



CEPAC Voting and Recommendation Summary
Catheter Ablation and Thoroscopic Off-Pump Surgical Ablation for Atrial Fibrillation
June 11, 2011

The New England Comparative Effectiveness Public Advisory Council (CEPAC) is an independent forum in which clinical and public policy experts can deliberate, in public, on evidence reviews of the clinical effectiveness and value of health care services. Through these deliberations, and summary votes held on key evidence questions, the 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, including recommendations for prioritizing future research. CEPAC is comprised of 19 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.

The topic for the first public meeting of CEPAC, held on June 11, 2011, was catheter ablation for the management of atrial fibrillation. Staff from the Institute for Clinical and Economic Review (ICER) had provided the CEPAC with an adapted evidence report that included the evidence review developed by the Agency for Healthcare Quality and Research (AHRQ), supplemented with new material and analyses. This supplementary material included subsequent published research, a review of evidence on emerging minimally-invasive surgical approaches to ablation, prevalence and utilization data from each New England state on atrial fibrillation treatments, and the results of a decision analysis to evaluate the clinical and cost-effectiveness of various management strategies. Two ablation clinical experts, Dr. Mark Estes of Tufts-New England Medical Center, and Dr. Thorald Sundt of the Massachusetts General Hospital, were nominated by national professional societies and were invited to participate in the meeting as resources for the CEPAC. The meeting was held on Saturday, June 11, 2011 in Boston, Massachusetts. All but one CEPAC member was in attendance; the meeting agenda and full attendance list are shown in Appendix A.

Voting Summary

CEPAC members voted on questions concerning the comparative clinical effectiveness and value of the three treatment options discussed: 1) second-line catheter ablation; 2) first-line catheter ablation; and 3) thorascopic off-pump (TOP) surgical ablation.

Question 1. Comparative clinical effectiveness: Second-line catheter ablation

For patients who have had sub-optimal response on anti-arrhythmic drugs (AADs), is the evidence adequate to demonstrate that radiofrequency ablation provides a net health benefit comparable or superior to continued management with AADs for the following patient populations:

- Younger patients (50-65) with paroxysmal AF and no other heart problems?
15 Yes; 1 No
 - If yes, is ablation comparable or superior to continued use of AADs?
14 Superior; 0 Comparable; 1 Abstain
- Patients aged 65-75 with persistent AF and congestive heart failure?
2 Yes; 13 No; 1 Abstain
 - If yes, is ablation comparable or superior to continued use of AADs?
NA
- Patients older than 75 with other serious medical conditions?
2 Yes; 14 No
 - If yes, is ablation comparable or superior to continued use of AADs?
NA

Question 2. Comparative clinical effectiveness: First-line catheter ablation

For recently diagnosed patients who have not had an extended trial of anti-arrhythmic drugs (AADs), is the evidence adequate to demonstrate that radiofrequency ablation provides a net health benefit as a first-line therapy comparable or superior to a trial of AADs for the following patient populations:

- Younger patients (50-65) with paroxysmal AF and no other heart problems?
0 Yes; 16 No
 - If yes, is ablation comparable or superior to a course of AADs?
NA
- Patients aged 65-75 with persistent AF and congestive heart failure?
0 Yes; 16 No
 - If yes, is ablation comparable or superior to a course of AADs?
NA
- Patients older than 75 with other serious medical conditions?
0 Yes; 16 No
 - If yes, is ablation comparable or superior to a course of AADs?
NA

Question 3. Comparative clinical effectiveness: Thorascopic, off-pump (TOP) surgical ablation

For patients who have had sub-optimal response on anti-arrhythmic drugs (AADs), is the evidence adequate to demonstrate that TOP surgical ablation provides a net health benefit comparable or superior to catheter ablation or continued management with AADs for the following patient populations:

- Younger patients (50-65) with paroxysmal AF and no other heart problems?
0 Yes; 16 No
 - If yes, is TOP surgical ablation comparable or superior to catheter ablation and/or to continued use of AADs?
NA
- Patients aged 65-75 with persistent AF and congestive heart failure?
0 Yes; 16 No
 - If yes, is TOP surgical ablation comparable or superior to catheter ablation and/or to continued use of AADs?
NA
- Patients older than 75 with other serious medical conditions?
0 Yes; 16 No
 - If yes, is TOP surgical ablation comparable or superior to catheter ablation and/or to continued use of AADs?
NA

Question 4. Comparative value: Second-line catheter ablation

NB: When the majority of CEPAC members vote that an intervention has comparable or superior net health benefit, then a question on comparative value is posed. For this topic, only the use of second-line catheter ablation for younger patients met this criterion.

At the reimbursement rates assumed in this analysis, does the evidence suggest that the comparative value of *second-line* catheter ablation compared to continued management with AADs is: 1) high value; 2) reasonable value; or 3) low value for the following patient populations:

- Younger patients (50-65) with paroxysmal AF and no other heart problems?
0 High; 13 Reasonable; 3 Low

Rationale for votes on comparative value

CEPAC members were asked to share the reasoning behind their “value” votes in order to elucidate the specific aspects of clinical evidence, results from the cost-effectiveness analysis, and possible value judgments that could have been weighed in this judgment. The reasons mentioned by individual CEPAC members are given below:

Among those voting for “reasonable” value

Patient-level perspective v. societal perspective

- A Council member tried to balance the competing concerns of the large impact ablation could have for individual patients with the alternative uses that policymakers might have to spend that money (e.g. immunizations).
- One Council member considered voting high value, but decided to vote reasonable because they did not like the use of word “value” and did not think it was clear who the value was for. They believe that ablation is high value for the individual, but not necessarily high value for society.
- A Council member expressed worry about voting in a way that could be construed as rationing, therefore, they assumed that if drugs didn’t work, the reimbursement rates presented in the analysis seemed to represent a reasonable value.

Quality of evidence and confidence in cost-effectiveness analysis

- A Council member felt the data were limited, but that where there are available data, the quality-adjusted life years (QALYs) and incremental cost-effectiveness ratios (ICERs) suggest substantial impact in patients of this age at what seems like a generally accepted “reasonable” cost.
- One Council member looked at cost-effectiveness analysis piece and decided that it is reasonable compared with other things we do.
- A Council member thought that the incremental cost-effectiveness ratios are in line with other interventions (though to the lay person they may look high).

Quality of life and productivity

- One Council member believed that the evidence on clinical outcomes from the model aligned with that from clinical trials and therefore had good face validity. They also commented that individual patients may have dramatically improved quality of life, and that there is not a lot of downside to trying the procedure.
- A Council member assumed that the quality of life gains would lead to productivity gains and weighed this as additional evidence of reasonable value for the money spent.
- One Council member believed that the preponderance of evidence showed that there was a better outcome with catheter ablation compared to drug use alone.

- According to a Council member, there were good reasons to believe a sizable subset of patients attain a better quality of life.
- One Council member cited data that indicate a quality of life improvement, thus catheter ablation is the logical next step for a clinician. They did not want catheter ablation as an option removed. They also believed that in terms of the financial component, for this population of younger patients you are already spending a certain amount on drugs.
- A Council member commented that if cost were the only consideration they would have voted low value, but the improved quality of life made it a reasonable value to balance out costs.

Among those voting for “low” value

Patient-level perspective v. societal perspective

- A Council member commented that the incremental effectiveness was small – couple months of QALY gain. They continued that the health system is going bankrupt, since we spend 20% of income on health care, and asked do we want that money to go to this procedure? They answered no – they would rather put the money toward interventions with a bigger impact such as smoking cessation or PCPs for everyone.

Quality of evidence and confidence in cost-effectiveness analysis

- One Council member believed that there was a lack of high-quality evidence that went into the decision analysis, especially in regard to the longer-term outcomes.
- A Council member referenced the cost-effectiveness analysis and the related assumptions and they had concerns with the durability of the effect of catheter ablation. They commented that the risks are up front at the time of the procedure and there is concern about whether or not the benefits last more than 12 months. Thus, if the benefit is for a shorter time than modeled in the decision analysis, ablation will be even less cost-effective.

Social value issues important for policymakers

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, or other social values that should be considered in medical policies related to the use of catheter ablation and TOP surgical ablation?

CEPAC members offered several items for consideration, including:

- The need to understand more about why ablation rates are considerably lower in women. This could represent under-treatment, appropriate treatment, or even over-treatment, but since there are no specified clinical reasons to assume that women would have a lower rate than men, this deserves further consideration by clinical societies, researchers, and policymakers.
- To the extent that atrial fibrillation is secondary to other conditions, such as hypertension, public health education to try to reduce risk factors for atrial fibrillation should be considered.

Policy recommendations

- For physician specialty societies:
 1. The early evidence on TOP surgical ablation is often missing data on key outcomes; as has been done with catheter ablation, standards should be set by the relevant surgical societies for the collection and reporting of outcomes of TOP.
 2. Professional societies should lead the effort in establishing training standards and promoting the establishment of registries to track outcomes that can be used for quality improvement and to guide shared decision-making with patients.
 3. EP cardiologists and cardiothoracic surgeons should work together to develop general guidelines on the number of “failed” catheter ablation attempts that should lead to serious consideration of TOP surgical ablation.
- For hospitals and other clinical providers:
 1. Hospitals should work with their clinicians and specialty societies to review existing training guidelines and, where needed, develop and implement new guidelines to ensure adequate training of clinicians and ancillary staff in the skills needed for catheter ablation and TOP surgical ablation.
 2. Each hospital should establish or participate in registries to gather data on the outcomes of patients undergoing catheter ablation or TOP surgical ablation. The data from these registries should be used to guide internal quality improvement and a synthesis of the findings should be made publically available to help patients, clinicians, and other stakeholders in making more informed decisions.
- For payers:
 1. Payers should consider collaborating with clinicians to develop shared decision-making tools for patients who are considering ablation treatment for atrial fibrillation.
 2. Payers should work with hospitals and other providers to assure that patients receiving any form of ablation are treated in institutions that set high standards for training and for consistent data generation on patient outcomes.
 3. Given that TOP surgical ablation is an emerging technique, payers should consider the designation of centers of excellence to assure: 1) appropriate multi-disciplinary care is available; 2) high training standards are established; 3) adequate volume is

available to support the development of clinical expertise; and 4) requirements for evidence generation can be assured to help guide future clinical and payer policies regarding appropriate patient selection for TOP surgical ablation.

Research recommendations

CEPAC members acknowledged that uncertainty remains regarding several important clinical and economic outcomes related to the management of patients with atrial fibrillation. In particular, they expressed hope that future research could address several key evidence gaps:

1. The durability of “successful” ablation treatments, i.e. further evidence on the cumulative relapse rate of ablation 5-10 years following initial treatment.
2. The impact of “successful” ablation on the reduction of stroke risk.
3. The identification of risk factors for atrial fibrillation, especially those over which patients have control.
4. The comparative clinical outcomes of patients treated with ablation who are taken off of warfarin.
5. The success rate of further attempts at catheter ablation following an initial unsuccessful ablation or relapse into atrial fibrillation following an initially successful ablation; and, the “threshold” number of attempts at ablation after which outcomes become equivalent or superior with TOP surgical ablation.
6. The comparative impact on patient-centered outcomes such as return to work, relative degree of disability, and quality of life for patients representing a broader spectrum of clinical and socio-demographic characteristics.
7. The relative risks and benefits of treatment for patient groups poorly represented in the clinical literature, including women, elderly patients over age 75 and patients with common cardiac conditions such as CHF, and frail patients with multiple comorbidities.
8. The impact of training and experience on outcomes for both catheter ablation and TOP surgical ablation.

The next public meeting of CEPAC will be in December 2011 at a location in New England to be determined. CEPAC members will be reviewing the adaptation of Nonpharmacologic Interventions for Treatment-Resistant Depression in Adults. Please visit <http://cepac.icer-review.org/> for the latest news and information about the New England Comparative Effectiveness Public Advisory Council.

Appendix A: Meeting Agenda and Attendee List

Public Meeting – Boston, MA

June 11, 2011

10:00 AM – 3:30 PM

AGENDA

10:00 – 10:15 AM: Meeting Convened and Introductions (*R. Lopez and S. Pearson*)

10:15 – 10:30 AM: Clinical Expert Presentations

Catheter Ablation Overview: N.A. Mark Estes, MD, Director, New England Cardiac Arrhythmia Center, Tufts Medical Center

Surgical Ablation Overview: Thor Sundt, MD, Chief, Division of Cardiac Surgery, Massachusetts General Hospital

10:30 – 11:30 AM: Adaptation Presentation (*ICER Team*)

11:30 AM - 12:15 PM: Q&A with ICER and Clinical Experts

12:15 – 1:00 PM – Public Comment

1:00 – 1:45 PM – Lunch

1:45 – 3:20 PM – Votes on Questions (*S. Pearson and R. Lopez*)

3:20 – 3:30 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	
R. William Corwin, MD	RI	Miriam Hospital	
Michael Deren, MD	CT	Private Practice	
Chuck Eaton, MD	RI	Memorial Hospital of Rhode Island, Center for Primary Care and Prevention	
John Fallon, MD (ex-officio)	MA	Blue Cross Blue Shield of Massachusetts	
Teresa Fama, MD	VT	Central Vermont Rheumatology	
Michael Farber, MD (ex-officio)	VT	State of Vermont	
Sandra Fritsch, MD	ME	Maine Medical Center	
Deidre Gifford, MD	RI	Rhode Island Chronic Care Sustainability Initiative	Salary funded by multi-stakeholder collaboration including Blue Cross Blue Shield of Rhode Island, United Health Care, Neighborhood Health Plan of Rhode Island and Tufts Health Plan
Claudia Gruss, MD (Vice Chair)	CT	Arbor Medical Group, LLC	Wellpoint shares held jointly with spouse in excess of \$10,000
Cy Jordan, MD	VT	Vermont Program for Quality in Health Care	
Jekkie Kim, MD, JD, MBA, LLM	MA	Health Care For All	
Thomas Lee, MD	MA	Partners Community HealthCare, Inc.	
Richard Lopez, MD (Chair)	MA	Atrius Health	
Lori Nerbonne, RN	NH	New Hampshire Patient Voices	
Keith Stahl, MD	NH	Family Health and Wellness Center	
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
<i>Member not in attendance:</i>			
Felix Hernandez, MD	ME	Eastern Maine Medical Center	

Clinical Experts

N.A. Mark Estes, MD, Director, New England Cardiac Arrhythmia Center, Tufts Medical Center

Thor Sundt, MD, Chief, Division of Cardiac Surgery, Massachusetts General Hospital

ICER Staff

Steven Pearson, MD, President

Dan Ollendorf, MPH, Chief Review Officer

Sarah Emond, MPP, Chief Operating Officer

Marc Silverstein, MD, Chief Decision Scientist

Kristen Migliaccio-Walle, BS, Senior Decision Scientist