The New England Comparative Effectiveness Public Advisory Council

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Ablation Strategies for Atrial Fibrillation: Supplemental Data and Analyses to the Comparative Effectiveness Review of the Agency for Healthcare Research and Quality

FINAL MEETING REPORT

Completed by:

The Institute for Clinical and Economic Review

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Introduction

To make informed healthcare decisions, patients, clinicians, and policymakers need to consider many different kinds of information. Rigorous evidence on the comparative clinical risks and benefits of alternative care options is always important; but along with this information, decision-makers must integrate other considerations. Patients and clinicians must weigh patients' values and individual clinical needs. Payers and other policymakers must integrate information about current patterns of utilization, and the impact of any new policy on access, equity, and the overall functioning of systems of care. All decision-makers, at one level or another, must also consider the costs of care, and make judgments about how to gain the best value for every healthcare dollar.

The goal of this initiative is to provide a forum in which all these different strands of evidence, information, and public and private values can be discussed together, in a public and transparent process. Initially funded by a three-year grant from the federal Agency for Healthcare Research and Quality (AHRQ), and backed by a consortium of New England state policy makers, the mission of the New England Comparative Effectiveness Public Advisory Council (CEPAC) is to provide objective, independent guidance on how information from adapted AHRQ evidence reviews can best be used across New England to improve the quality and value of health care services. CEPAC is an independent body of 19 members, composed of clinicians and patient or public representatives from each New England state with skills in the interpretation and application of medical evidence in health care delivery. Representatives of state public health programs and of regional private payers are included as ex-officio members of CEPAC. The latest information on the project, including guidelines for submitting public comments, is available online: cepac.icer-review.org.

The Institute for Clinical and Economic Review (ICER) is managing CEPAC and is responsible for developing adapted AHRQ reviews for CEPAC consideration. ICER is an academic research group based at the Massachusetts General Hospital's Institute for Technology Assessment. ICER's mission is to lead innovation in comparative effectiveness research through methods that integrate evaluations of clinical benefit and economic value. By working collaboratively with patients, clinicians, manufacturers, insurers and other healthcare stakeholders, ICER develops tools to support patient decisions and medical policy that share the goals of empowering patients and improving the value of healthcare services. More information about ICER is available at www.icer-review.org.

ICER has produced this set of complementary analyses to provide CEPAC with information relevant to clinical and policy decision-makers in New England. This adaptation is not meant to revisit the core scientific findings and conclusions of the AHRQ review on "Comparative Effectiveness of Radiofrequency Catheter Ablation for Atrial Fibrillation" but is intended to supplement those findings with: 1) updated information on catheter ablation published since the AHRQ review; 2) evidence regarding an additional management option, surgical ablation; 3) regional data on prevalence, utilization, and existing payer coverage policies; and 4) the results of a decision analytic model and budget impact analysis to support discussion of the comparative value of different patient management options. This report is part of an experiment in enhancing the use of evidence in practice and policy, and comments and suggestions to improve the work are welcome.

1. Background

1.1 The Condition

Atrial fibrillation (AF) is the most common cardiac arrhythmia in the US population (Fuster, 2006). AF occurs when rapid, disorganized electrical signals cause the atria (the two upper chambers of the heart) to “fibrillate”, or contract quickly and irregularly. This in turn causes some blood to pool in the atria rather than be pumped completely into the ventricles. AF can be asymptomatic but it may also be associated with several bothersome symptoms, including shortness of breath, difficulty with exercise, palpitations, general fatigue, dizziness, and confusion.

Importantly, AF is the second-leading cause of stroke, after atherosclerosis (Heron, 2009); the risk of stroke among those with AF is estimated to be fivefold higher than in patients without this disorder (National Stroke Association, 2010). AF and congestive heart failure (CHF) are also highly associated; about two-thirds of patients with CHF over age 65 are likely to have AF (Savelieva, 2004), and the presence of AF increases CHF severity (Maisel, 2003). In the symptomatic patient, the goals of treatment are therefore twofold: (1) to reduce AF symptoms and its contribution to comorbidity; and (2) to prevent stroke.

AF is classified as “paroxysmal” when episodes last 7 days or less and terminate spontaneously. “Persistent” AF occurs when episodes do not self-terminate and last longer than 7 days; this classification also includes a “long-standing” category, described as persistent AF for longer than one year. Finally, “permanent” AF describes a situation in which restoration of sinus rhythm is no longer considered possible.

The epidemiology of AF as well as the changing demographic in the US suggest a significant and growing health-system burden, as the prevalence of AF increases substantially with age (Feinberg, 1995) . An estimated 2.6 million Americans are currently diagnosed with AF, a number that is expected to grow nearly threefold by 2050 (Go, 2001). A study of temporal trends in AF hospital admission indicates a 60% rise in hospitalization rates from the early 1980s to the early 1990s, independent of changes in other risk factors (Friberg, 2003). Total annual costs of AF treatment are already estimated to amount to nearly $7 billion in the US (Coyne, 2006). Not surprisingly, there is significant interest on the part of patients, clinicians, policymakers, and other stakeholders in evaluating the clinical and economic impact of management options for AF.

1.2 Treatment Strategies

The two overarching goals of treatment for AF are (a) reduction or elimination of symptoms; and (b) stroke prevention. Control of heart rate with medications is often considered to be the most appropriate initial strategy for AF management for most patients who remain in AF following early attempts at restoration of normal sinus rhythm. For some patients, however, symptoms of AF are not adequately managed with rate control medications alone, leading to consideration of the options for restoration and maintenance of normal sinus rhythm. Nevertheless, it should be noted that stroke prevention strategies, including use of warfarin, aspirin, and newer agents such as dabigatran and rivaroxaban as well as the potential introduction of occlusive left atrial appendage devices, remain a cornerstone of AF management given the lack of conclusive data linking restoration of normal sinus rhythm to reduced risk of stroke.

Following a diagnosis of AF, initial restoration of normal heart rhythm is typically attempted through either electrical or pharmacologic cardioversion. This is usually a temporary solution, however, as 20-30% of patients do not convert immediately to sinus rhythm, and AF recurs in many patients who have initial success (Crandall, 2009).

As noted above, rate control with medications is often considered to be the most appropriate initial strategy for AF management, as it is well-accepted that slowing ventricular response both at rest and during activity will result in symptom improvement and likely reduce the risk of cardiovascular events (Dorian, 2010). Recent guidelines suggest that rate control medications be continued for long-term management in most AF patients, with the addition of rhythm control medications for patients who remain symptomatic despite adequate rate control, or for those with special considerations such as degree of symptoms, younger age, or higher activity levels (Camm, 2010). For patients such as these, the choice among rhythm control strategies becomes a paramount clinical concern, and given the number and variety of options, the comparative effectiveness of rhythm control strategies is a key question for clinical and policy decision-making.

Antiarrhythmic Drugs

Antiarrhythmic drugs (AADs) may be used to try to maintain sinus rhythm after electrical cardioversion, or they may be initiated independently (Gopinathannair, 2009). Many AADs are also known to have rate-control properties (Zimetbaum, 2007). It should be noted that AF recurrence is frequent even with the most effective AADs; in this context, success of rhythm control therapies is typically defined by reduction in the frequency and severity of symptoms, not by their elimination (Fuster, 2006).

There are many options among AADs, and the available drugs have differing levels and types of side effects (Reiffel, 2009). Among all AADs, amiodarone, although it is technically “off-label” for use in treating AF, is generally viewed as the most effective available drug at maintaining sinus rhythm. Amiodarone is frequently used in patients with underlying structural heart disease, as the risk of proarrhythmia (increased frequency and/or severity of atrial arrhythmias) in patients with heart disease is much lower with amiodarone than with other AADs (Zimetbaum, 2007). However, amiodarone’s relative effectiveness is counter-balanced by its potential to cause severe side effects such as thyroid dysfunction and pulmonary fibrosis, particularly with long-term use. Because of these risks, for many patients with AF amiodarone is considered a second-line agent, used only if another AAD fails to control the rhythm adequately.

Other common AADs include flecainide, dofetilide, propafenone, and ibutilide. Although not generally as effective as amiodarone at sustaining normal sinus rhythm, because these drugs offer lower risks for some long-term toxicities, they may be considered first-line agents for selected patients. Recently, a new non-iodinated amiodarone analogue, dronedarone, was approved by the FDA for use in patients with AF without severe heart failure (Stiles, 2009). The absence of iodine in dronedarone is thought to render the drug less toxic, but its comparative effectiveness vs. amiodarone and its optimal role in AF management is still controversial (Chan, 2009; Singh, 2010). Recently, reports have surfaced regarding incident cases of torsades de pointes and worsening CHF for patients on dronedarone, but their association with dronedarone use is still under investigation (US FDA Adverse Event Reporting System, 2010).

Guidelines published in 2010-2011 from the American College of Cardiology, American Heart Association, and European Society of Cardiology (Wann, 2011; Camm, 2010) recommend AAD treatment for patients in AF who have troublesome symptoms, who have a good chance of remaining in sinus rhythm, and who can tolerate AADs. The guidelines stress the importance of choosing an AAD based on individual characteristics of the patient. Note that while this report focuses on the use of catheter-based and surgical ablation, AAD management represents the "reference standard" treatment against which these procedures have been compared.

Catheter Ablation

Among patients with atrial fibrillation (AF), catheter ablation (CPT code 93651) is a common technique used to restore normal heart rhythm. During catheter ablation, abnormal tissue in the atrial space is destroyed to interrupt faulty electrical signals and restore normal sinus rhythm (Crandall, 2009). Ablation is most frequently accomplished using radiofrequency (RF) energy, which also cauterizes the lesions created. Cryothermal approaches also may be used to freeze tissue.

The most common type of catheter ablation performed is pulmonary vein isolation (PVI) (Callahan, 2009). The pulmonary vein is a common source of abnormal electrical activity that can trigger AF; the goal of PVI is therefore to create scars in the cardiac tissue that will interrupt all electrical communication between the pulmonary vein and the atria. Other sites of ablation may include the ligament of Marshall and the superior vena cava, although these are most frequently ablated as an adjunct to PVI rather than a substitute (Callahan, 2009). For patients with persistent or chronic AF, so-called "linear ablation" may be employed, in which pulmonary vein lesions are anchored to other ablation sites or the mitral valve in an attempt to create an unfavorable environment for sustained AF (Crandall, 2009).

Catheter ablation is performed in an electrophysiology (EP) lab. In most cases the location of catheter insertion is either the neck or groin area. One or more diagnostic catheters are inserted into the blood vessel and are moved toward the heart. The physician follows the catheter's progress via a special monitor connected to a fluoroscopic camera. The diagnostic catheters are used to study the arrhythmia. Once the physician determines the location of the cardiac tissue where abnormal rhythms can be sustained, this area can be ablated. Catheter ablation usually results in a same-day discharge or single overnight hospital stay. Rare but serious complications can occur, including stroke during the procedure, cardiac tamponade, and atrioesophageal fistula from the energy source. Some level of atrial fibrillation or flutter is not unexpected immediately following ablation, but this often gradually diminishes over several weeks; as such, the success of catheter ablation is typically not assessed until after a "blanking period", generally 3 months in duration (Calkins, 2007).

Proponents of catheter ablation argue that, by "curing" AF, the procedure provides permanent symptom relief and may produce electroanatomic remodeling of the atrial space, thereby reducing the risk of recurrence (Pappone, 2001). Others contend that the idea of a "cure" is oversold; recurrence of AF remains common after ablation, requiring multiple repeat ablations in many patients. Moreover, there remain questions about whether ablation offers significant long-term improvements in quality of life compared to rate-control strategies; and, even after a successful ablation, current guidelines recommend continuation of antithrombotic therapy based on patients' underlying risks for stroke.

Surgical Ablation

Surgical ablation techniques have evolved over the past 20 years and serve as a viable option for rhythm control among patients with atrial fibrillation (AF). Surgical ablation has historically been reserved for patients who are considering surgery for other cardiovascular conditions (e.g., valve replacement); however, the advent of minimally-invasive surgical techniques has led to the use of surgical ablation as a treatment for AF among patients with no other indication for cardiac surgery.

There are three major types of surgical techniques used in the treatment of AF. Like catheter ablation, all approaches seek to interrupt abnormal electrical impulses that cause AF, but surgical techniques also involve excision or exclusion of the left atrial appendage (LAA), which is thought to be the location of 60-90% of the thrombi that cause AF-related strokes (Blackshear, 1996):

1. **"Cox-Maze III" –** This procedure, which involves a full thoracotomy and cardiopulmonary bypass, is the original, "cut and sew" approach to surgical ablation of AF (Lee, 2009b). The surgeon creates multiple left and right atrial incisions, which are then sutured back together. This creates lesions of scar tissue, which interrupt re-entrant circuits, preventing abnormal electrical activity from circulating through the heart. The Cox-Maze, which is now in its third generation (i.e., Cox-Maze III), is a technically demanding procedure; as a result, only a limited number of centers worldwide perform it. (CPT codes 33254, 33255, 33258 if performed without bypass, and 33256, 33259 if done under bypass)

2. **"Cox-Maze IV" –** This procedure involves a smaller, "mini-thoracotomy" and cardiopulmonary bypass. The traditional cardiac incisions of the Cox-Maze III are replaced by radiofrequency and/or cryothermal lesions; in addition, isolation of the right and left pulmonary veins is accomplished using a slightly different method (Lall, 2007). This procedure is considered simpler to perform and is associated with reduced operating-room time relative to Cox-Maze III (Melby, 2006). (CPT codes 33254, 33255, 33258 if performed without bypass, and 33256, 33259 if done under bypass)

3. **Thoracoscopic "Off-Pump" (TOP) Approaches** – This procedure is done on a "beating heart" – the heart is not arrested via bypass. Use of a thorascope (a video telescope) helps surgeons guide the energy source to the atria. Radiofrequency energy applied to the outside of the heart (epicardial ablation) is used for lesion creation. This approach has many variants, but commonly involves pulmonary vein isolation at a minimum, as well as other potential ablation lines. Bipolar radiofrequency energy is typically employed, in contrast to the unipolar energy employed in catheter ablation. (CPT codes 33265, 33266)

All forms of surgical ablation require an inpatient stay in the hospital; the length of stay will vary depending on whether other cardiac surgical procedures are performed. All surgical approaches carry small risks of serious complications, including stroke, tamponade, coronary artery injury, phrenic nerve paralysis, and esophageal perforation (Lee, 2009a), in addition to traditional surgical risks (e.g., MI, infection). In addition, as with catheter ablation, temporary recurrence of AF in the 3-6 months post-surgery is common, and many patients receive AADs during this period to aid in the return to sinus rhythm.

Proponents of surgical ablation describe several advantages over catheter-based ablation techniques. First, removal of the left atrial appendage has been conservatively estimated to remove the source of approximately 50% of thromboembolic events in patients with chronic AF (Blackshear, 1996). In addition, some advocates believe the use of bipolar radiofrequency energy produces more effective lesions than unipolar energy (Bugge, 2005). On the other hand, it is argued that effective management of AF can be accomplished through non-invasive means for many patients, and the additional risks posed by surgery may outweigh any potential clinical benefits offered by surgery.

Importantly, the focus of the analyses that follow are on TOP surgical ablation, as it is more likely to be considered an alternative to catheter ablation or noninvasive management than more invasive surgical procedures, which are typically reserved for patients undergoing concomitant cardiovascular surgery or those for whom other management strategies have failed (Calkins, 2007).

2. Clinical Guidelines

2.1 Catheter Ablation

- The European Society of Cardiology (2010)
  http://www.escardio.org/guidelines-surveys/esc-guidelines/GuidelinesDocuments/guidelines-afib-FT.pdf
  Catheter ablation for paroxysmal AF should be considered for patients who have previously failed a trial of anti-arrhythmic medication. Ablation of persistent symptomatic AF that is refractory to anti-arrhythmic medication should be considered a treatment option.

- Heart Rhythm Society Task Force on Catheter and Surgical Ablation of Atrial Fibrillation (HRS, 2007)
  http://www.hrsonline.org/News/Media/press-releases/upload/HR-and-Euro-Copy-for-Print.pdf
  The Task Force considers the following indications to be appropriate for catheter ablation:
    - Symptomatic AF refractory or intolerant to at least one Class 1 or Class 3 AAD; or
    - Selected symptomatic patients with heart failure and/or reduced ejection fraction.

  In rare clinical situations, it may be appropriate to perform catheter ablation as first-line therapy. Catheter ablation should not be performed in patients with left atrial thrombi.

- The American College of Cardiology, American Heart Association, and Heart Rhythm Society Focused Updates Incorporated Into the ACC/AHA/ESC 2006 Guidelines (ACCF/AHA/HRS, 2011)
  http://www.hrsonline.org/ClinicalGuidance/upload/2011-ACCF-AHA-HRS-Focused-Update-on-the-Management-of-Patients-With-Atrial-Fibrillation.pdf
  Catheter ablation performed in experienced centers (> 50 AF catheter ablation cases per year) is useful in maintaining sinus rhythm in selected patients with significantly symptomatic, paroxysmal AF who have failed treatment with an antiarrhythmic drug and have normal or mildly dilated left atria, normal or mildly reduced LV function, and no severe pulmonary disease. Catheter ablation is reasonable to treat symptomatic, persistent AF and may be reasonable to treat symptomatic, paroxysmal AF in patients with significant left atrial dilatation or with significant LV dysfunction.

2.2 Surgical Ablation

- The European Society of Cardiology (2010)
  http://www.escardio.org/guidelines-surveys/esc-guidelines/GuidelinesDocuments/guidelines-afib-FT.pdf
  Minimally-invasive surgical ablation without concomitant cardiac surgery is feasible and may be performed in patients with symptomatic AF after failure of catheter ablation.

- Heart Rhythm Society Task Force on Catheter and Surgical Ablation of Atrial Fibrillation (HRS, 2007) http://www.hrsonline.org/News/Media/press-releases/upload/HR-and-Euro-Copy-for-Print.pdf
  Stand-alone atrial fibrillation surgery is an option for AF patients who either prefer surgery, have failed one or more catheter ablation attempts, or are not candidates for catheter ablation.

- The International Society of Minimally Invasive Cardiothoracic Surgery (ISMICS, 2009) http://journals.lww.com/innovjournal/Fulltext/2010/03000/Surgical_Ablation_for_Atrial_Fibrillation_in.3.aspx
  This consensus document focused attention of surgical ablation concomitant to other cardiac surgical procedures, and concluded that the various surgical ablation techniques are associated with improvements in achievement of normal sinus rhythm and no increase in peri-operative mortality or other complications relative to cardiac surgery without ablation. Applicability of these findings to the patient with stand-alone AF was deemed "uncertain", however.

3. Medicare, National and New England Private Insurer Coverage Policies

3.1 Catheter Ablation

National Payers

- Centers for Medicare and Medicaid Services (CMS): Medicare does not currently have a national coverage determination for the use of catheter ablation in the treatment of atrial fibrillation. A meeting of the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) meeting was held in October 2009 to discuss this topic. The evidence was judged to be adequate to evaluate catheter ablation for AF recurrence and symptom relief; there was also consensus that 2nd-line therapy with ablation improves health outcomes relative to standard care. However, a lack of evidence regarding catheter ablation's impact on long-term outcomes, as well as its effects among Medicare beneficiaries was noted; it was suggested that a "coverage with evidence development" policy may be appropriate. http://www.cms.gov/faca/downloads/id50c.pdf

- CIGNA: CIGNA considers transcatheter ablation of the pulmonary veins a medically necessary alternative to long-term AAD therapy for atrial fibrillation treatment for individuals who are (a) symptomatic for recurrent paroxysmal or persistent atrial fibrillation; and (b) have little or no left atrial enlargement present.

- Aetna: Cardiac catheter ablation procedures are considered medically necessary by Aetna for members with drug-resistant or drug-intolerant atrial tachycardia, atrial flutter, or either of these symptoms associated with p[ar]oxysmal atrial fibrillation; or, members with any of these conditions who do not want to undergo long-term drug therapy.

- Wellpoint/Anthem: Transcatheter radiofrequency ablation of arrhythmogenic foci in the pulmonary veins is considered medically necessary when the patient meets both of the following criteria:
  - Is symptomatic; AND
  - Is resistant or has intolerance to one or more AADs, or has a contraindication to the appropriate therapy

Regional Payers

- Blue Cross Blue Shield of Massachusetts: BCBSMA covers catheter ablation for the treatment of patients with recurrent supraventricular (atrial, sinoatrial) tachyarrhythmias (SVT) that are resistant or averse to drug therapy, and are undergoing ablation for the following:

- Ablation of the AV node,
- Modulation of the AV node using radiofrequency energy,
- Ablation of accessory pathways: AV re-entrant tachycardia/atrial fibrillation/other atrial tachyarrhythmias associated with rapid ventricular response via accessory pathways using radiofrequency energy
- Atrial flutter

(NOTE: No published policies on catheter ablation were found for other regional payers, including Harvard Pilgrim, Tufts, BCBSRI, BCBSVT, ConnectiCare, and MVP.)

3.2 Surgical Ablation

National Payers

- Centers for Medicare and Medicaid Services (CMS): Medicare has not made a national coverage decision for the use of surgical ablation in the treatment of atrial fibrillation. The three carriers for Medicare in New England are NGS, NHIC and WPSIC, and none has published coverage policies for any form of surgical ablation. A published local coverage decision in Florida considers both the Cox-Maze and minimally-invasive approaches, performed alone or in conjunction with other cardiovascular surgery, to be reasonable and necessary. http://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=48471&ver=2&ContrId=197&ContrVer=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=maze&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAABAAAAAA&

- CIGNA: The Maze procedure is covered when performed during cardiopulmonary bypass with or without concomitant surgery in patients who have medically refractory, intermittent symptomatic atrial fibrillation of any type for whom rhythm control is considered essential. CIGNA does not cover minimally-invasive, off-pump Maze procedures. They are considered experimental and investigational.

- Aetna: Both the Cox-Maze and minimally-invasive procedures are considered medically necessary for the following situations:
  - The patient is suffering hemodynamic consequences of chronic atrial fibrillation.
  - The patient cannot tolerate the side effects of drug therapy.
  - The patient is at high risk for thromboembolism due to:
    a. Experienced a previous episode of venous thromboembolism, yet other causes have been ruled out; or
    b. Long-standing atrial fibrillation has been documented in patients with mitral valve disease

- Wellpoint/Anthem: Both the Cox-Maze and minimally-invasive procedures are considered medically necessary for drug-resistant atrial fibrillation. They are also considered medically necessary for those with highly symptomatic atrial fibrillation who require other surgery for valvular, ischemic, or congenital heart disease.

Regional Payers

- Blue Cross Blue Shield of Massachusetts: The Cox-Maze procedure is covered, with or without concomitant cardiac surgery, when it is used for the treatment of drug-resistant atrial fibrillation or flutter. Minimally invasive, off-pump procedures are not covered as they are considered investigational.

  (NOTE: No published policies on surgical ablation were found for other regional payers, including Harvard Pilgrim, Tufts, BCBSRI, BCBSVT, ConnectiCare, and MVP.)

4. New Evidence Following AHRQ Review

4.1 Antiarrhythmic Drugs

No new studies have been published since the AHRQ review that provide significant new information about the approach to AAD treatment or relevant outcomes.

4.2 Catheter Ablation

Since the publication of the AHRQ review, additional evidence has become available regarding this procedure's short- and long-term effects. For example, in addition to the 4 randomized controlled trials (RCTs) that evaluated maintenance of normal sinus rhythm vs. medication management that were included in the AHRQ review, 4 new RCTs have been published (Oral, 2006; Jais, 2008; Forleo, 2009; Wilber, 2010) that involved comparisons of catheter ablation to AADs. While the findings of these RCTs were somewhat variable, findings from the more recent RCTs are essentially identical to those in the AHRQ review – i.e., that catheter ablation is approximately 3 times more likely than management with AADs to maintain normal sinus rhythm at 6-12 months post-procedure.

New observational data have also become available to document the long-term effects of catheter ablation, particularly with regard to recurrence of AF. For example, data from a very large series of patients (n=774) undergoing catheter ablation at the Mayo Clinic suggest that 47% of patients had at least one recurrence of AF over a mean of 3 years (Wokhlu, 2010). Similarly, findings from a series of 161 patients undergoing catheter ablation in Germany indicate a rate of AF recurrence of 53.4% over a median of 4.8 years of follow-up (Ouyang, 2010). This study also found that a second ablation was required in 41% of patients, and a third ablation was necessary in 7%. Finally, data from a series of 100 patients receiving catheter ablation in France reported rates of arrhythmia-free survival after a single ablation procedure of 40%, 37%, and 29% at one, 2, and 5 years respectively (Weerasooriya, 2011). Repeat ablation was common in this study, as 175 procedures were performed in total (median of 2 per patient).

The AHRQ review identified that the impact of catheter ablation is under-studied in elderly patients, despite the fact that 70% of patients with AF are 65 years of age or older (Go, 2001). Data from a series of 45 patients 65 years or older who underwent catheter ablation in Canada were recently published (Haegeli, 2010). There was one major complication. Three-quarters of these patients were free of symptomatic AF at 6 months, a rate similar to studies of younger patients reporting symptomatic AF. Eight patients (18%) required repeat ablation.

Finally, additional data have become available regarding the safety of catheter ablation. As described in the AHRQ review, peri-procedure stroke is a known serious complication of catheter ablation, and has been reported at ranges ranging from 0-7% (median 0.9%) (Ip, 2009). In a recent study examining rates of both symptomatic and "silent" cerebrovascular embolism in 232 patients undergoing catheter ablation (Gaita, 2010), a single patient had a symptomatic event (0.4%).

However, as documented on postablation cerebral MRI, new embolic lesions were noted in 33 patients (14%). Factors associated with the development of a new lesion included faster activated clotting time and the use of peri-procedure electrical or pharmacological cardioversion.

4.3 TOP Surgical Ablation

ICER has conducted a separate appraisal of the emerging evidence on TOP surgical ablation (Ollendorf, 2010; http://www.icer-review.org/index.php/a-fib-appraisal-1209.html). The ICER appraisal concluded that available evidence on the effectiveness of TOP surgical ablation was insufficient to make a reasonable judgment of comparative clinical effectiveness, as no RCTs have been conducted comparing this procedure to other interventions for AF, and the evidence that has been generated consists of small, single-center case series involving heterogeneous patient populations and variability in technique. We identified only a single additional study of TOP surgical ablation published since the date of the ICER appraisal (September, 2010). This was a series of 28 patients at a single center in North Carolina who underwent a "convergent" procedure that involved both a TOP surgical and catheter ablation approach (Kiser, 2010). Three patients (10%) developed serious complications, including pericardial effusion and phrenic nerve injury. At 6 months of follow-up, 76% of patients were free from AF as documented by 24-hour or 7-day Holter monitoring, and did not require AADs to maintain normal sinus rhythm, a rate within the range previously reported by ICER (62-88%).

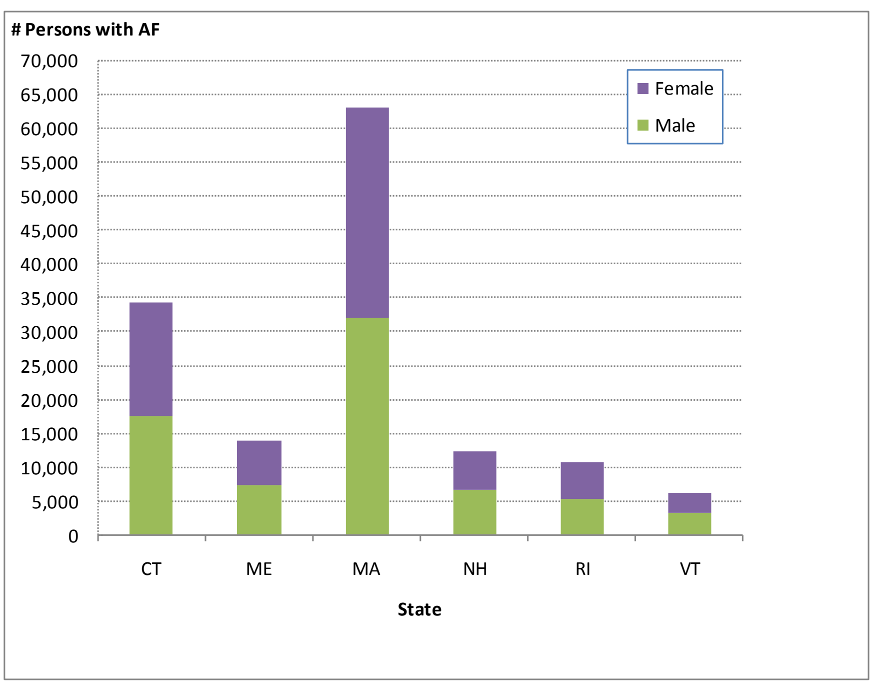
5. State-Specific Data

Analyses of state-specific information focused on publicly available data on hospitalization for AF management. Results shown are for catheter ablation only, since available data were not clinically detailed enough to identify cohorts of patients managed by medication alone, and TOP surgical ablation cannot be distinguished from other surgical approaches in current coding. Data shown are for 2008, the latest year in which estimates could be obtained from all 6 New England states.

5.1 AF Epidemiology

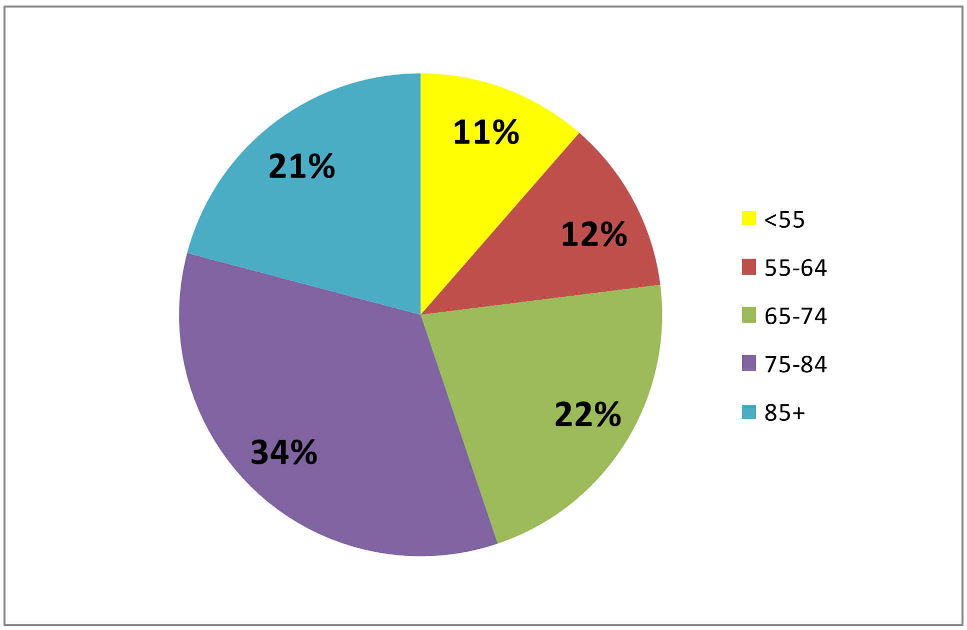
The prevalence of AF in each state was stratified by age and sex; estimates are reported by state in Appendix A. Population data were obtained from 2008 projections of the 2000 U.S. Census (series SC-EST2009-02-50). These were combined with age- and sex-specific estimates of AF prevalence obtained from an ongoing registry of nearly 18,000 adults with AF in a California health system, the AnTicoagulation and Risk Factors in Atrial Fibrillation (ATRIA) registry (Go, 2001). In this study, prevalence of AF ranged from 0.1% among women under age 55 to 11.1% in men aged over 85. Estimates of the total numbers of patients with AF are presented by sex in Figure 1 below; approximately equal numbers of men and women in each state were diagnosed with AF.

Figure 1. Estimated prevalence of atrial fibrillation in New England, by state and patient sex.



Overall, these estimates indicate that approximately 140,000 New Englanders had AF in 2008, an overall population prevalence of 1%. Not surprisingly, 70% of patients with AF were residents of Massachusetts or Connecticut, the two most populous states in the region. Prevalence ranged tightly between 0.94% in New Hampshire to 1.06% in Maine, and was influenced primarily by age distribution. The proportion of AF patients by age group is presented in Figure 2 below. The prevalence of AF increases notably with age, as more than 75% of patients were age 65 or older. The largest age group comprised individuals aged 75-84 years, representing over one-third of diagnosed patients.

Figure 2. Distribution of New England AF population, by age group.



Across all states, patients aged >80 years represented nearly 40% of the total AF estimated population. Reflecting general population trends, more women than men comprised the very elderly AF population (see Table 1 below).

Table 1. Prevalence of atrial fibrillation among persons age ≥80 years, by state and sex.

	State					
Sex	Connecticut	Maine	Massachusetts	New Hampshire	Rhode Island	Vermont
Male	5,423	2,171	9,797	1,840	1,749	940
Female	8,184	3,065	15,219	2,661	2,749	1,324
Total	13,608	5,236	25,016	4,501	4,498	2,264

5.2 Hospitalization Data: Catheter Ablation

Hospitalization information was obtained from AHRQ's Healthcare Cost and Utilization Project (H-CUP) online report function for Maine, Massachusetts, New Hampshire, and Rhode Island. Similarly-formatted reports were obtained individually from the Connecticut Office of Health Care Access and the Vermont Department of Banking, Insurance, Securities and Health Care Administration. Data were obtained for calendar year 2008, the latest year in which data were available for all states.

Hospitalizations for catheter ablation were identified based on an ICD-9-CM principal procedure code (37.34) among patients with a primary or secondary diagnosis of AF (ICD-9-CM 427.31). For each state, data on numbers of discharges, length of stay, mean hospital charges, and mean hospital costs were stratified by age group, sex, payer type, patient residence category, and race/ethnicity. Mean hospital costs were estimated by multiplying average statewide cost-to-charge ratios obtained from H-CUP by mean hospital charges. The economic measure of most interest to state decision-makers is the amount ***reimbursed*** by public and private payers for these services; unfortunately, reimbursement data are not publicly available. However, billed charges and estimated costs provide an important context for evaluation of potential budgetary impact in each state, as the amount reimbursed by most third-party payers is likely to fall somewhere between these 2 sets of values.

Finally, for age, sex, race/ethnicity, and payer type, rates of procedures per 1,000 population were calculated in combination with U.S. census data (for age, sex, and race/ethnicity) and data on payer type distribution in each state from the Kaiser Family Foundation (The Kaiser Family Foundation, 2009). All data are summarized for each New England state in Appendix B.

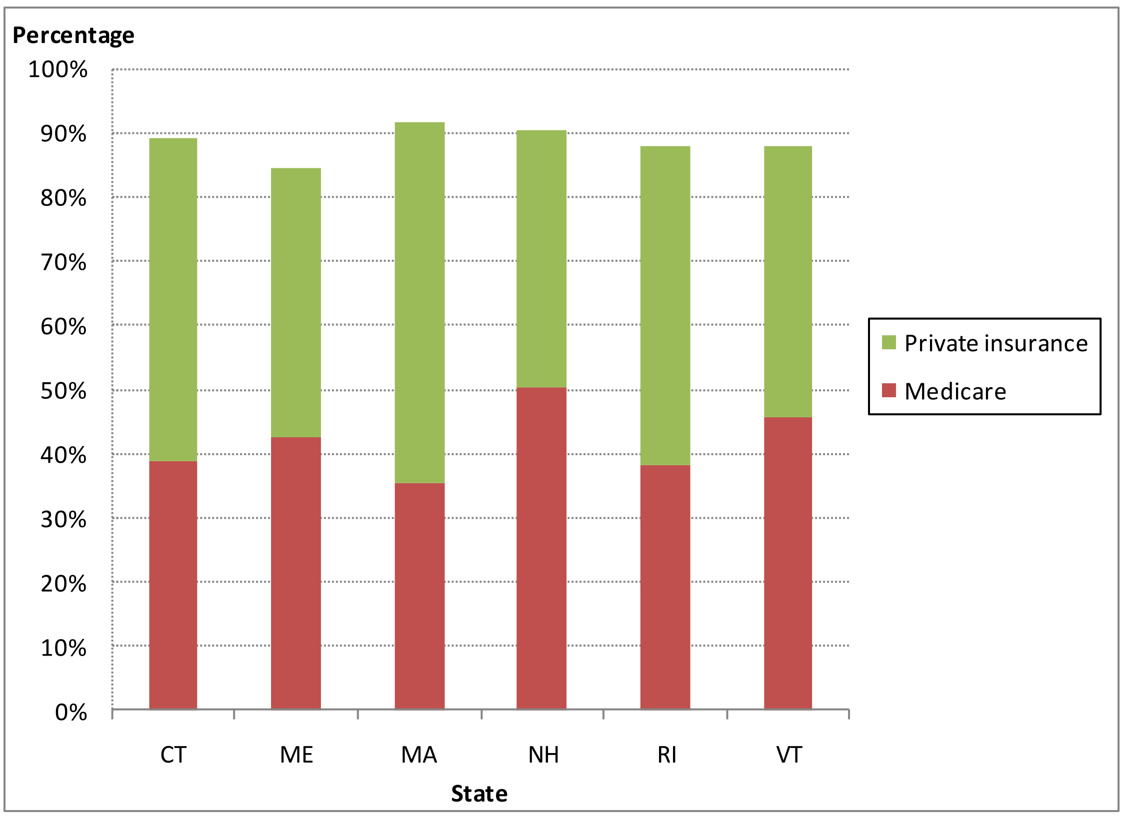
An important limitation of the publicly-available H-CUP data is the absence of detailed information on the geographic origin of hospital admissions for catheter ablation. Within a given state, the proportion of hospitalizations for catheter ablation that represent referrals from out of state is therefore unknown, making comparisons between states problematic.

Procedure Volume, Distribution, and Frequency

Across the region, over 2,900 hospitalizations for catheter ablation were reported in 2008, 60% of which occurred in Massachusetts. The demographic distribution of patients hospitalized for catheter ablation differed somewhat from that of the prevalent AF population. For example, although most patients with AF are older than age 65, approximately 60% of the hospitalizations for catheter ablation across the region were in patients younger than 65. In addition, while approximately equal numbers of men and women in New England have AF, nearly two-thirds of patients receiving catheter ablation in the region were male (range across states: 58.0-66.9%).

As can be seen in Figure 3 on the following page, across all New England states, approximately 40-45% of catheter ablations were paid for by Medicare, and 40-45% by private payers, with Medicaid and other payers responsible for roughly 10% of all cases (note that federal institutions, such as those maintained by the Departments of Defense and Veteran's Affairs, are not included in H-CUP). Medicaid recipients accounted for a relatively small proportion of catheter ablation hospitalizations. In the 3 states with sufficient volume to allow for public reporting of data, these percentages were 4.2% in Massachusetts, 6.2% in Connecticut, and 10.5% in Maine.

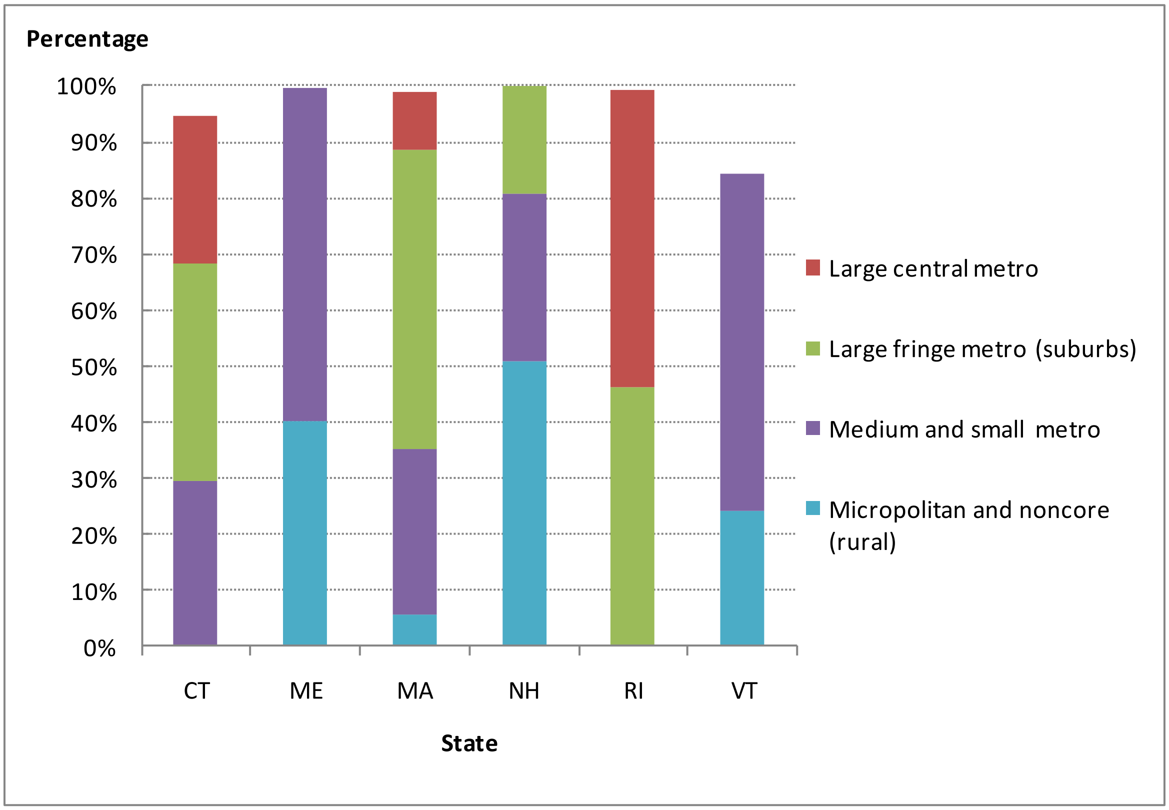
Figure 3. Proportion of catheter ablation hospitalizations with private insurance and Medicare payer types, by state.



NOTE: Insufficient volume of hospitalizations for Medicaid, uninsured, and other payer types to permit display across all states

The geographic distribution of patients hospitalized for catheter ablation varied widely across New England states. As can be seen in Figure 4 on the following page, the proportion of catheter ablations performed among residents of rural areas was highest in New Hampshire and Maine, whereas patient admissions from large central metro and suburban areas predominated in Massachusetts and Rhode Island.

Figure 4. Geographic distribution of hospitalizations for catheter ablation, by state and patient residence category.

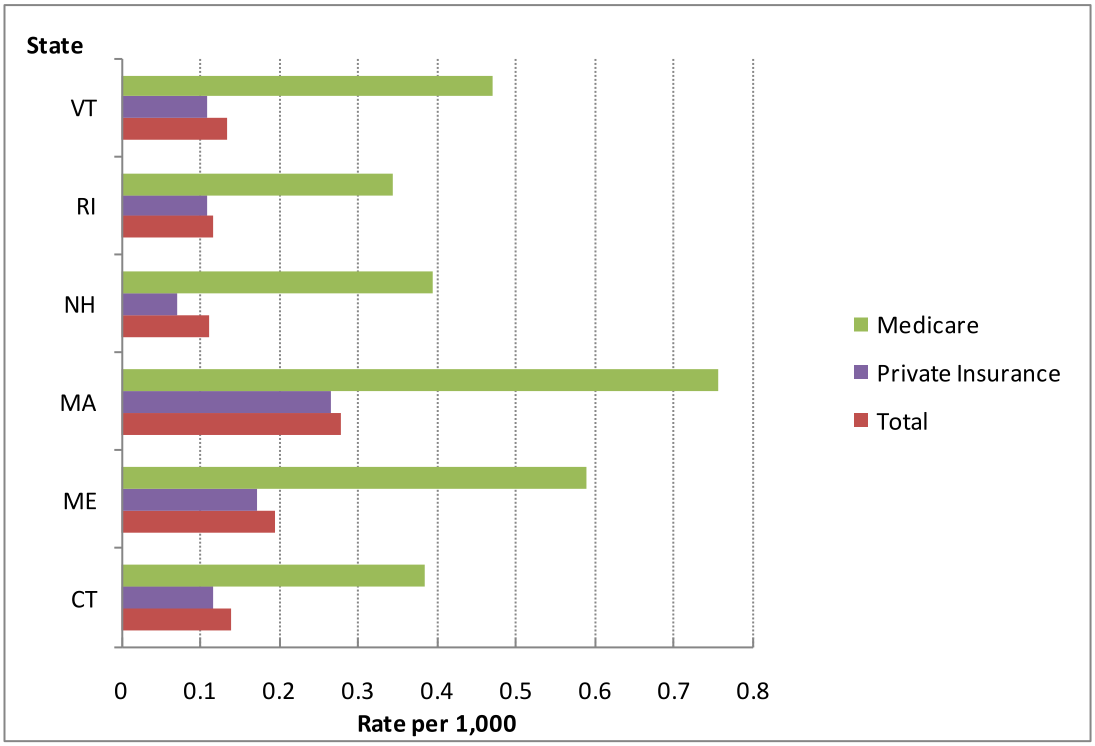


NOTE: Residence information was missing or of insufficient volume for public reporting in states where total sums to less than 100%

The frequency of catheter ablation (expressed as a rate per 1,000 persons in the overall population) also varied widely, ranging from 0.11 in New Hampshire to 0.28 in Massachusetts (see Figure 5 on the following page). Rates were 1.5-2 times higher among men. Across all states, while procedure volume was approximately equal for Medicare and private payers, the procedure *rate* among Medicare beneficiaries was 2.5-3 times higher than that observed among the privately insured (see Figure 5 on the following page), while the rate for patients with private insurance was similar to the overall statewide rate in most circumstances.

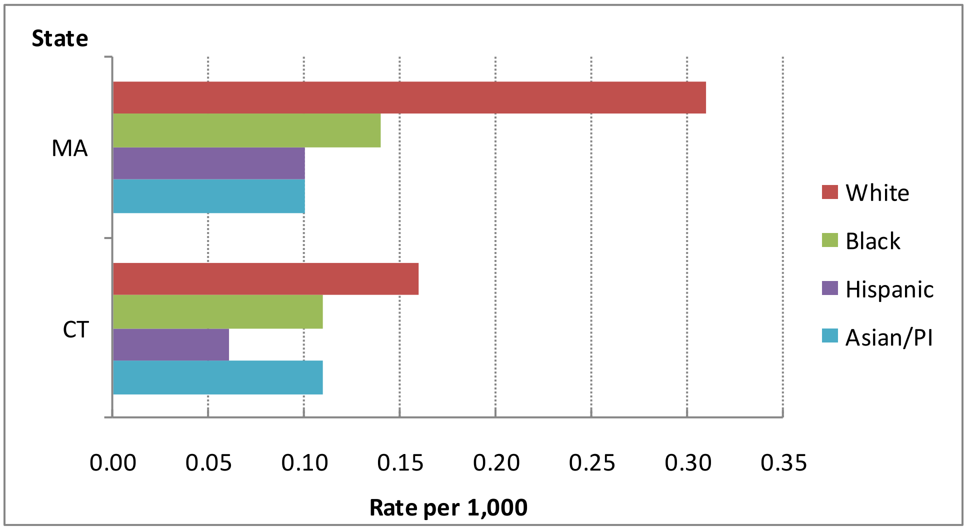
When expressed as a percentage of the total estimated number of persons with AF, ablation frequency ranged from 1.1% in Rhode Island to 2.9% in Massachusetts. The reported frequency in Massachusetts was more than 50% higher than the rate in the next highest state, Maine (1.8%). As noted previously, the extent to which these rates are driven by referral patterns from other New England states to Massachusetts versus regional practice variation cannot be determined from this data source.

Figure 5. Catheter ablation frequency per 1,000 population, by state and major payer type.



Procedure frequency differed notably across racial/ethnic categories in Connecticut and Massachusetts, the 2 states with sufficient reporting volume to display data across this stratification. In Connecticut, the rate among whites (0.16) was 45% higher than that among blacks or Asians (0.11), and nearly threefold higher than the rate among Hispanics (0.06). In Massachusetts, the rate among whites was 2-3 times higher than the rates in every other racial/ethnic category (see Figure 6 on the following page). Note that, because the H-CUP data were not further stratified by age or payer type within racial and ethnic categories, it was not possible to determine the extent to which disparities in ablation rates reflected differences in the demographic distribution within each race/ethnicity category.

Figure 6. Catheter ablation frequency per 1,000 population, by racial/ethnic category and state (Connecticut and Massachusetts only).



NOTE: PI: Pacific Islander

Resource Utilization, Costs, and Charges

Overall, average length of stay (LOS) for catheter ablation hospitalizations ranged from 2.3 days in Rhode Island to 3.9 days in New Hampshire. As shown in Table 2 below, average LOS was consistently longer among Medicare patients vs. those covered by private insurance. Differences in LOS by payer type were most pronounced in Maine and Massachusetts.

Table 2. Average length of stay for catheter ablation, by payer type and state.

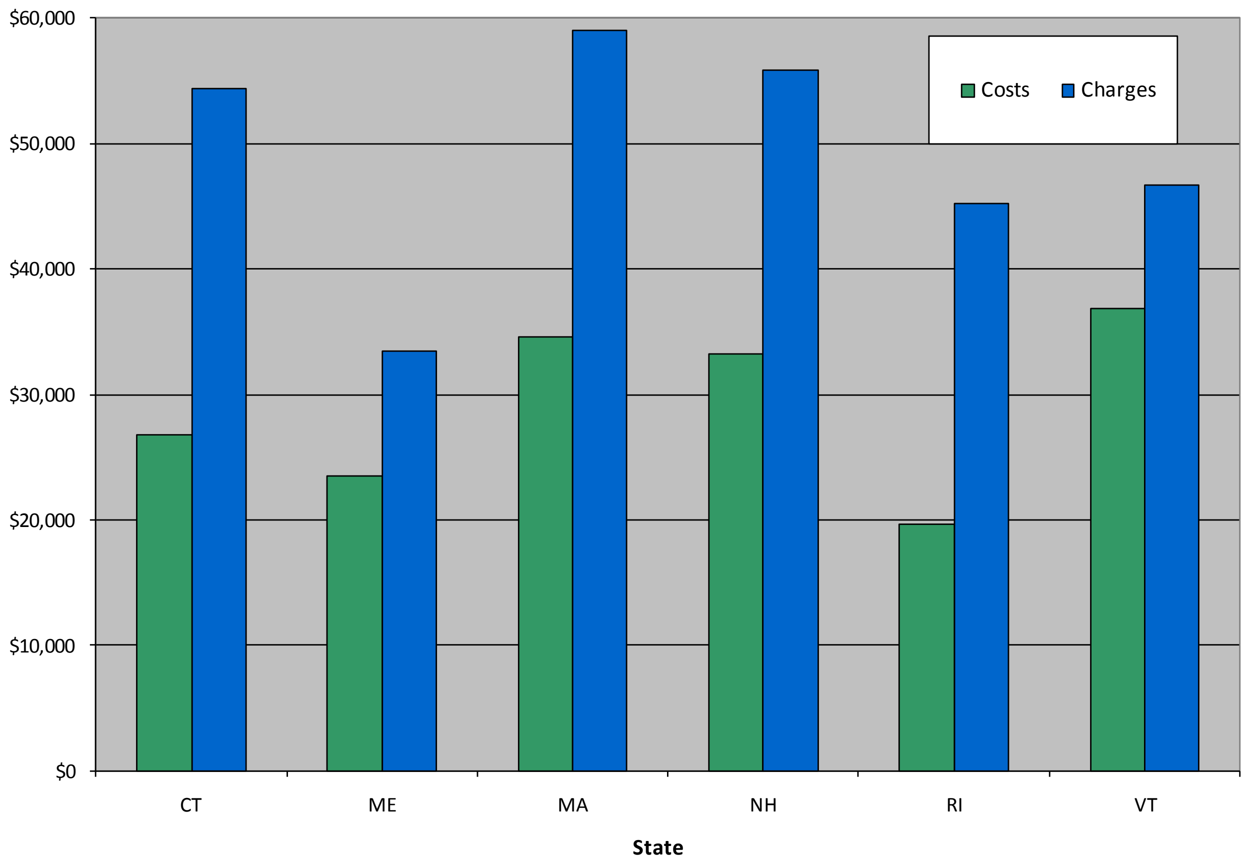
	State					
Payer Type	Connecticut	Maine	Massachusetts	New Hampshire	Rhode Island	Vermont
Medicare	4.2	4.0	3.8	4.2	2.7	4.0
Private Insurance	2.8	2.4	2.3	3.5	2.0	3.6

While no consistent differences in LOS were observed when data were stratified by patient sex or residence category, some differences were observed in Connecticut and Massachusetts across racial/ethnic categories. In Connecticut, for example, the average LOS among whites was 3.2 days, which was 20% lower than the average among Hispanics (4.0) and nearly 40% lower than that reported for blacks (5.1 days). Similar findings were observed in Massachusetts when comparing LOS values for whites vs. blacks (2.8 vs. 5.4 days respectively); however, average LOS in other racial/ethnic categories was similar to that reported for whites in Massachusetts.

Billed charges and estimated hospital costs also varied substantially by state, as illustrated in Figure 7 below. Mean billed charges were lowest in Maine ($33,520 per hospitalization), were higher but similar in Rhode Island and Vermont ($45,204 and $46,652 respectively), and were higher still in Connecticut ($54,368), Massachusetts ($59,076), and New Hampshire ($55,878).

Different patterns were noted when comparing mean hospital costs. On average, the highest average costs were observed in Vermont ($36,843), the state with the smallest discrepancy between billed charges and hospital costs. In contrast, average hospital costs were substantially lower in Rhode Island ($19,621) than in any other state, as this was the state with the greatest discrepancy between billed charges and hospital costs.

Figure 7. Mean hospital charges and costs for catheter ablation, by state.



6. Analysis of Comparative Value

The objective of the decision analysis was to describe the clinical outcomes, costs, and potential cost-effectiveness of management strategies for symptomatic atrial fibrillation (AF) in the New England region.

6.1 Methods

Strategies

A decision analytic model was constructed to evaluate multiple management strategies for patients with “moderately to highly symptomatic AF”; in other words, these are patients who may have failed first-line AAD therapy and whose symptoms (e.g., fatigue, palpitations) are significant enough that they cannot be managed adequately on rate control medications alone. The management strategies considered were: 1) primary LACA (left atrial catheter ablation); 2) secondary LACA (initial rhythm control with AADs and LACA for recurrent AF while on AADs); 3) secondary TOP (initial rhythm control with AADs and TOP for recurrent AF while on AADs); and 4) rhythm control (the referent strategy, rhythm control with AADs such as amiodarone).

Clinical and Economic Model

A detailed description of the clinical and economic model is available online at the ICER website (http://www.icer-review.org/index.php/a-fib-appraisal-1209.html). The model builds upon an extensive number of prior studies that use decision analytic models to evaluate new drugs, devices and procedures for the management of AF. Briefly, each strategy has a cardiovascular component for cardiovascular management and a stroke prevention component. The model design was guided by input from a national advisory group of clinical experts. A third party payer’s perspective was selected in order to approximate the evaluation of value of benefit for public and private payers. A five-year time horizon was selected as the timeframe that reflected a balance between short-term budgetary considerations and lifetime outcomes of the true societal perspective. A lifetime analysis is available in the full ICER report (http://www.icer-review.org/index.php/a-fib-appraisal-1209.html). Model probabilities and quality-of-life values were derived from the AHRQ review, a separate systematic review conducted by ICER, and the peer-reviewed medical literature. Payer costs were estimated based on average national Medicare payments to hospitals and physicians.

Patient Scenarios

The analyses look at the clinical and economic outcomes for three different types of patients with AF. These patient types are intended to represent common clinical “categories” of patients with symptomatic AF who may be candidates for these management strategies: a 60-year-old patient with paroxysmal AF with a low risk of stroke, a 65-year-old patient with long-standing persistent AF and heart failure with an intermediate risk of stroke, and a 75-year-old patient with persistent AF, hypertension and diabetes mellitus with a high risk of stroke. Clinical outcome probabilities for AF interventions are not gender specific. In the model all patients were assumed to be male to facilitate estimation of the probability of all-cause mortality and the baseline age-specific quality of life.

Key Assumptions about Atrial Fibrillation

The model assumes that patients with AF are managed with anticoagulation via warfarin or aspirin to prevent stroke, based on published guidelines. AF symptoms are associated with a decreased quality of life, and treatment with anticoagulation also is associated with reduced quality of life. Stroke risk is increased because of AF and reduced by warfarin or aspirin. Warfarin and aspirin increase intracranial hemorrhage risk. Stroke and hemorrhage may be mild or moderate/severe in impact and each condition may result in permanent disability. AADs have associated drug toxicity, most commonly amiodarone-associated thyroid function abnormality and rarely, pulmonary toxicity.

Key Assumptions about AF Management Strategies

There is no assumption in the model that catheter ablation strategies reduce mortality or the risk of stroke among patients with AF. However, based on the results of the AHRQ review, catheter ablation is assumed to be more effective than continued AADs over 1-2 years in returning patients to normal sinus rhythm (NSR), and the model does assume improvement in quality of life for patients in NSR. The reduced risk of recurrent AF following ablation is assumed to continue through 5 years.

The model assumes that patients may require more than one catheter ablation procedure; based on data from a national health plan, the average number of ablations received per patient is estimated at 1.4. While uncontrolled follow-up studies after LACA report a low risk of stroke following catheter ablation for patients in normal sinus rhythm and suggest that for some patients oral anticoagulation may be stopped, our analysis followed the recommendations of current guidelines and assumed that anticoagulation would continue. Finally, the ICER systematic review found no evidence of improved effectiveness for TOP surgical ablation compared to primary or secondary catheter ablation; in these analyses the effectiveness of TOP was considered to be hypothetical, and was assumed to be the same as the effectiveness of LACA.

Analysis of Clinical Outcomes, Costs, and Cost-Effectiveness

The decision analytic model was designed as a Markov model with discrete clinical states (AF, normal sinus rhythm, disability due to stroke, disability due to hemorrhage, or death) and in the model the patients' transition between these states at three-month intervals. Our analysis summarizes the expected clinical outcomes, costs, and cost-effectiveness of AF management strategies over a 5-year time horizon for each of the three strategies. Our analysis was conducted from a public payer's perspective. Costs and quality of life are discounted by 3% per year to express the 5-year results as net present value of costs and quality of life as recommended by the US Panel on Cost-effectiveness in Health and Medicine (Gold, 1996). The expected value of the 5-year costs and quality-adjusted life-years (QALYs) were used to estimates the cost-effectiveness of the ablation strategies compared to rhythm control. The cost-effectiveness is expressed as an incremental cost-effectiveness ratio (ICER) and in our analysis summarizes 5-year costs per QALY gained. The analysis included a probabilistic sensitivity analysis and microsimulation using 10,000 samples to assess the clinical outcomes and components of total costs allowing for uncertainty in clinical data and payer costs; small differences in the total costs and QALYs shown in Tables 3 & 4 compared to the cost-effectiveness analysis in Table 5 result from sampling variation.

State Variation in 5-Year Estimated Payer Costs for AF Management

The 60 year-old patient with paroxysmal AF and no comorbidity selected for our first patient scenario will most likely have private insurance. Actual or expected private insurance payments for AF management strategies in New England were not readily available. We therefore developed a set of private payer costs to provide an alternative to the Medicare payer costs assumed for the primary analysis. Alternative private payer costs were estimated based on hospital costs for catheter ablation among privately insured patients in each state ,which were divided by our baseline estimate for catheter ablation payer costs ($11,231, based on Medicare payments) to derive an factor to estimate likely payments by private insurers. This factor ranged from 1.7 to 3.5 across the states and was applied to hospitalizations for AF management for primary and secondary catheter ablation, TOP surgical catheter ablation, and stroke and hemorrhage.

Sensitivity Analyses of Payer Costs over Time

The primary LACA strategy, the secondary LACA strategy and the secondary TOP surgical ablation strategy all have higher initial payer costs (due to payer costs for the procedure itself) than the AAD rhythm control strategy. An analysis of the time course of payer costs for the AF management strategies was done for the younger patient scenario to examine whether total, longer-term payer costs for each strategy converge at some point in time.

Sensitivity Analyses of Increased Use of LA Catheter Ablation Strategies

A separate analysis of an increase in the use of primary LACA or secondary LACA in the mix of AF strategies was performed to examine the potential effect on overall average 5-year costs across all management strategies. This analysis assumed a 10% increase in the use of primary or secondary LACA above a baseline mix consisting of: 50% secondary LACA, 6.25% primary LACA, 6.25% secondary TOP ablation, and 37.5% rhythm control. The baseline mix of management strategies was derived in consultation with multiple AF clinical experts.

6. 2 Results

Clinical Outcomes

The 5-year clinical outcomes of each management strategy for the 3 patient scenarios are shown in Table 3 on the following page. It is important to repeat that ablation strategies for AF have not been shown to improve mortality or to reduce the risk of stroke. Among moderately or highly symptomatic patients with AF, the primary impact on longer-term patient outcomes of ablation strategies derives from improvements in quality of life that can result from return to normal sinus rhythm.

Table 3. Clinical outcomes over 5 years, by atrial fibrillation management strategy.

	Atrial Fibrillation Management Strategy			
AF Patient Scenario & Outcomes	Primary LACA	Secondary LACA	Secondary TOP*	Rhythm Control
Age 60 Paroxysmal AF				
Life-Years & QALYs				
Life-Years	4.82	4.78	4.77	4.78
Quality-Adjusted Life-Years (QALYs)	3.72	3.72	3.72	3.60
Procedures & Complications				
LACA Procedures	1.502	0.910	0.252	0.000
Major complications	0.019	0.013	0.028	0.000
Stroke peri-procedure	0.006	0.003	0.005	0.000
Adverse Events				
Drug toxicity episodes	0.000	0.290	0.290	0.316
Stroke	0.024	0.023	0.023	0.021
Intracranial hemorrhage	0.006	0.008	0.007	0.009
Age 65 Persistent AF with CHF				
Life-Years & QALYs				
Life-Years	4.74	4.70	4.70	4.71
Quality-Adjusted Life-Years (QALYs)	3.40	3.37	3.37	3.26
Procedures & Complications				
LACA Procedures	1.801	1.049	0.398	0.000
Major complications	0.021	0.014	0.029	0.000
Stroke peri-procedure	0.006	0.003	0.005	0.000
Adverse Events				
Drug toxicity episodes	0.000	0.279	0.279	0.305
Stroke	0.037	0.039	0.035	0.035
Intracranial hemorrhage	0.006	0.008	0.007	0.009
Age 75 Persistent AF with DM & HTN				
Life-Years & QALYs				
Life-Years	4.49	4.40	4.38	4.41
Quality-Adjusted Life-Years (QALYs)	3.00	2.97	2.98	2.86
Procedures & Complications				
LACA Procedures	1.744	0.984	0.367	0.000
Major complications	0.020	0.012	0.030	0.000
Stroke peri-procedure	0.007	0.003	0.004	0.000
Adverse events				
Drug toxicity episodes	0.000	0.267	0.267	0.292
Stroke	0.046	0.043	0.046	0.037
Intracranial hemorrhage	0.018	0.018	0.012	0.020

*Based on hypothetical effectiveness (assumed to be equivalent to LACA)
LACA = Left Atrial Catheter Ablation
TOP = Thoracoscopic Off-Pump Surgical Ablation

The results of the model show that both primary and secondary LACA strategies produce higher QALYs than rhythm control. Primary and secondary LACA have nearly identical QALYs, the result of a balancing of the higher procedure-related complications for primary LACA and the higher drug toxicity for secondary LACA. The secondary TOP strategy has the same outcomes as the secondary LACA strategy, a consequence of our assumption of equivalent effectiveness.

The relative QALY advantage for primary and secondary LACA strategies are found in each of the 3 patient scenarios, although the magnitude of the advantage is diminished among the older cohorts since older patients live fewer years with the increased quality of life associated with ablation.

Third-Party Payer Costs

The 5-year expected procedure and total payer costs are shown in Table 4 below using baseline (i.e., Medicare) estimates. The major driver of payer costs is the cost of procedures, with higher costs for primary LACA compared to secondary LACA, and both LACA strategies 2-3 times more expensive over 5-years than rhythm control. The secondary TOP strategy is the most expensive strategy, with higher payer costs due to the higher initial costs of surgical ablation. Although older patients have increased all-cause mortality and hence fewer life-years, payer costs nevertheless increase with increasing age and comorbidity, reflecting the increasing risk of recurrent AF and AF-related outcomes (stroke and intracranial hemorrhage).

Table 4. Five-year payer costs by atrial fibrillation management strategy (baseline costs).

	Atrial Fibrillation Management Strategy			
AF Patient Scenario & Costs	Primary LACA	Secondary LACA	Secondary TOP	Rhythm Control
Age 60 Paroxysmal AF				
Total Costs	$17,925	$15,337	$25,207	$6,062
Procedure Costs	$16,531	$9,741	$19,520	$0
Age 65 Persistent AF with CHF				
Total Costs	$21,657	$17,340	$27,009	$6,464
Procedure Costs	$19,750	$11,302	$20,944	$0
Age 75 Persistent AF with DM & HTN				
Total Costs	$23,495	$18,988	$27,383	$8,710
Procedure Costs	$19,219	$10,657	$19,812	$0

LACA = Left Atrial Catheter Ablation

TOP = Thoracoscopic Off-Pump Surgical Ablation

Cost-Effectiveness of Atrial Fibrillation Management Strategies

The cost-effectiveness of the primary LACA strategy compared to rhythm control and the secondary LACA strategy compared to rhythm control was first analyzed using baseline Medicare costs (see Table 5 below). These analyses reflect the 5-year time horizon. Both primary and secondary LACA strategies were more effective (produced higher QALYs) and more expensive than rhythm control. The incremental cost-effectiveness ratios for catheter ablation strategies ranged from approximately $75,000 per QALY in the 60-year-old cohort to $112,000 per QALY in the 75-year-old cohort with several comorbidities and higher stroke risk. There were relatively small differences in the estimated cost-effectiveness ratios for primary and secondary LACA.

The cost-effectiveness of the secondary TOP strategy was not analyzed because the evidence on clinical outcomes was judged insufficient for reasonable estimates of key patient outcomes.

Table 5. Cost-effectiveness analysis – 5-year time horizon (baseline payer costs).

Scenario/Strategy	Cost	Incremental Cost	Effectiveness (QALYs)	Incremental Effectiveness (QALYs)	ICER ($/QALYs)
Age 60 Paroxysmal AF					
Rhythm Control	$6,063		3.60		
Primary LACA	$17,926	$11,863	3.75	0.16	$75,561
Rhythm Control	$6,063		3.60		
Secondary LACA	$15,334	$9,271	3.72	0.12	$76,620
Age 65 Persistent AF with CHF					
Rhythm Control	$6,465		3.26		
Primary LACA	$21,659	$15,194	3.40	0.14	$107,759
Rhythm Control	$6,465		3.26		
Secondary LACA	$17,337	$10,872	3.37	0.11	$95,368
Age 75 Persistent AF with HTN and DM					
Rhythm Control	$8,952		2.86		
Primary LACA	$23,690	$14,738	3.00	0.13	$111,652
Rhythm Control	$8,952		2.86		
Secondary LACA	$19,187	$10,235	2.97	0.11	$95,654

LACA = Left Atrial Catheter Ablation

Table 6. Estimated 5-year private-pay costs of atrial fibrillation management strategies, by state.

		State					
Variables	Baseline Model	Connecticut	Massachussets	Maine	New Hampshire	Rhode Island	Vermont
Hospital Admissions for LACA							
Medicare Charges		$54,917	$57,411	$34,027	$53,192	$47,471	$45,541
Medicare Costs		$27,104	$33,640	$23,836	$31,694	$20,604	$35,966
Medicare Cost/Charge Ratio		0.49	0.59	0.70	0.60	0.43	0.79
Private Insurance Charges		$53,658	$60,543	$35,549	$60,094	$42,760	$49,743
Private Insurance Costs (Estimated)		$26,483	$35,475	$23,501	$35,807	$18,559	$39,285
ICER AF Clinical and Economic Model							
LACA - Medicare Payments (Baseline Estimate)	$11,231	$11,231	$11,231	$11,231	$11,231	$11,231	$11,231
Ratio (Private Insurance Costs/Baseline Payment Estimate)	1.00	2.36	3.16	2.09	3.19	1.65	3.50
State-Specific Hospitalization Cost Estimates Used in ICER Model							
LACA with no or minor complication	$11,231	$26,483	$35,475	$23,501	$35,807	$18,559	$39,285
LACA with major complication	$17,024	$40,142	$53,773	$35,623	$54,276	$28,132	$59,548
LACA, permanent disability, annual additional charges	$2,990	$7,050	$9,444	$6,257	$9,533	$4,941	$10,459
TOP with no complications	$26,818	$63,237	$84,709	$56,117	$85,502	$44,316	$93,807
TOP with major complication	$46,358	$109,312	$146,430	$97,005	$147,800	$76,606	$162,156
TOP with minor complication	$32,270	$76,092	$101,930	$67,525	$102,884	$53,326	$112,877
TOP, permanent disability, annual additional charges	$2,990	$7,050	$9,444	$6,257	$9,533	$4,941	$10,459
Estimated 5-Year Costs of AF Management Strategies for Age 60 Paroxysmal AF from ICER Model							
Primary LACA	$17,926	$42,024	$56,200	$37,240	$56,731	$29,444	$62,224
Secondary LACA	$15,334	$30,037	$38,686	$27,118	$39,010	$22,361	$42,362
Secondary TOP	$25,200	$53,384	$69,963	$47,788	$70,584	$38,670	$77,009
Rhythm Control	$6,063	$7,368	$8,135	$7,109	$8,164	$6,686	$8,462

LACA = Left Atrial Catheter Ablation
TOP = Thoracoscopic Off-Pump Surgical Ablation

Estimated New England State-Specific Private Payer Costs for AF Management

As described previously in the Methods section, we analyzed potential New England state-specific variation in 5-year private payer costs for AF in our 60-year-old paroxysmal AF patient scenario. Table 6 on the previous page summarizes the cost estimates used in our analysis, state-specific average charges and costs for LACA hospitalizations, the adjusted cost estimates used to estimate state-specific costs for AF management strategies, and our estimated 5-year costs for each AF management strategy. Our baseline costs used the Medicare fee schedule, and the average hospital charge and cost estimates by state for LACA indicated that our baseline Medicare fee schedule cost estimates would need to be inflated by a factor of 1.65 to 3.50 across the 6 New England states to approximate private insurance payments. Note that these inflation factors were only applied to hospitalization events (i.e., procedures, major complications, and adverse events), so other costs (e.g., drugs, minor complications) were not affected.

The estimated 5-year private payer costs for the AF management strategies are shown in the bottom section of Table 6. Across all strategies, the highest costs were observed in Vermont, and the lowest costs were seen for Rhode Island.

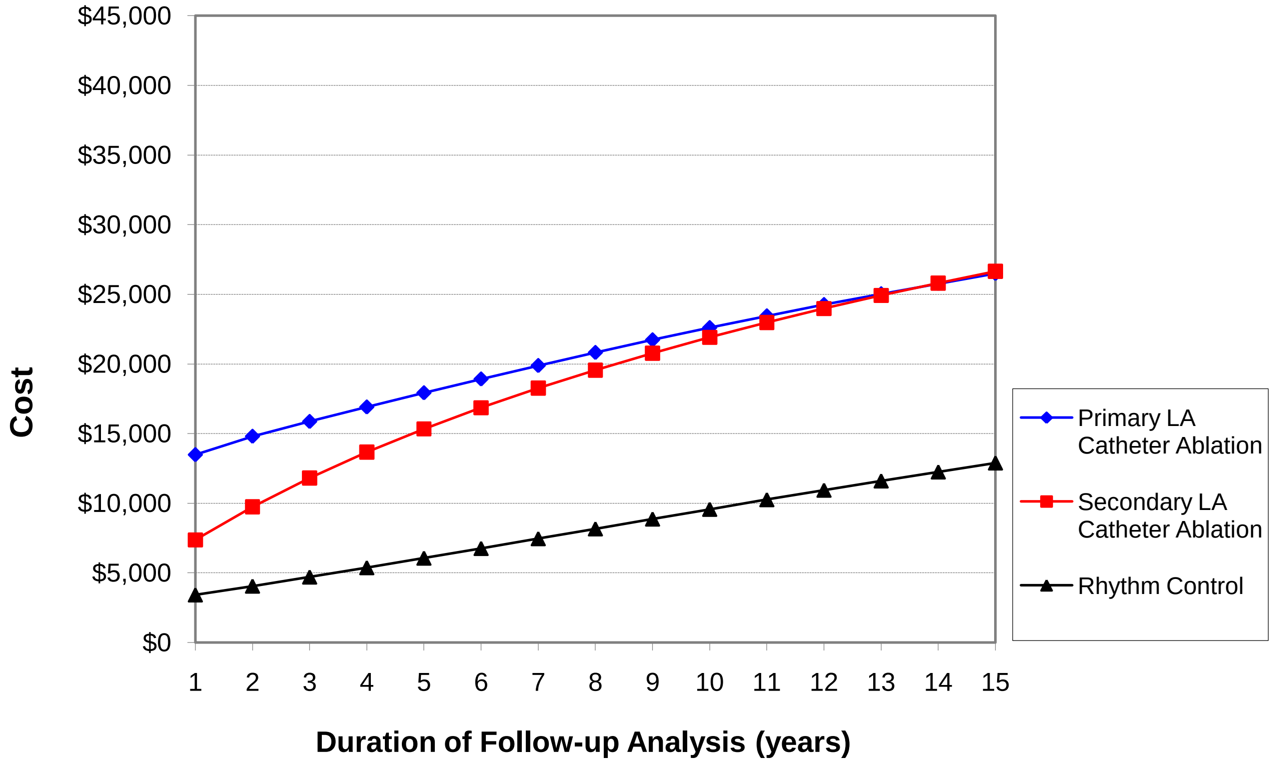
Sensitivity Analysis of Costs over Time

In comparison to the rhythm control strategy, primary and secondary LACA strategies have high initial LACA procedure costs and improved QALYs accruing over subsequent years. An analysis of the time horizon of costs for the AF management strategies is therefore of interest. Further, the time course of costs can vary based on actual costs. The costs of AF management strategies by year for the patient age 60 with paroxysmal AF assuming baseline costs (Figure 8 on the following page) are contrasted with strategy costs based on private-pay estimates for Massachusetts (Figure 9 on page 33). Both analyses express future costs in current-year dollars to assist in present day decisions about AF management.

Note that TOP surgical ablation is not included in this analysis due to uncertainty regarding its true effectiveness.

In Figure 8, the payer costs (in current year dollars) of the rhythm control strategy essentially increase linearly over time due to ongoing use of medical services for recurrent AF, and AF-related outcomes of stroke, intracranial hemorrhage and drug toxicity. The payer costs of the secondary LACA strategy increase more rapidly and then level off due to the higher payer costs for initial and repeat LACAs with lower costs resulting from lower future recurrence of AF and lower occurrence of AF-related outcomes. The primary LACA strategy has even higher initial payer costs as all patients have the procedure. However, the payer costs of the two LACA strategies converge over time, due to a lower rate of AF recurrence with the primary LACA strategy, and are essentially equivalent at 14 years. Similar trends in cost are observed when using private-pay estimates for Massachusetts (see Figure 9 on page 33). However, due to the higher incremental differences in these estimates, strategy costs remain highest for primary LACA even after a 15-year duration of observation.

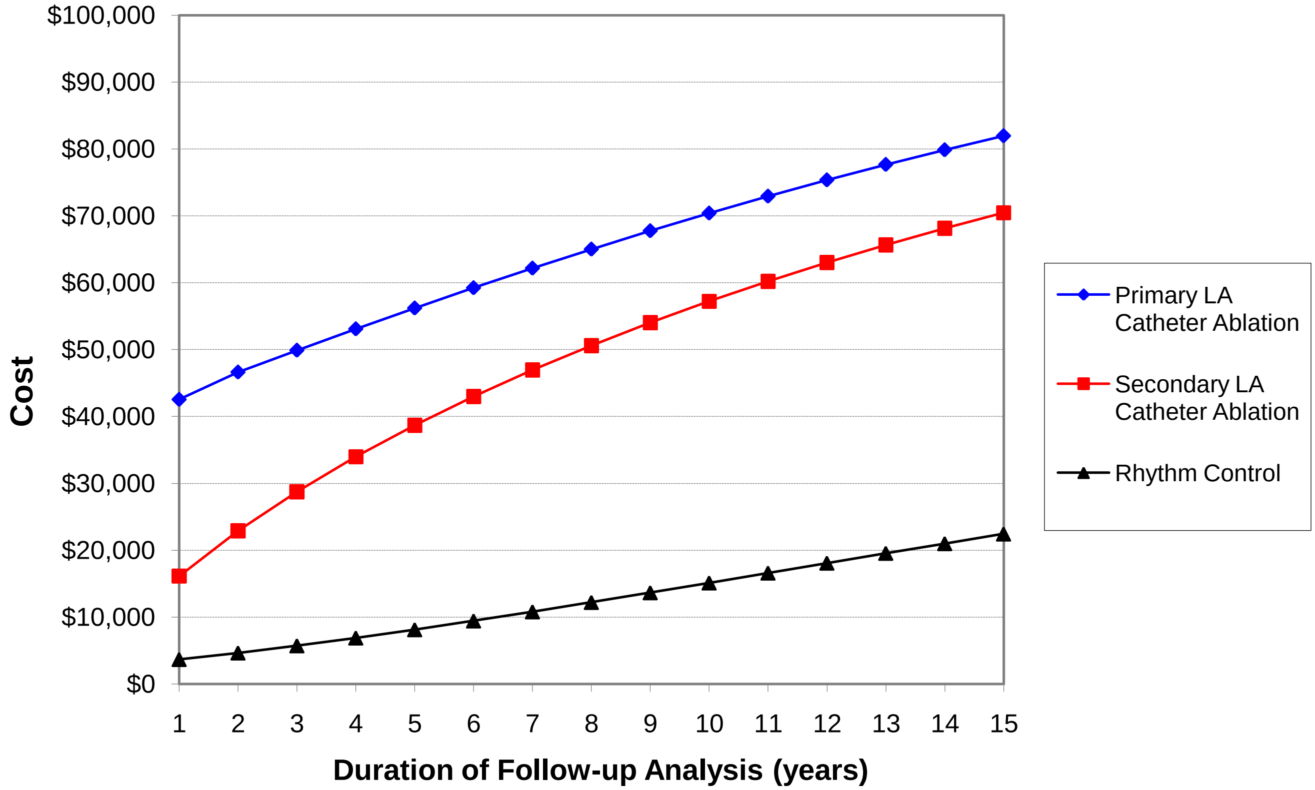
Figure 8. Sensitivity of duration of time horizon to strategy cost estimates. Figures using baseline Medicare costs for 60-year-old patients with paroxysmal AF.



Sensitivity Analysis of Costs to Increased Use of Catheter Ablation Strategies

In our hypothetical simulation of potential shifts in practice patterns, as the proportion of the population receiving secondary LACA increases to 60% (from an estimated baseline of 50%), and the percentage receiving rhythm control declines to 27.5% from 37.5%, the overall average 5-year payer costs for AF management across all strategies in Massachusetts, assuming private-pay cost estimates, increase from $30,279 to $33,334, an increase of $3,055 (10.1%). Simulating an increase in the proportion of primary LACA to 16.25% (above an estimated baseline of 6.25%) at the expense of rhythm control as above, the overall average costs of AF management increase from $30,279 to $35,085, an increase of $4,806 (15.9%). Corresponding changes in QALYs were modest. For the secondary and primary LACA shifts described above, overall average 5-year QALYs would improve from a baseline of 3.67 to 3.69 in both cases (0.4%).

Figure 9. Sensitivity of duration of time horizon to strategy cost estimates (Massachusetts private-pay costs for 60-year-old patient with paroxysmal AF).



6.3 Estimated Statewide Budgetary Impact

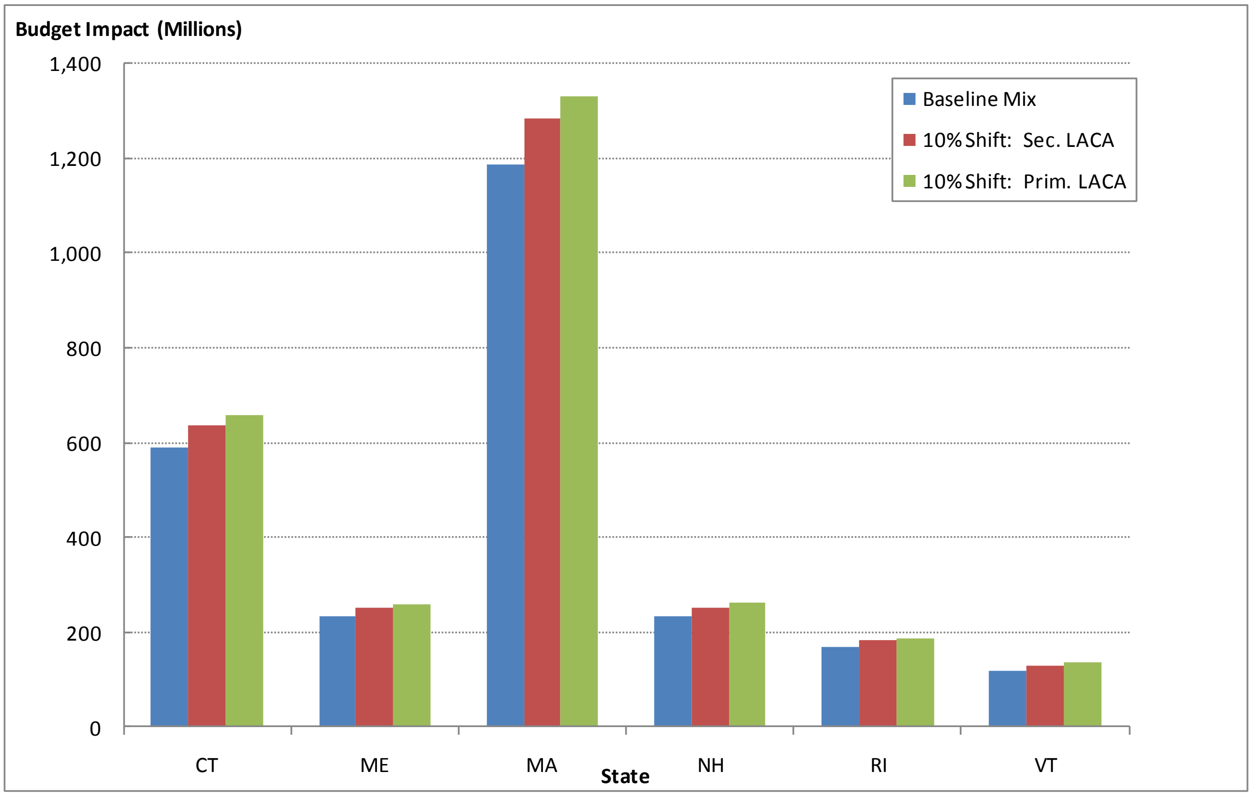
Separate analyses were conducted to estimate the 5-year budgetary impact of treatment for symptomatic AF. Data on average strategy costs for the 4 management strategies of interest within each patient scenario were combined with information on the assumed distribution of management strategies as mentioned previously (i.e., secondary LACA: 50%; primary LACA: 6.25%; secondary TOP: 6.25%; rhythm control with AADs, 37.5%).

Overall average payer costs were then estimated for each patient scenario by multiplying strategy-specific costs by the proportions above. Following this, average payer cost data were combined with the estimated proportion of patients in each scenario category, based on information on age and AF type from the ATRIA registry (Go, 2001):

- Age 60, paroxysmal: 24%
- Age 65, persistent w/CHF: 32%
- Age 75, persistent w/DM, HTN: 44%

Finally, weighted average payer costs were multiplied by the estimated number of persons in each state with AF as described in Section 5 to calculate the state-specific and overall budgetary impact of AF. Calculations were performed using state-specific private-pay cost estimates for younger, paroxysmal patients and baseline (Medicare) cost estimates for the other patient populations. Budgetary impact over a 5-year period is presented in Figure 10 below assuming the "baseline" treatment mix, and demonstrating the impact of shifting patterns of care towards increased LACA.

Figure 10. Estimated 5-year budgetary impact of AF treatment, by state.



LACA: Left atrial catheter ablation

Over 5 years, the budgetary impact of AF treatment is estimated to be approximately $2.5 billion across all New England states. State-specific impacts are affected by both the size of the AF population and variation in the estimated private-pay costs for treating younger patients with paroxysmal disease. When a shift in treatment mix toward secondary LACA was assumed, total budgetary impact increased by approximately $200 million (8%) over 5 years. A slightly larger increase was observed when a shift toward primary LACA was assumed, resulting in an increase of regional budgetary impact of approximately $300 million (11%).

6.4 Comparison of ICER Analysis to Published Cost-Effectiveness Analyses

In our cost-effectiveness analysis, secondary LACA had ICERs of $76,561, $95,368, and $95,654 per QALY for a patients at low, intermediate, and high stroke risk respectively. Previously published studies of LACA differ in the interventions studied, perspective, time horizon, patient populations, effects of ablation on restoration of normal sinus rhythm and stroke risk, and other measures.

Despite important differences in individual studies, a consistent pattern of increased costs, increased effectiveness, and ICERs generally in the $35,000 to $100,000 range emerges from models of LACA-based treatment strategies in comparison to rhythm control with AADs.

One published article of a decision analytic model of LACA compared to rate control in a lifetime analysis found that LACA produced ICERs of $98,900 and $51,800 in AF patients at low and intermediate stroke risk respectively (Chan, 2006). In contrast to our model, this study assumed that patients in normal sinus rhythm after LACA had a lower risk of stroke than AF patients treated with AADs, which may explain the lower ICERs in this study.

Another study from a US perspective of radiofrequency catheter ablation (RFA) with sequential selection of AAD and repeat RFA compared to AADs alone found that over 5 years RFA had an ICER of $51,431 per QALY for a 60 year old patient with paroxysmal AF and no structural heart disease (Reynolds, 2009). The ICER was sensitive to the cost of the ablation, the time horizon, and the quality of life after RFA compared to AADs. When the cost of an RFA procedure was greater than $20,000, the ICER was approximately $100,000 per QALY gained.

A technology assessment of ablation procedures was reported by the Canadian Agency for Drugs and Technologies in Heath (CADTH) in 2010 (Assasi, 2010). A five-year time horizon was used but this study also assumed a reduction in stroke risk following RFA for patients whose heart rhythm returned to normal sinus. The study found that for a patient age 65 with intermediate stroke risk the secondary RFA compared to AADs had an ICER of CAN $59,194 ($57,418 in 2010 US dollars). In alternative analyses assuming no impact on stroke risk from successful RFA, the ICER of RFA compared to AADs was $86,129 (2010 US $83,545), similar to our ICER of $95,654 for a patient at similar stroke risk.

In a study set in the UK National Health Service of RFA compared to AADs over a five-year time horizon, RFA produced an ICER of £27,745 per QALY ($38,329 in 2006 USD) for low stroke risk, £25,510 per QALY ($46,938 US) for intermediate risk, and £20,381 per QALY ($37,501 US) for high risk patients (McKenna, 2009). In this study patients in NSR were assumed to have a lower risk of stroke based on an analysis from the AFFIRM RCT (Sherman, 2005).

Finally, a study of RFA compared to AADs from Sweden using estimated 2006 Swedish costs (SEK converted to 2006 US $) that took a lifetime horizon found that RFA would result in lower costs ($25,460 for RFA compared to $30,440 for AADs) and higher QALYs (9.46 for RFA compared to 8.68 for AADs). In a sensitivity analysis assuming 5%, 10% or 15% annual risks of recurrent AF after RFA, the ICERs of RFA compared to AADs were $82,800, $26,460, and $48,310 per QALY respectively (Eckard, 2009).

7. Questions and Discussion

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) thoracoscopic off-pump (TOP) surgical ablation.

<u>Question 1. Comparative clinical effectiveness: Second-line catheter ablation</u>
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

<u>Question 2. Comparative clinical effectiveness: First-line catheter ablation</u>
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: Thoracoscopic, 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.

- <u>For hospitals and other clinical providers:</u>

  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.

- <u>For payers:</u>

  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.

References

Assasi N, Blackhouse G, Xie F, et al. "Ablation procedures for rhythm control in patients with atrial fibrillation: Clinical and Cost-Effectiveness Analyses." Ottawa: Canadian Agency for Drugs and Technologies in Health; 2010 (CADTH technology report; no. 128).

Blackshear, J. L. and Odell, J. A. (1996). "Appendage obliteration to reduce stroke in cardiac surgical patients with atrial fibrillation." Ann Thorac Surg 61(2): 755-759.

Bugge, E., Nicholson, I. A. and Thomas, S. P. (2005). "Comparison of bipolar and unipolar radiofrequency ablation in an in vivo experimental model." Eur J Cardiothorac Surg 28(1): 76-80; discussion 80-72.

Calkins, H., Brugada, J., Packer, D. L., Cappato, R., Chen, S. A., Crijns, H. J., Damiano, R. J., Jr., Davies, D. W., Haines, D. E., Haissaguerre, M., Iesaka, Y., Jackman, W., Jais, P., Kottkamp, H., Kuck, K. H., Lindsay, B. D., Marchlinski, F. E., McCarthy, P. M., Mont, J. L., Morady, F., Nademanee, K., Natale, A., Pappone, C., Prystowsky, E., Raviele, A., Ruskin, J. N. and Shemin, R. J. (2007). "HRS/EHRA/ECAS expert Consensus Statement on catheter and surgical ablation of atrial fibrillation: recommendations for personnel, policy, procedures and follow-up. A report of the Heart Rhythm Society (HRS) Task Force on catheter and surgical ablation of atrial fibrillation." Heart Rhythm 4(6): 816-861.

Callahan, T. D. t., Di Biase, L., Horton, R., Sanchez, J., Gallinghouse, J. G. and Natale, A. (2009). "Catheter ablation of atrial fibrillation." Cardiol Clin 27(1): 163-178, x.

Camm AJ, Kirchhof P, Lip GYH, et al. for the Task Force for the Management of Atrial Fibrillation of the European Society of Cardiology (2010). "Guidelines for the management of atrial fibrillation." European Heart Journal doi:10.1093/eurheartj/ehq278 (Epub ahead of print).

Chan, P.S., Nallamothu B.K., Oral H. (2009). “Amiodarone or dronedarone for atrial fibrillation: too early to know the winner?” J Am Coll Cardiol 54(12):1096-8.

Chan, P. S., Vijan, S., Morady, F. and Oral, H. (2006). "Cost-effectiveness of radiofrequency catheter ablation for atrial fibrillation." J Am Coll Cardiol 47(12): 2513-2520.

Coyne, K. S., Paramore, C., Grandy, S., Mercader, M., Reynolds, M. and Zimetbaum, P. (2006). "Assessing the direct costs of treating nonvalvular atrial fibrillation in the United States." Value Health 9(5): 348-356.

Crandall, M. A., Bradley, D. J., Packer, D. L. and Asirvatham, S. J. (2009). "Contemporary management of atrial fibrillation: update on anticoagulation and invasive management strategies." Mayo Clin Proc 84(7): 643-662.

Dorian, P. (2010). "Rate control in atrial fibrillation". N Engl J Med 362(15): 1439-1441.

Eckard, N., Davidson, T., Walfridsson, H., Levin L.Å. (2009) “Cost-effectiveness of catheter ablation treatment for patients with symptomatic atrial fibrillation.” J Atrial Fibrillation 1(8):461-70.

Feinberg, W. M., Blackshear, J. L., Laupacis, A., Kronmal, R. and Hart, R. G. (1995). "Prevalence, age distribution, and gender of patients with atrial fibrillation. Analysis and implications." Arch Intern Med 155(5): 469-473.

Forleo, G.B., Mantica, M., De Luca, L., et al. (2009) “Catheter ablation of atrial fibrillation in patients with diabetes mellitus type 2: results from a randomized study comparing pulmonary vein isolation versus antiarrhythmic drug therapy.” J Cardiovasc Electrophysiol 20(1):22-8. Epub 2008 Sep 3.

Friberg, J., Buch, P., Scharling, H., Gadsbphioll, N. and Jensen, G. B. (2003). "Rising rates of hospital admissions for atrial fibrillation." Epidemiology 14(6): 666-672.

Fuster, V., Ryden, L. E., Cannom, D. S., Crijns, H. J., Curtis, A. B., Ellenbogen, K. A., Halperin, J. L., Le Heuzey, J.-Y., Kay, G. N., Lowe, J. E., Olsson, S. B., Prystowsky, E. N., Tamargo, J. L., Wann, S., ACC/AHA TASK FORCE MEMBERS, Smith, S. C., Jr, Jacobs, A. K., Adams, C. D., Anderson, J. L., Antman, E. M., Hunt, S. A., Nishimura, R., Ornato, J. P., Page, R. L., Riegel, B., ESC COMMITTEE FOR PRACTICE GUIDELINES, Priori, S. G., Blanc, J.-J., Budaj, A., Camm, A. J., Dean, V., Deckers, J. W., Despres, C., Dickstein, K., Lekakis, J., McGregor, K., Metra, M., Morais, J., Osterspey, A. and Zamorano, J. L. (2006). "ACC/AHA/ESC 2006 Guidelines for the Management of Patients With Atrial Fibrillation--Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the European Society of Cardiology Committee for Practice Guidelines (Writing Committee to Revise the 2001 Guidelines for the Management of Patients With Atrial Fibrillation): Developed in Collaboration With the European Heart Rhythm Association and the Heart Rhythm Society." Circulation 114(7): 700-752.

Gaita, F., Caponi, D., Pianelli, M., et al. (2010) “Radiofrequency catheter ablation of atrial fibrillation: a cause of silent thromboembolism? Magnetic resonance imaging assessment of cerebral thromboembolism in patients undergoing ablation of atrial fibrillation.” Circulation 122(17):1667-73. Epub 2010 Oct 11.

Go, A. S., Hylek, E. M., Phillips, K. A., Chang, Y., Henault, L. E., Selby, J. V. and Singer, D. E. (2001). "Prevalence of diagnosed atrial fibrillation in adults: national implications for rhythm management and stroke prevention: the AnTicoagulation and Risk Factors in Atrial Fibrillation (ATRIA) Study." JAMA 285(18): 2370-2375.

Gold, M. (1996). "Panel on cost-effectiveness in health and medicine." Med Care 34(12 Suppl): DS197-199.

Gopinathannair, R., Sullivan, R. M. and Olshansky, B. (2009). "Update on medical management of atrial fibrillation in the modern era." Heart Rhythm 6(8 Suppl): S17-22.

Haegeli, L.M., Duru, F., Lockwood, E.E., et al. (2010) “Ablation of atrial fibrillation after the retirement age: considerations on safety and outcome.” J Interv Card Electrophysiol 28(3):193-7. Epub 2010 Jun 16.

Heron, M. and Tejada-Vera, B. (2009). "Deaths: leading causes for 2005." Natl Vital Stat Rep 58(8): 1-97.

Ip, S., Terasawa, T., Balk, E. M., Chung, M., Alsheikh-Ali, A. A., Garlitski, A. C. and Lau, J. (2009). Comparative Effectiveness of Radiofrequency Catheter Ablation for Atrial Fibrillation. Comparative Effectiveness Review Rockville, MD.

Jaïs, P., Cauchemez, B., Macle, L., Daoud, E., Khairy, P., Subbiah, R., Hocini, M., Extramiana, F., Sacher, F., Bordachar, P., Klein, G., Weerasooriya, R., Clémenty, J. and Haïssaguerre, M. (2008). "Catheter ablation versus antiarrhythmic drugs for atrial fibrillation: the A4 study." Circulation 118(24): 2498-2505.

The Kaiser Family Foundation, statehealthfacts.org. Data Sources: Urban Institute, 2009; Kaiser Commission on Medicaid and the Uninsured, 2009; Current Population Survey (CPS: Annual Social and Economic Supplements; U.S. Census Bureau, 2009 and 2010).

Kiser, A.C., Landers, M., Horton, R., et al. (2010) “The convergent procedure: a multidisciplinary atrial fibrillation treatment.” Heart Surg Forum 13(5):E317-21.

Lall, S. C., Melby, S. J., Voeller, R. K., Zierer, A., Bailey, M. S., Guthrie, T. J., Moon, M. R., Moazami, N., Lawton, J. S. and Damiano, R. J., Jr. (2007). "The effect of ablation technology on surgical outcomes after the Cox-maze procedure: a propensity analysis." J Thorac Cardiovasc Surg 133(2): 389-396.

Lee, A. M., Melby, S. J. and Damiano, R. J., Jr. (2009a). "The surgical treatment of atrial fibrillation." Surg Clin North Am 89(4): 1001-1020, x-xi.

Lee, R., Kruse, J. and McCarthy, P. M. (2009b). "Surgery for atrial fibrillation." Nat Rev Cardiol 6(8): 505-513.

Maisel, W. H. and Stevenson, L. W. (2003). "Atrial fibrillation in heart failure: epidemiology, pathophysiology, and rationale for therapy." Am J Cardiol 91(6A): 2D-8D.

McKenna, C., Palmer, S., Rodgers, M., Chambers, D., Hawkins, N., Golder, S., Van Hout, S., Pepper, C., Todd, D. and Woolacott, N. (2009). "Cost-effectiveness of radiofrequency catheter ablation for the treatment of atrial fibrillation in the United Kingdom." Heart 95(7): 542-549.

Melby, S. J., Zierer, A., Bailey, M. S., Cox, J. L., Lawton, J. S., Munfakh, N., Crabtree, T. D., Moazami, N., Huddleston, C. B., Moon, M. R. and Damiano, R. J., Jr. (2006). "A new era in the surgical treatment of atrial fibrillation: the impact of ablation technology and lesion set on procedural efficacy." Ann Surg 244(4): 583-592.

National Stroke Association (2010). "Controllable Risk Factors: Atrial Fibrillation." from http://www.stroke.org/site/PageServer?pagename=afib.

Ollendorf, D.A., Silverstein, M.D., Bobo, T., Pearson, S.D. (2010) "Final Appraisal Document: Rhythm Control and Stroke Prevention Strategies for Patients with AtrialFibrillation." Boston, MA: Institute for Clinical and Economic Review, September 2010 (http://www.icer-review.org/index.php/a-fib-appraisal-1209.html).

Oral, H., Pappone, C., Chugh, A., Good, E., Bogun, F., Pelosi, F., Jr., Bates, E. R., Lehmann, M. H., Vicedomini, G., Augello, G., Agricola, E., Sala, S., Santinelli, V. and Morady, F. (2006). "Circumferential pulmonary-vein ablation for chronic atrial fibrillation." N Engl J Med 354(9): 934-941.

Ouyang, F., Tilz, R., Chun, J., et al. (2010) "Long-term results of catheter ablation in paroxysmal atrial fibrillation: lessons from a 5-year follow-up." Circulation 122(23):2368-77. Epub 2010 Nov 22.

Pappone, C., Oreto, G., Rosanio, S., Vicedomini, G., Tocchi, M., Gugliotta, F., Salvati, A., Dicandia, C., Calabrò, M. P., Mazzone, P., Ficarra, E., Di Gioia, C., Gulletta, S., Nardi, S., Santinelli, V., Benussi, S. and Alfieri, O. (2001). "Atrial electroanatomic remodeling after circumferential radiofrequency pulmonary vein ablation: efficacy of an anatomic approach in a large cohort of patients with atrial fibrillation." Circulation 104(21): 2539-2544.

Reiffel, J. A. (2009). "Cardioversion for atrial fibrillation: treatment options and advances." Pacing Clin Electrophysiol 32(8): 1073-1084.

Reynolds MR, Zimetbaum P, Josephson ME, et al. (2009). "Cost-effectiveness of radiofrequency catheter ablation compared with antiarrhythmic drug therapy for paroxysmal atrial fibrillation." Circ Arrhythm Electrophysiol 2(4): 362-369.

Savelieva, I. and John Camm, A. (2004). "Atrial fibrillation and heart failure: natural history and pharmacological treatment." Europace 5 Suppl 1: S5-19.

Sherman, D.G., Kim, S.G., Boop, B.S., et al.; National Heart, Lung, and Blood Institute AFFIRM Investigators. (2005) "Occurrence and characteristics of stroke events in the Atrial Fibrillation Follow-up Investigation of Sinus Rhythm Management (AFFIRM) study. " Arch Intern Med 165(10):1185-91.

Singh, D., Cingolani, E., Diamond, G. A. and Kaul, S. (2010). "Dronedarone for atrial fibrillation have we expanded the antiarrhythmic armamentarium?" J Am Coll Cardiol 55(15): 1569-1576.

Stiles, S. (2009). FDA advisory panel recommends dronedarone approval for atrial fib. http://www.theheart.org/.

U.S. Food & Drug Administration Adverse Events Reporting System (AERS). (2010). Potential Signals of Serious Risks/New Safety Information Identified from the Adverse Event Reporting System (AERS) between April - June 2010. Accessed September 9, 2010 at: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm223734.htm.

Wann, L.S., Curtis, A.B., January, C.T., et al. (2011 Writing Group Members). (2011). "2011 ACCF/AHA/HRS focused update on the management of patients with atrial fibrillation (updating the 2006 guideline): a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. " Heart Rhythm 8(1):157-76.

Wilber, D.J., Pappone, C., Neuzil, P., et al.; (2010) "ThermoCool AF Trial Investigators. Comparison of antiarrhythmic drug therapy and radiofrequency catheter ablation in patients with paroxysmal atrial fibrillation: a randomized controlled trial." JAMA 303(4):333-40.

Weerasooriya, R., Khairy, P., Litalien, J., et al. (2011) "Catheter ablation for atrial fibrillation: are results maintained at 5 years of follow-up? " J Am Coll Cardiol 57(2):160-6.

Wokhlu, A., Monahan, K. H., Hodge, D. O., Asirvatham, S. J., Friedman, P. A., Munger, T. M., Bradley, D. J., Bluhm, C. M., Haroldson, J. M. and Packer, D. L. (2010). "Long-term quality of life after ablation of atrial fibrillation the impact of recurrence, symptom relief, and placebo effect." J Am Coll Cardiol 55(21): 2308-2316.

Zimetbaum, P. (2007). "Amiodarone for atrial fibrillation." N Engl J Med 356(9): 935-941.

Appendix A

Prevalence of Atrial Fibrillation in New England

		AF Prevalence Estimates*	Connecticut		Maine		Massachusetts		New Hampshire		Rhode Island		Vermont	
		%	Population**	Estimated # of Persons with AF	Population**	Estimated # of Persons with AF	Population**	Estimated # of Persons with AF	Population**	Estimated # of Persons with AF	Population**	Estimated # of Persons with AF	Population**	Estimated # of Persons with AF
Males														
	<55	0.2	1,314,936	2,630	470,250	941	2,455,243	4,910	495,558	991	392,031	784	226,442	453
	55-59	0.9	107,566	968	47,812	430	201,148	1,810	44,873	404	32,402	292	22,775	205
	60-64	1.7	87,920	1,495	39,539	672	160,972	2,737	35,966	611	26,347	448	18,304	311
	65-69	3.0	63,326	1,900	27,866	836	113,307	3,399	25,066	752	18,445	553	12,909	387
	70-74	5.0	46,193	2,310	21,457	1,073	85,075	4,254	18,351	918	13,845	692	9,228	461
	75-79	7.3	38,123	2,783	16,952	1,237	70,230	5,127	14,649	1,069	11,535	842	7,083	517
	80-84	10.3	28,569	2,943	11,928	1,229	52,462	5,404	10,029	1,033	9,205	948	5,189	534
	85+	11.1	22,349	2,481	8,490	942	39,583	4,394	7,273	807	7,218	801	3,656	406
	Total		1,708,982	17,508	644,294	7,360	3,178,020	32,034	651,765	6,586	511,028	5,361	305,586	3,275
				1.02%		***1.14%***		***1.01%***		***1.01%***		***1.05%***		***1.07%***
Females														
	<55	0.1	1,301,157	1,301	470,331	470	2,451,490	2,451	488,521	489	390,715	391	223,723	224
	55-59	0.4	114,338	457	49,702	199	215,201	861	45,557	182	34,465	138	23,457	94
	60-64	1.0	96,689	967	40,552	406	178,070	1,781	37,003	370	28,350	284	18,654	187
	65-69	1.7	72,300	1,229	30,569	520	131,859	2,242	26,963	458	21,374	363	13,610	231
	70-74	3.4	57,510	1,955	24,786	843	106,002	3,604	21,090	717	17,474	594	10,501	357
	75-79	5.0	52,323	2,616	21,981	1,099	97,639	4,882	18,468	923	16,627	831	9,353	468
	80-84	7.2	46,435	3,343	18,166	1,308	86,581	6,234	15,648	1,127	15,611	1,124	7,757	559
	85+	9.1	53,198	4,841	19,310	1,757	98,733	8,985	16,857	1,534	17,858	1,625	8,408	765
	Total		1,793,950	16,710	675,397	6,601	3,365,575	31,039	670,107	5,800	542,474	5,350	315,463	2,884
				0.93%		***0.98%***		***0.92%***		***0.87%***		***0.99%***		***0.91%***
Both Sexes														
	<55		2,616,093	3,931	940,581	1,411	4,906,733	7,362	984,079	1,480	782,746	1,175	450,165	677
	55-59		221,904	1,425	97,514	629	416,349	2,671	90,430	586	66,867	429	46,232	299
	60-64		184,609	2,462	80,091	1,078	339,042	4,517	72,969	981	54,697	731	36,958	498
	65-69		135,626	3,129	58,435	1,356	245,166	5,641	52,029	1,210	39,819	917	26,519	619
	70-74		103,703	4,265	46,243	1,916	191,077	7,858	39,441	1,635	31,319	1,286	19,729	818
	75-79		90,446	5,399	38,933	2,337	167,869	10,009	33,117	1,993	28,162	1,673	16,436	985
	80-84		75,004	6,286	30,094	2,537	139,043	11,637	25,677	2,160	24,816	2,072	12,946	1,093
	85+		75,547	7,322	27,800	2,700	138,316	13,378	24,130	2,341	25,076	2,426	12,064	1,171
	TOTAL		***3,502,932***	***34,219***	***1,319,691***	***13,962***	***6,543,595***	***63,074***	***1,321,872***	***12,386***	***1,053,502***	***10,711***	***621,049***	***6,159***
				0.98%		***1.06%***		***0.96%***		***0.94%***		***1.02%***		***0.99%***

Based on 2008 Census Estimates; Stratified by Age and Sex

Sources: Population: US Census Bureau, Population Division (Series SC-EST2009-02-50)

AF Prevalence: Go AS, Hylek EM, Phillips KA, et al. Prevalence of diagnosed atrial fibrillation in adults. National implications for rhythm management and stroke prevention: the AnTicoagulation and Risk Factors In Atrial Fibrillation (ATRIA) Study. JAMA 2001;285:2370-75.

Appendix B

Hospitalization Data for Catheter Ablation in New England

State Statistics - 2008 Connecticut
Outcomes by Patient and Hospital Characteristics for
Catheter Ablation (ICD-9-CM Principal Procedure Code 37.34)

		Total number of discharges		LOS (length of stay), days (mean)	Charges, $ (mean)	Costs, $ (mean)†	Procedures/1000‡
All discharges		484	100.00%	3.4	54,368	26,833	0.14
	1-17	*	*	*	*	*	*
	18-44	64	13.22%	2.7	53,090	26,202	0.05
	45-64	218	45.04%	2.9	53,874	26,589	0.23
	65-74	107	22.11%	3.8	55,590	27,436	0.45
	75+	85	17.56%	4.7	55,313	27,299	0.35
Sex	Male	308	63.64%	3.4	55,848	27,563	0.18
	Female	176	36.36%	3.4	51,778	25,554	0.10
Payer	Medicare	188	38.84%	4.2	54,917	27,104	0.38
	Medicaid	30	6.20%	3.4	55,666	27,473	0.08
	Private insurance	244	50.41%	2.8	53,658	26,482	0.12
	Uninsured	*	*	*	*	*	*
	Other	15	3.10%	2.1	54,891	27,091	0.11
Patient residence (or zip code)	Large central metro	127	26.24%	3.8	62,738	30,963	
	Large fringe metro (suburbs)	189	39.05%	3.7	47,574	23,480	
	Medium and small metro	142	29.34%	2.7	55,533	27,408	
	Micropolitan and noncore (rural)	*	*	*	*	*	
	Missing	22	4.55%	1.9	45,428	22,420	
Race/ethnicity	White	410	84.71%	3.2	54,554	26,924	0.16
	Black	35	7.23%	5.1	54,127	26,714	0.11
	Hispanic	25	5.17%	4.0	54,921	27,106	0.06
	Asian/Pacific Islander	14	2.89%	2.5	45,285	22,350	0.11
	Other	0	0.00%	N/A	N/A	N/A	N/A

State statistics from the Connecticut Office of Health Care Access, a division of the Department of Public Health - inpatient discharge database for fiscal 2008. Values based on 10 or fewer discharges are suppressed to protect confidentiality of patients and are designated with an asterisk (*).

†Costs estimated using statewide average cost-to-charge ratios provided by HCUP

‡Estimated using discharge data from state in combination with information on population strata from the U.S. Census and other sources

State Statistics - 2008 Maine
Outcomes by Patient and Hospital Characteristics for Catheter Ablation (ICD-9-CM Principal Procedure Code 37.34)

		Total number of discharges		LOS (length of stay), days (mean)	Charges, $ (mean)	Costs, $ (mean)†	Procedures/1000‡
All discharges		257	100.00%	3.1	33,520	23,481	0.19
Age group	1-17	*	*	*	*	*	*
	18-44	48	18.68%	2.0	30,540	21,394	0.11
	45-64	109	42.41%	2.5	34,236	23,982	0.28
	65-84	85	33.07%	4.3	35,849	25,112	0.49
	85+	*	*	*	*	*	*
Sex	Male	149	57.98%	3.1	34,657	24,278	0.23
	Female	108	42.02%	3.0	31,950	22,381	0.16
Payer	Medicare	109	42.41%	4.0	34,027	23,836	0.59
	Medicaid	27	10.51%	2.0	31,978	22,401	0.09
	Private insurance	108	42.02%	2.4	33,549	23,501	0.17
	Uninsured	*	*	*	*	*	*
	Other	*	*	*	*	*	*
Patient residence	Large fringe metro (suburbs)	*	*	*	*	*	
	Medium and small metro	153	59.53%	3.2	34,089	23,879	
	Micropolitan and noncore (rural)	103	40.08%	2.9	32,702	22,908	
Race/ethnicity	White	232	90.27%	2.9	33,851	23,713	
	Black	*	*	*	*	*	
	Native American	*	*	*	*	*	
	Other	*	*	*	*	*	

State statistics from HCUP State Inpatient Database 2008, Agency for Healthcare Research and Quality (AHRQ), based on data collected by the Maine Health Data Organization and provided to AHRQ. Values based on 10 or fewer discharges or fewer than 2 hospitals in the State statistics (SID) are suppressed to protect confidentiality of patients and are designated with an asterisk (*).

†Costs estimated using statewide average cost-to-charge ratios provided by HCUP

‡Estimated using discharge data from HCUP in combination with information on population strata from the U.S. Census and other sources

State Statistics - 2008 Massachusetts
Outcomes by Patient and Hospital Characteristics for Catheter Ablation (ICD-9-CM Principal Procedure Code 37.34)

		Total number of discharges		LOS (length of stay), days (mean)	Charges, $ (mean)	Costs, $ (mean)†	Procedures/1000‡
All discharges		1,814	100.00%	2.9	59,076	34,615	0.28
Age group	<1	*	*	*	*	*	*
	1-17	52	2.87%	2.4	54,710	32,057	0.04
	18-44	234	12.90%	2.2	56,119	32,883	0.10
	45-64	850	46.86%	2.6	62,075	36,372	0.48
	65-84	632	34.84%	3.4	57,884	33,916	0.85
	85+	45	2.48%	4.8	39,869	23,361	0.33
Sex	Male	1,195	65.88%	2.8	60,375	35,376	0.38
	Female	619	34.12%	3.0	56,569	33,146	0.18
Payer	Medicare	644	35.50%	3.8	57,411	33,640	0.76
	Medicaid	76	4.19%	3.7	52,448	30,731	0.06
	Private insurance	1,021	56.28%	2.3	60,543	35,475	0.26
	Uninsured	22	1.21%	4.5	53,886	31,574	0.07
	Other	49	2.70%	2.8	62,412	36,570	0.75
	Missing	*	*	*	*	*	*
Patient residence	Large central metro	188	10.36%	3.3	56,819	33,293	
	Large fringe metro (suburbs)	970	53.47%	2.8	56,368	33,029	
	Medium and small metro	538	29.66%	2.9	62,749	36,767	
	Micropolitan and noncore (rural)	100	5.51%	3.0	70,982	41,591	
	Missing	18	0.99%	2.9	52,668	30,861	
Race/ethnicity	White	1,607	88.59%	2.8	59,820	35,051	0.31
	Black	53	2.92%	5.4	48,883	28,642	0.14
	Hispanic	52	2.87%	2.8	52,874	30,981	0.10
	Asian/Pacific Islander	33	1.82%	2.3	46,955	27,513	0.10
	Native American	*	*	*	*	*	*
	Other	14	0.77%	1.9	50,517	29,600	N/A
	Missing	52	2.87%	3.7	63,516	37,217	N/A

State statistics from HCUP State Inpatient Database 2008, Agency for Healthcare Research and Quality (AHRQ), based on data collected by the Massachusetts Division of Health Care Finance and Policy and provided to AHRQ.Values based on 10 or fewer discharges or fewer than 2 hospitals in the State statistics (SID) are suppressed to protect confidentiality of patients and are designated with an asterisk (*).

†Costs estimated using statewide average cost-to-charge ratios provided by HCUP

‡Estimated using discharge data from HCUP in combination with information on population strata from the U.S. Census and other sources

State Statistics - 2008 New Hampshire
Outcomes by Patient and Hospital Characteristics for
Catheter Ablation (ICD-9-CM Principal Procedure Code 37.34)

		Total number of discharges		LOS (length of stay), days (mean)	Charges, $ (mean)	Costs, $ (mean)†	Procedures/1000‡
All discharges		145	100.00%	3.9	55,878	33,294	0.11
Age group	1-17	*	*	*	*	*	*
	18-44	*	*	*	*	*	*
	45-64	72	49.66%	3.4	56,794	33,840	0.19
	65-84	60	41.38%	4.6	54,056	32,209	0.40
	85+	*	*	*	*	*	*
Sex	Male	97	66.90%	3.8	57,207	34,086	0.15
	Female	48	33.10%	4.1	53,192	31,694	0.07
Payer	Medicare	73	50.34%	4.2	52,021	30,996	0.39
	Medicaid	*	*	*	*	*	*
	Private insurance	58	40.00%	3.5	60,094	35,807	0.07
	Uninsured	*	*	*	*	*	*
	Other	*	*	*	*	*	*
Patient residence	Large fringe metro (suburbs)	28	19.31%	4.0	61,108	36,411	
	Medium and small metro	43	29.66%	4.4	53,451	31,849	
	Micropolitan and noncore (rural)	74	51.03%	3.6	55,308	32,955	
Race/ethnicity	White	135	93.10%	3.7	55,044	32,798	
	Asian/Pacific Islander	*	*	*	*	*	
	Other	*	*	*	*	*	
	Missing	*	*	*	*	*	

State statistics from HCUP State Inpatient Database 2008, Agency for Healthcare Research and Quality (AHRQ), based on data collected by the New Hampshire Department of Health & Human Services and provided to AHRQ. Values based on 10 or fewer discharges or fewer than 2 hospitals in the State statistics (SID) are suppressed to protect confidentiality of patients and are designated with an asterisk (*).

†Costs estimated using statewide average cost-to-charge ratios provided by HCUP

‡Estimated using discharge data from HCUP in combination with information on population strata from the U.S. Census and other sources

State Statistics - 2008 Rhode Island
Outcomes by Patient and Hospital Characteristics for Catheter Ablation (ICD-9-CM Principal Procedure Code 37.34)

		Total number of discharges		LOS (length of stay), days (mean)	Charges, $ (mean)	Costs, $ (mean)†	Procedures/1000‡
All discharges		123	100.00%	2.3	45,204	19,621	0.12
Age group	18-44	*	*	*	*	*	*
	45-64	56	45.53%	2.0	43,718	18,976	0.20
	65-84	42	34.15%	2.9	48,396	21,006	0.34
	85+	*	*	*	*	*	*
Sex	Male	75	60.98%	2.6	47,090	20,439	0.15
	Female	48	39.02%	1.9	42,259	18,342	0.09
Payer	Medicare	47	38.21%	2.7	47,471	20,604	0.34
	Medicaid	*	*	*	*	*	*
	Private insurance	61	49.59%	2.0	42,760	18,559	0.11
	Uninsured	*	*	*	*	*	*
	Other	*	*	*	*	*	*
Patient residence	Large central metro	65	52.85%	2.3	45,542	19,767	
	Large fringe metro (suburbs)	57	46.34%	2.3	45,185	19,612	
	Medium and small metro	*	*	*	*	*	
Race/ethnicity	White	107	86.99%	2.2	44,867	19,474	
	Black	*	*	*	*	*	
	Hispanic	*	*	*	*	*	
	Missing	*	*	*	*	*	

State statistics from HCUP State Inpatient Database 2008, Agency for Healthcare Research and Quality (AHRQ), based on data collected by the Rhode Island Department of Health and provided to AHRQ. Values based on 10 or fewer discharges or fewer than 2 hospitals in the State statistics (SID) are suppressed to protect confidentiality of patients and are designated with an asterisk (*).

†Costs estimated using statewide average cost-to-charge ratios provided by HCUP

‡Estimated using discharge data from HCUP in combination with information on population strata from the U.S. Census and other sources

State Statistics - 2008 Vermont
Outcomes by Patient and Hospital Characteristics for Catheter Ablation (ICD-9-CM Principal Procedure Code 37.34)

		Total number of discharges		LOS (length of stay), days (mean)	Charges, $ (mean)	Costs, $ (mean)†	Procedures/1000‡
All discharges		83	100.00%	3.7	46,652	36,843	0.13
Age group	18-44	*	*	*	*	*	*
	45-64	33	39.76%	4.0	51,117	40,370	0.18
	65-74	35	42.17%	3.7	45,625	36,032	0.76
	75+	*	*	*	*	*	*
Sex	Male	52	62.65%	3.4	47,314	37,366	0.17
	Female	31	37.35%	4.1	45,541	35,966	0.10
Payer	Medicare	38	45.78%	4.0	46,136	36,436	0.47
	Medicaid	*	*	*	*	*	*
	Private insurance	35	42.17%	3.6	49,743	39,285	0.11
	Uninsured	*	*	*	*	*	*
	Other	*	*	*	*	*	*
Patient residence	Large fringe metro (suburbs)	*	*	*	*	*	
	Medium and small metro	50	60.24%	4.1	49,556	39,137	
	Micropolitan and noncore (rural)	20	24.10%	3.2	44,796	35,378	
	Missing	*	*	*	*	*	
Race/ethnicity	White	N/A	N/A	N/A	N/A	N/A	
	Black	N/A	N/A	N/A	N/A	N/A	
	Missing	N/A	N/A	N/A	N/A	N/A	

State statistics from the Vermont Department of Banking, Insurance, Securities and Health Care Administration for calendar 2008. Values based on 10 or fewer discharges are suppressed to protect confidentiality of patients and are designated with an asterisk (*).

†Costs estimated using statewide average cost-to-charge ratios provided by HCUP

‡Estimated using discharge data from state in combination with information on population strata from the U.S. Census and other sources