 1 Abstain

2. **Based on reimbursement levels provided with this report, would you judge the comparative value of parent behavior training compared to usual care to be of 1) high value; 2) reasonable value; or 3) low value compared to usual care?**

   CEPAC Vote: 5 High 7 Reasonable 1 Abstain

Long-term effectiveness of ADHD treatment for children 6 years and older

1. **Based on reimbursement levels provided with this report, would you judge the long-term comparative value of other medications compared to MPH to be 1) high value; 2) reasonable value; or 3) low value compared to usual care?**

   CEPAC Vote: 0 High 2 Reasonable 5 Low

2. **Based on reimbursement levels provided with this report, would you judge the long-term comparative value of combined medications and behavioral/psychosocial treatments compared to medication alone to be 1) high value; 2) reasonable value; or 3) low value compared to usual care?**

CEPAC Vote: 2 High 3 Reasonable 3 Low 2 Abstain

Comments: Some members of CEPAC voted that combined medication and behavioral/psychosocial interventions had low long term comparative value because the evidence suggests that only certain subpopulations benefit from combined therapy. Members of CEPAC who voted that combination therapies have high comparative long-term value relative to medication alone cited the MTA study, the largest study comparing the long-term effectiveness of MPH to the combination of MPH and psychosocial and/or behavioral interventions. Their view was that the added clinical benefits of combination therapy seen in the MTA appeared well worth the additional cost.

Broader Considerations of Public Health, Equity, and Access

The final question of the meeting explored broader considerations of public health, equity, and access:

- **Are there any considerations related to public health, equity, disparities in access or outcomes for specific patient populations, or other social values that should be considered in medical policies related to the use of medications, parent behavior training, or other psychosocial interventions for preschoolers and people 6 years old and over for the treatment of ADHD?**

CEPAC stated that even though the council did not formally vote on the long-term effectiveness of school-based interventions, school-based interventions are an especially important component of ADHD treatment as they may provide the only access to behavioral/psychosocial interventions for low-income and/or rural patients.

Roundtable Discussion and Policy Implications

Following the CEPAC votes and deliberation, CEPAC engaged in a roundtable discussion with a panel composed of two representatives from the clinical expert community, one patient community representative, one private payer, and one public payer (names shown in the meeting participant section of this report). The goal of the roundtable was to explore the implications of CEPAC votes for clinical practice and payer policies. The topics discussed included:

Treatment of preschoolers

CEPAC and the panelists discussed the role of parent behavior training and medication in the preschool population. There was general agreement that the strength of evidence for parent behavior training, combined with residual uncertainty about appropriate diagnosis of ADHD in younger children and potential long-term effects of medication, make parent behavior training the appropriate first-line treatment for most preschoolers. Roundtable representatives raised concerns about the availability of qualified therapists in many geographical areas, and clinical experts described their experience of referrals of many children and families who received inadequate behavioral therapy.

Although parent behavior training was highly touted, the clinical experts felt that there were clear cases when the severity of symptoms and/or family issues made medication an appropriate first-line therapy, especially in cases where the child is at risk of harming themselves or others. Payers discussed broad concerns with the rising use of psychotropic medications in all children, including increased use of stimulants, other ADHD drugs, and anti-psychotics. Clinical experts and payers agreed that if medication is used to treat ADHD in a preschool patient that the most appropriate initial choice is MPH unless there are specific contraindications, such as anxiety disorder or tics. In regards to parent behavior training,

payers shared that they do not receive many requests to cover specific manual-based programs, although that may be because the sessions can be billed as family or individual therapy. One clinical expert explained that there is no widely used, available CPT code for performing parent behavior training when the child is not present, or for when parents receive training in a group setting. Often, clinicians need to give the parents themselves a diagnosis in order to be reimbursed for parent behavior training.

Treatment of school-age children

There was broad agreement that the evidence supports medication as a first-line therapy for school-age children with ADHD who have been appropriately diagnosed, but panelists commented that evidence from clinical trials, as well as their own anecdotal experience, suggests that many children are not monitored adequately during the initiation of therapy, leading many children to be "under-dosed." As with preschool children, it was argued that stimulant medication is the appropriate starting drug for most school-age children who do not have anxiety disorders or tics.

There was also discussion of the appropriate role of behavioral therapy in this age group. The CEPAC vote to confirm AHRQ's judgment of "insufficient" data on parent behavior training for school-age children led to calls for further research in this area. For other forms of behavioral therapy the panelists concurred with CEPAC that for children of parents who do not wish to initiate medication, and for children who remain significantly symptomatic despite adequate medication dosing, behavioral therapy can often be helpful, and represents a good value when used in this way. Unfortunately, the clinical experts and payers noted that the quality of behavioral therapy is very uneven, and that access to high quality therapists can be limited. They recommended efforts by payers to help support co-management of many patients by primary care pediatricians and clinical experts. Co-management may offer a mechanism to improve both medication dosing and the appropriate use of behavioral therapy in many children. In New Hampshire, there is a pilot program to train community health centers to deliver a program called "Helping the Noncompliant Child" using telepsychiatry to try to address the lack of access to psychosocial interventions throughout the state. In addition, panelists discussed the need to engage parents in managing their child's care.

Barriers to appropriate care

Panelists discussed several other important barriers to providing appropriate, cost-effective care to children with ADHD. One barrier is the shortage of child psychiatrists serving the Medicaid population in New England, making it very challenging for many pediatricians and families to get the expert guidance and care needed for many children. The patient representative noted that in some clinics patients are only able to see a psychiatrist for consideration of medication if they are also getting individual psychotherapy from that psychiatrist or one of the psychiatrist's colleagues, even though many children will have symptoms successfully treated with medication alone.

Another important barrier to appropriate care is the lack of standard outcome measures in primary care practice and children's mental health. Without standard outcome measures to evaluate the response to treatment, the selection and intensity of therapies can be misjudged. In addition, without good outcome measures in regular use efforts at quality improvement and co-management of patients are impossible.

Importantly, clinical experts also emphasized that ADHD is both one of the most under-diagnosed and most over-diagnosed conditions, meaning that while many children receive treatment for ADHD when it is not appropriate, many others do not receive treatment that could prove effective. Some CEPAC members voiced concern that over-diagnosis is more common among children of lower socio-economic status, and thus there could potentially be an overuse of medication among this subpopulation. Though diagnosis for ADHD is beyond the scope of the final report and CEPAC meeting, the quality of ADHD diagnosis has important implications for the appropriateness of treatment for children with the condition.

Patient engagement

Panelists discussed the role of parents in improving the quality of care for children with ADHD. Some panelists suggested that parents should be educated to utilize checklists and other tools to ensure quality treatment when their child is undergoing a trial of medication. However, some provider panelists had concerns that many parents do not have the time or capacity to make effective use of these tools.

Panelists agreed that more information should be available to help parents become better educated consumers of mental health services. Panelists suggested that many parents are unaware of the scope of service options available or how to access behavioral/psychosocial services, particularly parent behavior training programs.

Future evidence needs

The panel and CEPAC did not spend much time discussing specific future research needs, although discussion throughout the day emphasized the lack of adequate evidence in several areas, particularly in medication outcomes for preschoolers and the marginal added value of behavior therapy approaches for school-aged children. Panelists did raise the idea that it would be helpful to launch an intervention to increase access to parent behavior training for families with younger children affected by ADHD, and to measure the overall care costs for families receiving parent behavior training compared to costs for families opting for medication treatment. The hypothesis was raised that even though parent behavior training is more expensive than medication, its effectiveness might offset other health care costs so that it would be confirmed to be not only effective but also "high value." Panelists also expressed interest in understanding all the costs associated with ADHD, including societal costs, so that policymakers have all the information required to set appropriate policies for ADHD care. CEPAC further discussed the need

for future research to elucidate the structure and goals of parent behavior training and any ongoing maintenance therapy in order to better inform policy.

Summary: Policy Implications

For clinicians

- Before preschoolers and patients over the age of 6 are treated for ADHD, appropriate diagnostic criteria should be used, including the ruling out of co-morbid conditions such as obstructive sleep apnea.
- Healthcare providers should encourage the use of parent behavior training as a first-line therapy for preschoolers with ADHD.
- For preschoolers who do require medication based on the severity of their symptoms, MPH should be considered as a first-line treatment, except in the presence of certain clinical indications, like tics, anxiety disorder, and potential for diversion. Of the children under five receiving medication for ADHD in 2010 in New England, 40.9% received methylphenidate.
- Patients who do require medication should be monitored and evaluated for appropriate dosing and titration.
- For school-aged children, medication combined with behavioral/psychosocial interventions may be of reasonable value for patients who have not adequately responded to medication alone and/or present with severe symptoms.
- Clinicians should adopt uniform and universal standards for evidence-based outcome measurement to aid in the treatment of ADHD patients.
- Practitioners should embrace the use of innovative care approaches such as telepsychiatry to improve the care of patients with ADHD.
- Providers should adopt standardized approaches to parent behavior training and further evaluate these services in order to make more transparent the costs and savings associated with parent behavior training methods.
- Providers should conduct further research to help clarify the typical duration, goals, and optimum number of visits for parent behavior training programs, as well as the role of ongoing maintenance or supportive treatment.

For payers

- Payers should identify and encourage the use of a CPT code that supports billing for parent behavior training in the care of preschool children with ADHD. If one does not exist, stakeholders should lobby the American Medical Association (AMA) for the creation of one.
- Payers should create and support payment structures that encourage innovative care delivery, such as co-management of patients via telepsychiatry.
- Payers should heighten efforts to reduce administrative burden for clinicians seeking exemptions from clinical policies for clinically appropriate reasons.

- Payers should support transparency in the analysis of costs data by making claims data and other metrics available for researchers so the true costs of ADHD care can be assessed and discussed.
- Payers and providers should work together to identify potential barriers to accessing parent behavior training programs.

For patients

- Patient advocacy groups should provide resources to help parents become educated consumers of the various treatment options for ADHD.

Appendix A

New England Comparative Effectiveness Public Advisory Council

Public Meeting – Durham, NH

June 1, 2012

10:00 AM – 4:00 PM

10:00 – 10:15 AM: Meeting Convened and Opening Remarks *(Ned Helms, MA and Steven Pearson, MD)*

10:15 – 11:00 AM: Evidence Presentation

11:00 AM – 12:30 PM: Q&A with ICER

12:30 PM – 1:00 PM: Lunch

1:00 PM – 1:30 PM: Public Comment

1:30 – 2:30 PM: Votes on Questions

2:30 – 3:50 PM: Stakeholder Roundtable: Discussion on Implications of CEPAC Votes

3:50 – 4:00 PM: Close

MEETING PARTICIPANTS

CEPAC Members

Name	State	Organization	Disclosures
Ellen Andrews, PhD	CT	CT Health Policy Project	
Robert Aseltine, PhD	CT	University of Connecticut Health Center	
D. Joshua Cutler, MD	ME	MaineHealth and Maine Heart Center	
Teresa Fama, MD	VT	Central Vermont Rheumatology	
Austin Frakt, PhD	MA	Boston University School of Medicine and Boston University School of Public Health	
Claudia Gruss, MD (Vice Chair)	CT	Arbor Medical Group, LLC	Wellpoint shares held jointly with spouse in excess of $10,000
Felix Hernandez, MD	ME	Eastern Maine Medical Center	
Christopher Jones, PhD	VT	University of Vermont College of Medicine	
William Cyrus Jordan, MD	VT	Vermont Medical Society's Foundation for Research and Education	
Joseph Kozachek, MD (ex-officio)	CT	Aetna	
Richard Lopez, MD (Chair)	MA	Atrius Health	
William McQuade, DSc*	RI	State of Rhode Island	
Keith A. Stahl, MD	NH	Family Health and Wellness Center	
Roger Snow, MD (ex-officio)	MA	Commonwealth of Massachusetts	
Mitchell Stein, MBA	ME	Consumers for Affordable Health Care	
William Taylor, MD	MA	Harvard Medical School	Also employed by Harvard Pilgrim Health Care Institute (HPHCI), which receives funding from Harvard Pilgrim Health Care; Payments also received as a medical consultant to malpractice insurers
Members not in attendance:			
R. William Corwin, MD	RI	Miriam Hospital	
Charles Eaton, MD	RI	Alpert Medical School of Brown University and Memorial Hospital	
Sandhya Rao, MD	MA	Massachusetts General Physician Organization	
Lori Nerbonne, RN	NH	New Hampshire Patient Voices	

*ICER appointed Dr. William McQuade to serve as an ex-officio for this meeting as no council member from Rhode Island is able to attend.

Roundtable Panelists

- Craig Donnelly, MD, Dartmouth-Hitchcock Medical Center
- Michael Farber, MD, State of Vermont
- Kirsten Murphy, BA, NH Council on Autism Spectrum Disorders
- Jeffrey Simmons, MD, Blue Cross Blue Shield of Massachusetts
- Sarah Stearns, PhD, Dartmouth-Hitchcock Medical Center

ICER

- Steve Pearson, MD, President
- Daniel Ollendorf, MPH, Chief Review Officer
- Sarah Emond, MPP, Chief Operating Officer
- Kristen Migliaccio-Walle, BS, Senior Decision Scientist
- Jennifer Colby, PharmD, Research Associate
- Sarah Jane Reed, Program Coordinator

Appendix B

Reasons for Voting "No"

When over half of the Council votes "no," indicating that they believe the evidence is not adequate to demonstrate that an intervention is as good or better than a comparator, CEPAC members who voted "no" will be asked to choose from a set of reasons to explain the rationale for their vote:

1. Insufficient quantity of evidence (i.e. too few studies)
2. Risk of bias inherent in study designs
3. Uncertainty over validity of surrogate outcome measures
4. Uncertainty over duration of clinical benefit
5. Uncertainty over the rates or magnitude of clinical benefits
6. Uncertainty over the rates or severity of potential harms
7. Inconsistency of results of studies
8. Limited generalizability of the evidence to "real world" patients or clinicians
9. There is adequate evidence that the intervention is inferior to the comparator