Washington State Health Care Authority

Health Technology Assessment

Catheter Ablation Procedures For Supraventricular Tachyarrhythmia

Including Atrial Flutter & Atrial Fibrillation

Draft Report - Public Comments

April 17, 2013

Health Technology Assessment Program (HTA)
Washington State Health Care Authority
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RESPONSES TO DRAFT REPORT

Spectrum Research is an independent vendor contracted to produce evidence assessment reports for the Washington HTA program. For transparency, all comments received during the public comment period are included in this response document. Comments related to program decisions, process, or other matters not pertaining to the evidence report are acknowledged through inclusion only.

This document responds to comments from the following parties:

Draft Report

1. Sharon Crowell, MD; The Vancouver Clinic
2. Tim Dewhurst, MD; Washington Chapter of the American College of Cardiology
3. Gregory Hallas, MD; Vancouver, Washington
4. Daniel Highkin, MD
5. John MacGregor, MD; PeaceHealth St. Joseph Medical Center, Bellingham, Washington
6. Providence Health & Services; Renton, Washington
7. James A. Reiss, MD, MPH; PeaceHealth Southwest Medical Center, Vancouver, Washington
8. Ben R. Stokes; Heartland Partners, LLC; Seattle, Washington
9. Robert D. Swenson, MD, FACC; The Vancouver Clinic, PeaceHealth Southwest Medical Center, Vancouver, Washington

Specific responses pertaining to each comment are included in Table 1.

	Comment	Response
Sharon Crowell, MD; The Vancouver Clinic		
1.	Greetings; It has come to my attention that your agency is proposing that catheter ablation for PSVT, WPW, and other arrhythmias may not be the most cost effective strategy for management of these problems. I would like to offer my opinion. I am a general internist. For most of my 30 year career, I had no choice but to manage patients with medications for arrhythmias. Medical management of arrhythmias is difficult for patients, especially young, active people. All of the medications have side effects, most notably fatigue and impaired exercise tolerance. Some of the medications have life threatening side effects. Compliance can be difficult; non-compliance results in breakthrough symptoms. Not all patients have complete symptom control on medicines. Living with PSVT or WPW is anxiety provoking. Patients with these conditions have shared with me that they are always on alert for the next attack, and worry if they might drop dead with one of their attacks. It has been very gratifying to see my patients back after catheter ablation. Not only has the fear resolved, they feel much better off the medications. I have also seen patients benefit greatly from ablation therapy for atrial flutter. This rhythm disturbance is very difficult to treat with medications. I distinctly remember a middle aged woman who was hospitalized several times for rapid atrial flutter in spite of my best efforts at controlling her rhythm problem with medications. She is	*Thank you for your comments.*

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	now symptom free after ablation. I am writing to ask that you consider the significant improvement in quality of life after catheter ablation in your decision making process. Based on my experience caring for these patients, I believe it is wrong deny patients access to potentially curative, very effective treatment. I am dismayed by the thought of not having this therapeutic option to offer patients. Sincerely, Sharon Crowell, MD Chairman of the Board, The Vancouver Clinic	
Tim Dewhurst, MD; Washington Chapter of the American College of Cardiology		
2.	The questions as framed by the state focus on the procedures because of cost and efficacy, with safety a lower level of concern. The summary notes that at five year and lifetime horizons ablation therapy is cost effective based on current standards of acceptable cost of QALY. The reviewers have looked for only the highest quality published evidence, which does not always exist, even for established treatments. I do note with concern that no physicians (let alone any expert in the field) participated in authorship of this document. For example, there is no published trial that would meet their criteria showing that pacemakers are useful for complete heart block. Given the evolution in this field, the peer-reviewed published literature is at least 1-2 years behind the current state of the art. Even with that, there is evidence in the report that RF ablation works for a variety of conditions.	*Thank you for your comments.* *While no clinicians are authors on the document, we have sought input from clinicians who are experts in the field throughout the process. Key questions were formed, inclusion and exclusion criteria framed, and the report written with the input of a clinical expert in the field (Ramakota Reddy, MD). In addition, three clinical peer reviewers who are experts in the field have reviewed the draft report, and their input will be taken into account when generating the final report. Finally, our clinical expert will be present at the public meeting in May to answer any questions posed by the Health Technology Clinical*

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	Cryo-ablation is a newer, promising technique of ablation that does not have as much data. As further evidence of its effectiveness and/or cost effectiveness comes out, it should be continuously re-evaluated. Alternative therapies, especially anti-arrhythmic drugs, are often insufficient in efficacy, cost and safety, especially for younger patients. In short, cardiac ablation procedures are a tool with reasonable cost, efficacy and safety that should not be restricted in use by administrative decision makers. The choice of a treatment to treat a particular problem should be based on a discussion between the patient and physician with all alternatives discussed and on the table, and mutual agreement on what is best for that patient. Thank you for consideration of these comments. Sincerely, Tim Dewhusrt. MD, FACC Vice-President, WA ACC	*Committee about the technology.*
Gregory Hallas, MD; Vancouver, Washington		
3.	To whom it may concern: I have been practicing medicine for 25 years. My specialty is internal medicine. During my career I have seen many patients with cardiac dysrhythmias. Early in my career, I would treat these patients with medications to control their condition. This was	*Thank you for your comments.*

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	mostly unsatisfactory. The monitoring and risky side effects made it challenging to safely use them. Patients mostly had side effects that had a significant impact on their quality of life. When ablation procedures became widely available this changed for many patients. With the correct procedure (in a susceptible cardiac condition) they often had very good results-often curative-without the consequences of lifetime medications (and their attendant side effect/issues/costs/monitoring, etc) To consider eliminating this procedure (Catheter Ablation Procedures for Supraventricular Tachyarrhythmia (SVTA) Including Atrial Flutter, Atrial Fibrillation) from our options for treating cardiac conduction conditions would be financially unsound. Although the immediate cost is sizeable, what is not accounted for is the significant cost of medication –for life, monitoring of said mediactions-for life (often including labs), the cost of treating and managing the unintended complications of these medications in some of the patients, and potentially the lost productivity (when these meds are used in younger patients they often are more fatigued, mentally dulled and become less productive/active) of patients using these meds. Also as a patient is less active due to more fatigue, etc, they gain weight, and the attendant consequences of that –given a large enough pool of people-will increase overall healthcare costs to the system. The adage “penny wise and pound foolish” applies to any decision eliminating this procedure from our management of patients with specific cardiac conduction disorders. Pleas consider this and do not limit our patients access to these procedures	

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	Respectfully, Gregory J Hallas MD Vancouver, Washington	
Daniel Highkin, MD		
4.	Greetings; It has come to my attention that your agency is proposing that catheter ablation for PSVT, WPW, and other arrhythmias may not be the most cost effective strategy for management of these problems. I would like to offer my opinion. I am a general internist. For most of my 30 year career, I had no choice but to manage patients with medications for arrhythmias. Medical management of arrhythmias is difficult for patients, especially young, active people. All of the medications have side effects, most notably fatigue and impaired exercise tolerance. Some of the medications have life threatening side effects. Compliance can be difficult; non-compliance results in breakthrough symptoms. Not all patients have complete symptom control on medicines. Living with PSVT or WPW is anxiety provoking. Patients with these conditions have shared with me that they are always on alert for the next attack, and worry if they might drop dead with one of their attacks. It has been very gratifying to see my patients back after catheter ablation. Not only has the fear resolved, they feel much better off the medications. I have also seen patients benefit greatly from ablation therapy for	*Thank you for your comments.*

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John MacGregor, MD; PeaceHealth St. Joseph Medical Center, Bellingham, Washington		
5.	The Draft Evidence Report spends a lot of time and effort calling into question the quality of the science behind ablation therapy for a number of arrhythmia conditions. Meanwhile, the results of the lion's share of data on the topics in question are pretty compelling and confirm what we as Clinical Cardiac Electrophysiologists all face on a daily basis caring for patients: the drugs for these conditions generally have poor long term safety and efficacy. Ablation therapy has evolved as standard of care for the conditions addressed at this point in the history of medicine. Why? Because the drugs don't work, and because catheter ablation is a far cry from sending a patient in for open heart surgery just to address an arrhythmia in the absence of another surgical indication. I would expect a voice in any further discussions regarding	*Thank you for your comments.* *We have sought input from clinicians who are experts in the field throughout the process. Key questions were formed,*

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	'appropriateness' of current practice patterns. As the authors of the report (who do not appear to be clinicians) point out, "Information in this report is not a substitute for sound clinical judgment." It seems there isn't much allowance made for sound clinical judgment, more of an attack on current clinical practice patterns for reasons that aren't made explicitly clear. Respectfully, John F. MacGregor, MD, FHRS Associate Medical Director, Cardiac Electrophysiology PeaceHealth St. Joseph Medical Center 2979 Squalicum Parkway, Suite 101 Bellingham, WA 98225 (360) 734-2700 fax: (360) 734-8362 jmacgregor@peacehealth.org	*inclusion and exclusion criteria framed, and the report written with the input of a clinical expert in the field (Ramakota Reddy, MD). In addition, three clinical peer reviewers who are experts in the field have reviewed the draft report, and their input will be taken into account when generating the final report. Finally, our clinical expert will be present at the public meeting in May to answer any questions posed by the Health Technology Clinical Committee about the technology.*
Providence Health & Services; Renton, Washington		
6.	Dear Concerned Party: On behalf of Providence Health & Services, thank you for allowing us the opportunity to provide comments to the draft evidence report for Catheter Ablation Procedures for Supraventricular Tachyarrhythmia including Atrial Flutter & Atrial Fibrillation. **About Providence** Providence is a not-for-profit Catholic health care ministry	*Thank you for your comments.*

	Comment	Response
	committed to providing for the needs of the communities it serves – particularly those that are poor and vulnerable. Providence's comprehensive scope of services includes 27 hospitals, 250 physician clinics, senior services, supportive housing and many other health and educational services. Providence employs more than 53,000 individuals, both religious and non-religious, across five states – Alaska, California, Montana, Oregon and Washington – and offers both insured and self-insured employee health plans. Guided by a willingness to adapt to meet changing times and unmet community needs, Providence collaborates with a diverse range of partners to provide a lasting community benefit. In 2012, our system provided $823 million in community benefit, including $272 million in free and discounted care for those who could not afford to pay. Providence is continually striving to improve quality, increase access and reduce the cost of care in all of the communities we serve. Below, please find comments, to the draft evidence report, as provided by our Cardiologists at Providence Health & Services: **Catheter Ablation of Supraventricular Arrhythmias** Catheter ablation of supraventricular arrhythmias has been the standard approach for managing various types of arrhythmias for over 20 years. Whether the energy is radiofrequency or cryoablation, the destruction of the arrhythmogenic focus has been the standard for curing various arrhythmias. The literature supports over a 90% success rate for arrhythmias involving accessory pathways, Wolff-Parkinson-White, and AV node reentry tachycardia. Likewise, focal atrial tachycardias are readily amenable to catheter ablations. Unfortunately, drug therapy is	

	Comment	Response
	wholly inadequate in the majority of these patients, requiring lifelong medications that try to decrease the frequency and/or severity of the episodes but never render them free of the arrhythmia. The complication rates associated with ablation of these arrhythmias is significantly below 3% and the cure rates are significantly above 90%. Atrial flutters are also supraventricular arrhythmias that involve reentry in the upper chambers. These arrhythmias are also successfully ablated with either radiofrequency energy and/or cryoenergy with a high success rate and very low complication rate. Again, drugs are wholly inadequate for controlling these arrhythmias and certainly are not curable in any of these patients. It requires lifelong medication with the goal to decrease the frequency and severity of episodes, whereas ablative technology allows for a curative procedure. Atrial fibrillation management has evolved significantly over the last 20 years and our ablative strategies have evolved as well. Unfortunately there is no long-term data in terms of arrhythmia cure, stroke, and or death but the literature is replete with one year arrhythmia-free patients post ablation that is significantly above 50% and approaches 70-80% in multiple trials. Again, antiarrhythmic therapy is notoriously poor at maintaining normal sinus rhythm at one year. While rate control and antithrombotic therapy is appropriate for many patients, many others remain severely limited with symptoms requiring more aggressive management strategies. If ablation of atrial fibrillation was 100% safe or 100% successful, it would be offered to many more patients. Since success is less than 100% and the risk of the procedure is real in greater than 2% or 3%, careful selection and education are	

	Comment	Response
	crucial. The ACCF/AHA/HRS clinical guidelines consistently review the various peer review trials and make appropriate recommendations in terms of the utilization of technology and drugs in the management of various cardiac arrhythmias. The use of ablation to modify the atrial substrate involved in these clinical supraventricular arrhythmias has become the standard of care across the country and throughout the world. <u>Pulmonary Vein Isolation (PVI) V. Anti-Arrhythmic Drugs (AADs)</u> As stated in the evidence report, the quality of evidence is low. The numbers are too small and the follow-up is too short to provide any meaningful insight into mortality benefit. The best data available thus far is retrospective and a single center suggesting an improvement in mortality. Currently, there is an ongoing CABANA trial that is looking into this very question, but there has been difficulty enrolling patients. However, there is clear data showing that patients do better in sinus rhythm than atrial fibrillation. At this time, ablation is our best strategy at achieving sinus rhythm. In addition, ablation has a 30-82% improvement in symptoms compared to AADs. The above argument also holds true for PVI v. AAD in regards to stroke and CHF. The data on mortality, stroke and CHF when comparing PVI to AADs is almost impossible to use. The study follow-up is only 12 months in all but one of the assessments and these are patients followed very regularly, not your usual follow-up.	*The overall quality of evidence for PVI versus AADs is" moderate" for the outcome of freedom from recurrence and "low" for procedure-unrelated mortality, stroke, and congestive heart failure. The overall quality of evidence for PVI versus AADs is "low" for procedure-related mortality. In general, the highest quality data comes from randomized controlled trials.* *The overall quality of evidence for freedom from recurrence and procedure-unrelated stroke for PVI versus Cox-Maze surgery is "insufficient", which means that the evidence*

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	PVI v. Cox-Maze Procedure This cohort study had almost 300 patients, but was flawed by a lower than expected success rate in the PVI group (only 56% as compared to the approximately 70% seen in most multicenter studies). In addition, the assessment did not consider the higher incidence of complications and morbidity seen in the Cox-Maze patient groups. Ablation v. No Treatment The numbers included in the study were obviously too small and the follow-up clearly too short to be included in this discussion. Catheter Ablation v. Surgery In regards to Atrial Flutter, Atrioventricular Reciprocating Tachycardia, Atrioventricular Nodal Reciprocating Tachycardia and mixed Supraventricular Tachycardia, the treatment of choice clearly favors ablation. There is improvement in symptoms and freedom from recurrence when compared to antiarrhythmic drugs. In regards to the surgical option, it is highly invasive and only	*does not permit a conclusion (see Appendix D). All adverse events were reported in Key Question 3 (section 4.4.1). In this study, the following adverse events were reported for the PVI group: 4.6% had pericardial effusion requiring pericardiocentesis, 9.8% developed pulmonary vein stenosis (14/19 required treatment), peripheral vascular complications (groin hematomas, femoral arterial pseduoaneurysm, or femoral arteriovenous fistula) occurred in 3.1%, and no data were reported for the surgery group. The following adverse events were reported for the surgery group: nonfatal myocardial infarction occurred in 1%, nonfatal renal failure in 1%, and nonfatal respiratory failure in 1%, and no data were reported for the PVI group.* *For ablation versus surgery, the overall quality of evidence for freedom from recurrence in patients with AVNRT, improvement of symptoms in patients with AVRT is "insufficient", which means that the evidence does not permit a conclusion (see Appendix D).* *For ablation versus AADs in patients with atrial flutter, the overall quality of evidence for freedom from recurrence was "moderate" and favored ablation, for procedure unrelated mortality the overall quality of evidence was "low", with no*

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	considered in extreme cases. Ablation v. AADs The mortality data was not significant when looking at ablation v. AADs in atrial flutter. If the discussion were around right-sided flutter, there is clearly a benefit from ablation. There is significant evidence that over the years there have been deaths attributed to AADs. It would be an extremely rare case where you would treat a patient with AADs over ablation for flutter. In regards to atrial fibrillation, the mainstay of treatment is PVI. There is freedom from recurrence regardless of the methods: radiofrequency, cryo, surgery. Additional ablation with left or right-sided lines and CFE is very problematic. There is no standardization, follow-up is ambiguous and the mortality data is very brief. Thank you again for the opportunity to provide our comments on the draft evidence report. If you have question or would like additional information, please contact Jennifer Warren, Regulatory Services Manager, Government & Public Affairs, at (425) 525-3191 or via email at jennifer.warren@providence.org.	*difference between treatment groups. For ablation versus AADs, the overall quality of evidence for improvement of symptoms in patients with AVNRT or AVRT was "insufficient" and in a study with various SVT diagnoses, the quality of evidence was "low" for greater improvement of symptoms following ablation versus AADs.* *There were no reported procedure- or treatment-related deaths in patients with atrial flutter following ablation or AADs; the overall quality of this evidence was "low".*
James A. Reiss, MD, MPH; PeaceHealth Southwest Medical Center, Vancouver, Washington		
7.	To Whom It May Concern: I support continued funding of catheter ablation procedures for	*Thank you for your comments.*

	Comment	Response
	supraventricular tachyarrhythmia (SVT) including atrial flutter and atrial fibrillation. As an electrophysiologist, I perform curative procedures for patients with otherwise life-limiting and even life-threatening arrhythmia. Withdrawl of funding would withhold from deserving patients this therapy which has made dramatic advances in efficacy and safety in the last 25 years. Sincerely, James A. Reiss, MD MPH PeaceHealth Southwest Medical Center, Vancouver, Washington	
Ben R. Stokes; Heartland Partners, LLC; Seattle, Washington		
8.	Dear Sir or Madam, Thank you for providing this opportunity for public comment regarding Catheter Ablation Procedures for Supraventricular Tachyarrhythmia. The Health Technology Assessment Program (HTA) is an important program, designed to determine whether or not certain health services used by state government are safe and effective. Specifically, the HTA seeks to 1) Make health care safer by relying on scientific evidence and a committee of practicing clinicians; 2) Make coverage decisions of state agencies more consistent; 3) Make state purchased health care more cost effective by paying for medical tools and procedures that are proven to work; and 4) Make the coverage decision process more open and inclusive by sharing information, holding public meetings, and publishing decision	*Thank you for your comments.*

	Comment	Response
	criteria and outcomes. My comments are in relation to the HTA Goal #3:) "Making state purchased health care more cost effective by paying for medical tools and procedures that are proven to work." As the Draft Evidence Report describes, Catheter ablation is curative for > 90% and low risk in patients with AVNRT; symptomatic Wolff-Parkinson-White Syndrome; and typical atrial flutter. Within these patient groups, it is the treatment of choice according to all international cardiovascular and electrophysiology societies. In comparison, all anti arrhythmic drugs have significant side effects and limited efficacy. Patients treated with these agents require regular outpatient follow up visits as well as intensive monitoring. I urge you to support the continued use of Catheter Ablation for treatment of SVT. Kind Regards, Ben R. Stokes /President Heartland Partners, LLC 800 Fifth Avenue, Suite 4100 Seattle, WA 98104 Toll Free: 866-307-3876 Fax: 360- 838-1219 brs@heartlandpartners.net	
Robert D. Swenson, MD, FACC; The Vancouver Clinic, PeaceHealth Southwest Medical Center, Vancouver, Washington		

	Comment	Response
9.	Having reviewed the extensive documents summarizing the use of catheter ablation procedures in patients with SVT I am concerned that the following "big picture" could be missed- 1. Catheter ablation is curative for > 90% in patients with AVNRT with low risks that are accurately described in your documents. It is the treatment of choice for patients with recurrent episodes according to all international cardiovascular and electrophysiology societies. All anti arrhythmic drugs have significant side effects and limited efficacy. Patients treated with these agents require regular outpatient follow up visits as well as intensive monitoring for the development of coronary artery disease and other forms of structural heart disease associated with ageing because of the increased risk of pro arrhythmia in these settings. 2. Catheter ablation is the treatment of choice for patients with symptomatic Wolff-Parkinson-White Syndrome because of the risk of sudden cardiac death in these patients. Again this therapy is curative in > 90% of these patients with low risk. Both AVNRT and WPW often present in patients before the age of 20 years old. Surely your committee recognizes the limitations of initiating lifelong pharmacologic therapy in this age group. When this form of therapy became available in the early 1990's many patients over the age of 60 years old did not elect to pursue this option because of their age and expectations. In 2013 patients in their 70's routinely desire this form of therapy as opposed drug therapy given their active lifestyle and expected longevity. 3. Catheter ablation is curative in >90% of patients with typical atrial flutter and is the treatment of choice for these patients. Pharmacologic therapy is associated with lower efficacy rates and	*Thank you for your comments.*

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	greater risks in patients with this rhythm disorder compared with the other arrhythmias discussed in this review. Prior to the advent of catheter ablation many of these patients required permanent pacemaker therapy for rate stabilization. 4. Catheter ablation is less effective but still extremely useful in other forms of SVT, particularly in patients whose arrhythmias are not controlled with anti arrhythmic drugs or who do not tolerate these agents because of side effects. 5. Catheter ablation has a lesser role in the treatment of patients with atrial fibrillation but has been shown to reduce symptoms and repeat hospitalizations in patients with paroxysmal atrial fibrillation who cannot be controlled with anti arrhythmic drugs. It's usefulness in patients with persistent atrial fibrillation is less clear. The risks associated with this type of catheter ablation procedure is higher than for the situations discussed above and the long term safety and outcome data is still limited. Catheter ablation therapy became widely available at the same time that managed care gained favor across the United States. Despite that I am not aware of any managed care organization or insurance product that restricted the use of this technology for the treatment of patients with the above noted arrhythmias as recommended by standard guidelines. Surely this reflects the efficacy and safety of this form of therapy for our patients. Thank you for the opportunity to provide this input. Robert D Swenson MD Partner of The Vancouver Clinic Staff Member of Peace Health Southwest Washington Medical Center since 1987 Vancouver, WA	

Masters, Christine V. (HCA)

Subject: FW: Public Comment for: Catheter Ablation Procedures for Supraventricular Tachyarrhythmia (SVTA) Including Atrial Flutter, Atrial Fibrillation

From: Sharon Crowell MD [mailto:scrowell@tvc.org]
Sent: Friday, April 05, 2013 11:43 AM
To: HCA ST Health Tech Assessment Prog
Subject: Public Comment for: Catheter Ablation Procedures for Supraventricular Tachyarrhythmia (SVTA) Including Atrial Flutter, Atrial Fibrillation

Greetings;

It has come to my attention that your agency is proposing that catheter ablation for PSVT, WPW, and other arrhythmias may not be the most cost effective strategy for management of these problems.

I would like to offer my opinion. I am a general internist. For most of my 30 year career, I had no choice but to manage patients with medications for arrhythmias. Medical management of arrhythmias is difficult for patients, especially young, active people. All of the medications have side effects, most notably fatigue and impaired exercise tolerance. Some of the medications have life threatening side effects. Compliance can be difficult; non-compliance results in breakthrough symptoms. Not all patients have complete symptom control on medicines. Living with PSVT or WPW is anxiety provoking. Patients with these conditions have shared with me that they are always on alert for the next attack, and worry if they might drop dead with one of their attacks.

It has been very gratifying to see my patients back after catheter ablation. Not only has the fear resolved, they feel much better off the medications.

I have also seen patients benefit greatly from ablation therapy for atrial flutter. This rhythm disturbance is very difficult to treat with medications. I distinctly remember a middle aged woman who was hospitalized several times for rapid atrial flutter in spite of my best efforts at controlling her rhythm problem with medications. She is now symptom free after ablation.

I am writing to ask that you consider the significant improvement in quality of life after catheter ablation in your decision making process. Based on my experience caring for these patients, I believe it is wrong deny patients access to potentially curative, very effective treatment. I am dismayed by the thought of not having this therapeutic option to offer patients.

Sincerely,
Sharon Crowell, MD
Chairman of the Board, The Vancouver Clinic

Washington Chapter
American College of Cardiology
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P.O. Box 6906 Tacoma WA 98417
Toll Free 1-877-460-5880

April 5, 2013

Josh Morse, MPH
Program Director
Health Technology Assessment Program
Washington State Health Care Authority
P.O. Box 42712
Olympia, WA 98504-2712

Re: Health Technology Assessment For
Catheter Ablation Procedures For Supraventricular Tachyarrhythmia (Svta) Including Atrial Flutter, Atrial Fibrillation

The questions as framed by the state focus on the procedures because of cost and efficacy, with safety a lower level concern. The summary notes that at five year and lifetime horizons ablation therapy is cost effective based on current standards of acceptable cost of QALY. They looked for only the highest quality published evidence.

There is no published trial that would meet their criteria showing that pacers are useful for complete heart block. Given the movement in this field, the peer-reviewed published literature is about 2-3 years behind the current state of the art. Even with that, there is evidence in the report that RF ablation works.

Cryo ablation is newer and without as much data and is **likely better because of shorter procedures and higher safety,** however the data is still being reported.
.
We should make sure that Cryo is not carved out as bad, rather further evidence should be examined as it becomes available.

Alternative therapies to ablation are all insufficient, especially for younger pre-Medicare patients.

Please let me know if I can provide more information to your assessment.

Sincerely,

Timothy A. Dewhurst. MD, FACC
Vice-President, WA ACC

Masters, Christine V. (HCA)

From: Gregory Hallas MD <ghallas@tvc.org>
Sent: Friday, April 05, 2013 1:31 PM
To: 'shtap@hca.wa.gov'
Subject: Public Comment for: Catheter Ablation Procedures for Supraventricular Tachyarrhythmia (SVTA) Including Atrial Flutter, Atrial Fibrillation

Follow Up Flag: Follow up
Flag Status: Completed

To whom it may concern:

I have been practicing medicine for 25 years. My specialty is internal medicine. During my career I have seen many patients with cardiac dysrhythmias. Early in my career, I would treat these patients with medications to control their condition. This was mostly unsatisfactory. The monitoring and risky side effects made it challenging to safely use them. Patients mostly had side effects that had a significant impact on their quality of life. When ablation procedures became widely available this changed for many patients. With the correct procedure (in a susceptible cardiac condition) they often had very good results-often curative-without the consequences of lifetime medications (and their attendant side effect/issues/costs/monitoring, etc)

To consider eliminating this procedure (Catheter Ablation Procedures for Supraventricular Tachyarrhythmia (SVTA) Including Atrial Flutter, Atrial Fibrillation) from our options for treating cardiac conduction conditions would be financially unsound. Although the immediate cost is sizeable, what is not accounted for is the significant cost of medication –for life, monitoring of said mediactions-for life (often including labs), the cost of treating and managing the unintended complications of these medications in some of the patients, and potentially the lost productivity (when these meds are used in younger patients they often are more fatigued, mentally dulled and become less productive/active) of patients using these meds. Also as a patient is less active due to more fatigue, etc, they gain weight, and the attendant consequences of that –given a large enough pool of people-will increase overall healthcare costs to the system. The adage “penny wise and pound foolish” applies to any decision eliminating this procedure from our management of patients with specific cardiac conduction disorders.

Pleas consider this and do not limit our patients access to these procedures

Respectfully,

Gregory J Hallas MD
Vancouver, Washington

Masters, Christine V. (HCA)

From: Daniel Highkin MD <dhighkin@tvc.org>
Sent: Friday, April 05, 2013 12:58 PM
To: HCA ST Health Tech Assessment Prog
Subject: Catheter ablations

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Flag Status: Completed

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Daniel Highkin, MD

Masters, Christine V. (HCA)

From: MacGregor, John (MD) <JMacGregor@peacehealth.org>
Sent: Friday, April 05, 2013 12:59 PM
To: HCA ST Health Tech Assessment Prog
Subject: Public Comment for: Catheter Ablation Procedures for Supraventricular Tachyarrhythmia (SVTA) Including Atrial Flutter, Atrial Fibrillation

Follow Up Flag: Follow up
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Respectfully,

John F. MacGregor, MD, FHRS
Associate Medical Director, Cardiac Electrophysiology
PeaceHealth St. Joseph Medical Center
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April 5, 2013

Health Technology Assessment Program
P.O. Box 42712
Olympia, WA 98504-2712

RE: Comments on Draft Evidence Report for Catheter Ablation Procedures for Supraventricular Tachyarrhythmia (SVTA) Including Atrial Flutter & Atrial Fibrillation

Dear Concerned Party:

On behalf of Providence Health & Services, thank you for allowing us the opportunity to provide comments to the draft evidence report for Catheter Ablation Procedures for Supraventricular Tachyarrhythmia including Atrial Flutter & Atrial Fibrillation.

About Providence

Providence is a not-for-profit Catholic health care ministry committed to providing for the needs of the communities it serves – particularly those that are poor and vulnerable. Providence's comprehensive scope of services includes 27 hospitals, 250 physician clinics, senior services, supportive housing and many other health and educational services. Providence employs more than 53,000 individuals, both religious and non-religious, across five states – Alaska, California, Montana, Oregon and Washington – and offers both insured and self-insured employee health plans.

Guided by a willingness to adapt to meet changing times and unmet community needs, Providence collaborates with a diverse range of partners to provide a lasting community benefit. In 2012, our system provided $823 million in community benefit, including $272 million in free and discounted care for those who could not afford to pay. Providence is continually striving to improve quality, increase access and reduce the cost of care in all of the communities we serve.

Below, please find comments, to the draft evidence report, as provided by our Cardiologists at Providence Health & Services:

Catheter Ablation of Supraventricular Arrhythmias

Catheter ablation of supraventricular arrhythmias has been the standard approach for managing various types of arrhythmias for over 20 years. Whether the energy is radiofrequency or cryoablation, the destruction of the arrhythmogenic focus has been the standard for curing various arrhythmias. The literature supports over a 90% success rate for arrhythmias involving accessory pathways, Wolff-Parkinson-White, and AV node reentry tachycardia. Likewise, focal atrial tachycardias are readily amenable to catheter ablations. Unfortunately, drug therapy is wholly inadequate in the majority of these patients, requiring lifelong medications that try to decrease the frequency and/or severity of the episodes but never render them free of the arrhythmia. The complication rates associated with ablation of these arrhythmias is significantly below 3% and the cure rates are significantly above 90%.

Atrial flutters are also supraventricular arrhythmias that involve reentry in the upper chambers. These arrhythmias are also successfully ablated with either radiofrequency energy and/or cryoenergy with a high success rate and very low complication rate. Again, drugs are wholly inadequate for controlling these arrhythmias and certainly are not curable in any of these patients. It requires lifelong medication with the goal to decrease the frequency and severity of episodes, whereas ablative technology allows for a curative procedure.

Atrial fibrillation management has evolved significantly over the last 20 years and our ablative strategies have evolved as well. Unfortunately there is no long-term data in terms of arrhythmia cure, stroke, and or death but the literature is replete with one year arrhythmia-free patients post ablation that is significantly above 50% and approaches 70-80% in multiple trials. Again, antiarrhythmic therapy is notoriously poor at maintaining normal sinus rhythm at one year. While rate control and antithrombotic therapy is appropriate for many patients, many others remain severely limited with symptoms requiring more aggressive management strategies. If ablation of atrial fibrillation was 100% safe or 100% successful, it would be offered to many more patients. Since success is less than 100% and the risk of the procedure is real in greater than 2% or 3%, careful selection and education are crucial.

The ACCF/AHA/HRS clinical guidelines consistently review the various peer review trials and make appropriate recommendations in terms of the utilization of technology and drugs in the management of various cardiac arrhythmias. The use of ablation to modify the atrial substrate involved in these clinical supraventricular arrhythmias has become the standard of care across the country and throughout the world.

Pulmonary Vein Isolation (PVI) V. Anti-Arrhythmic Drugs (AADs)

As stated in the evidence report, the quality of evidence is low. The numbers are too small and the follow-up is too short to provide any meaningful insight into mortality benefit. The best data available thus far is retrospective and a single center suggesting an improvement in mortality. Currently, there is an ongoing CABANA trial that is looking into this very question, but there has been difficulty enrolling patients. However, there is clear data showing that patients do better in sinus rhythm than atrial fibrillation. At this time, ablation is our best strategy at achieving sinus rhythm. In addition, ablation has a 30-82% improvement in symptoms compared to AADs. The above argument also holds true for PVI v. AAD in regards to stroke and CHF.

The data on mortality, stroke and CHF when comparing PVI to AADs is almost impossible to use. The study follow-up is only 12 months in all but one of the assessments and these are patients followed very regularly, not your usual follow-up.

PVI v. Cox-Maze Procedure

This cohort study had almost 300 patients, but was flawed by a lower than expected success rate in the PVI group (only 56% as compared to the approximately 70% seen in most multicenter studies). In addition, the assessment did not consider the higher incidence of complications and morbidity seen in the Cox-Maze patient groups.

Ablation v. No Treatment

The numbers included in the study were obviously too small and the follow-up clearly too short to be included in this discussion.

Catheter Ablation v. Surgery

In regards to Atrial Flutter, Atrioventricular Reciprocating Tachycardia, Atrioventricular Nodal Reciprocating Tachycardia and mixed Supraventricular Tachycardia, the treatment of choice clearly favors ablation. There is improvement in symptoms and freedom from recurrence when compared to antiarrhythmic drugs. In regards to the surgical option, it is highly invasive and only considered in extreme cases.

Ablation v. AADs

The mortality data was not significant when looking at ablation v. AADs in atrial flutter. If the discussion were around right-sided flutter, there is clearly a benefit from ablation. There is significant evidence that over the years there have been deaths attributed to AADs. It would be an extremely rare case where you would treat a patient with AADs over ablation for flutter.

In regards to atrial fibrillation, the mainstay of treatment is PVI. There is freedom from recurrence regardless of the methods: radiofrequency, cryo, surgery. Additional ablation with left or right-sided lines and CFE is very problematic. There is no standardization, follow-up is ambiguous and the mortality data is very brief.

Thank you again for the opportunity to provide our comments on the draft evidence report. If you have question or would like additional information, please contact Jennifer Warren, Regulatory Services Manager, Government & Public Affairs, at (425) 525-3191 or via email at jennifer.warren@providence.org.

Masters, Christine V. (HCA)

From: reiss9271@comcast.net
Sent: Friday, April 05, 2013 1:14 PM
To: HCA ST Health Tech Assessment Prog
Subject: Comment on proposed changes for funding Catheter Ablation Procedures for Supraventricular Tachyarrhythmia (SVTA) Including Atrial Flutter, Atrial Fibrillation

Follow Up Flag: Follow up
Flag Status: Completed

To Whom It May Concern:

I support continued funding of catheter ablation procedures for supraventricular tachyarrhythmia (SVT) including atrial flutter and atrial fibrillation. As an electrophysiologist, I perform curative procedures for patients with otherwise life-limiting and even life-threatening arrhythmia. Withdrawl of funding would withhold from deserving patients this therapy which has made dramatic advances in efficacy and safety in the last 25 years.

Sincerely,

James A. Reiss, MD MPH
PeaceHealth Southwest Medical Center, Vancouver, Washington.

Masters, Christine V. (HCA)

From: Ben Stokes <BRS@HeartlandPartners.net>
Sent: Friday, April 05, 2013 5:01 PM
To: HCA ST Health Tech Assessment Prog
Subject: Public Comment for: Catheter Ablation Procedures for Supraventricular Tachyarrhythmia (SVTA) Including Atrial Flutter, Atrial Fibrillation

Follow Up Flag: Follow up
Flag Status: Flagged

To:
Washington State Health Care Authority
Health Technology Assessment

From:
Ben R. Stokes

Dear Sir or Madam,

Thank you for providing this opportunity for public comment regarding Catheter Ablation Procedures for Supraventricular Tachyarrhythmia.

The Health Technology Assessment Program (HTA) is an important program, designed to determine whether or not certain health services used by state government are safe and effective. Specifically, the HTA seeks to 1) Make health care safer by relying on scientific evidence and a committee of practicing clinicians; 2) Make coverage decisions of state agencies more consistent; 3) Make state purchased health care more cost effective by paying for medical tools and procedures that are proven to work; and 4) Make the coverage decision process more open and inclusive by sharing information, holding public meetings, and publishing decision criteria and outcomes. My comments are in relation to the HTA Goal #3:) "Making state purchased health care more cost effective by paying for medical tools and procedures that are proven to work."

As the Draft Evidence Report describes, Catheter ablation is curative for > 90% and low risk in patients with AVNRT; symptomatic Wolff-Parkinson-White Syndrome; and typical atrial flutter. Within these patient groups, it is the treatment of choice according to all international cardiovascular and electrophysiology societies. In comparison, all anti arrhythmic drugs have significant side effects and limited efficacy. Patients treated with these agents require regular outpatient follow up visits as well as intensive monitoring.

I urge you to support the continued use of Catheter Ablation for treatment of SVT.

Kind Regards,

Ben R. Stokes | President
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Masters, Christine V. (HCA)

From: robert Swenson <bswenson@comcast.net>
Sent: Thursday, April 04, 2013 8:55 PM
To: HCA ST Health Tech Assessment Prog
Subject: Public Comment for: Catheter Ablation Procedures for Supraventricular Tachyarrhythmia (SVTA) Including Atrial Flutter, Atrial Fibrillation

Follow Up Flag: Follow up
Flag Status: Completed

To:
Washington State Health Care Authority
Health technology Assessment

From:
Robert D Swenson MD FACC

April 4, 2013

Having reviewed the extensive documents summarizing the use of catheter ablation procedures in patients with SVT I am concerned that the following "big picture" could be missed-

1. Catheter ablation is curative for > 90% in patients with AVNRT with low risks that are accurately described in your documents.
It is the treatment of choice for patients with recurrent episodes according to all international cardiovascular and electrophysiology societies.
All anti arrhythmic drugs have significant side effects and limited efficacy. Patients treated with these agents require regular outpatient follow up visits as well as intensive monitoring for the development of coronary artery disease and other forms of structural heart disease associated with ageing because of the increased risk of pro arrhythmia in these settings.
2. Catheter ablation is the treatment of choice for patients with symptomatic Wolff-Parkinson-White Syndrome because of the risk of sudden cardiac death in these patients.
Again this therapy is curative in > 90% of these patients with low risk.
Both AVNRT and WPW often present in patients before the age of 20 years old. Surely your committee recognizes the limitations of initiating lifelong pharmacologic therapy in this age group. When this form of therapy became available in the early 1990's many patients over the age of 60 years old did not elect to pursue this option because of their age and expectations. In 2013 patients in their 70's routinely desire this form of therapy as opposed drug therapy given their active lifestyle and expected longevity.
3. Catheter ablation is curative in >90% of patients with typical atrial flutter and is the treatment of choice for these patients. Pharmacologic therapy is associated with lower efficacy rates and greater risks in patients with this rhythm disorder compared with the other arrhythmias discussed in this review. Prior to the advent of catheter ablation many of these patients required permanent pacemaker therapy for rate stabilization.
4. Catheter ablation is less effective but still extremely useful in other forms of SVT, particularly in patients whose arrhythmias are not controlled with anti arrhythmic drugs or who do not tolerate these agents because of side effects.
5. Catheter ablation has a lesser role in the treatment of patients with atrial fibrillation but has been shown to reduce symptoms and repeat hospitalizations in patients with paroxysmal atrial fibrillation who cannot be controlled with anti arrhythmic drugs. It's usefulness in patients with persistent atrial fibrillation is less clear. The risks associated with this type of catheter ablation procedure is higher than for the situations discussed above and the long term safety and outcome data is still limited.

Catheter ablation therapy became widely available at the same time that managed care gained favor across the United States. Despite that I am not aware of any managed care organization or insurance product that restricted the use of this technology for the treatment of patients with the above noted arrhythmias as recommended by standard guidelines. Surely this reflects the efficacy and safety of this form of therapy for our patients.

Thank you for the opportunity to provide this input.

Robert D Swenson MD
Partner of The Vancouver Clinic
Staff Member of Peace Health Southwest Washington Medical Center since 1987 Vancouver, WA