

A09/S/b

2013/14 NHS STANDARD CONTRACT FOR CARDIOLOGY: ELECTROPHYSIOLOGY AND ABLATION SERVICES (ADULT)

PARTICULARS, SCHEDULE 2- THE SERVICES, A- SERVICE SPECIFICATIONS

Service Specification No.	A09/S/b
Service	Cardiology: Electrophysiology and Ablation Services (Adult)
Commissioner Lead	
Provider Lead	
Period	12 months
Date of Review	

1. Population Needs

1.1 National/local context and evidence base

Electrophysiology studies and **ablations** are usually performed for symptomatic fast heart rhythms. The electrophysiology study allows the specialist to diagnose the precise problem and judge where to perform ablation. ablation involves heating (or in some instances freezing) small areas of heart muscle in order to cause irreversible damage and thereby prevent heart racing. The most common procedures are for supraventricular tachycardia (SVT), atrial flutter, and atrial fibrillation (AF), but ablation can also be performed for ventricular arrhythmias.

Symptomatic heart racing (tachycardia) affects at least 1% of the population. Episodes are unpredictable and symptoms include palpitation, chest pain, shortness of breath, dizziness and even passing out. Most patients feel extremely uncomfortable when they have heart racing and many are concerned that their symptoms could be life threatening. In most cases the heart racing is not dangerous but in some cases it can be life-threatening.

Atrial Fibrillation - the commonest form of cardiac arrhythmia (heart racing) is atrial fibrillation (AF). This affects 1.9% of the UK population, about 2 million people, (<u>http://www.improvement.nhs.uk/graspaf/</u>) and is much more common in older subjects. Approximately 4% of the population over 65yrs are affected by AF, and 10% of those older than 80 years. Most patients with AF are treated by tablets alone but in patients with AF who have troublesome symptoms despite medication ablation should be recommended. Prospective, randomised studies have shown a clear

reduction in symptoms from ablation therapy compared with medication alone.. Furthermore, ablation therapy has been shown to be cost effective for these patients (<u>http://heart.bmj.com/content/95/7/542.short</u>). ablation is therefore recommended by NICE and current international guidelines for patients whose symptoms cannot be controlled by medication

(http://guidance.nice.org.uk/CG36/Guidance/pdf/English) .

The use of ablation for symptomatic AF has increased significantly over the past 10 years in the UK. In 2010 approximately 5000 ablation procedures for AF were performed. There is a good understanding that treating AF with ablation early within its clinical course gives better results than after it has been present for many years. In addition there is evidence that in individuals who have advanced heart disease that ablation results are less successful.

AF has historically been classified into 3 groups: *paroxysmal* - where AF starts and stops of its own accord; *persistent* where AF requires medical intervention, in the form of electrical cardioversion, to restore normal sinus rhythm; and *permanent* – where AF is accepted in the long-term.

The initial studies of AF ablation were performed mainly on younger patients with **paroxysmal AF** and structurally normal hearts. In general this represents a group of patients early in the clinical course of their AF illness. A cost-effectiveness analysis of these studies has shown that ablation is cost-effective in comparison to medical therapy in this group of patients (reference 3).

Ablation is now also increasingly used in patients with *persistent AF*. Some of these patients have this pattern of AF early within their clinical course and have been shown in observational studies to have similarly good results to patients with paroxysmal AF. It is important for the clinical aspects that predict the best chances of a successful result. In general, however, patients with *persistent AF* more often require repeat procedures to achieve a successful result and longer- term follow-up data is not yet available. Guidance on patient selection for ablation in *persistent AF* has been published by Heart Rhythm UK. This area is not covered by the 2006 NICE AF guidance (CG 36), but is currently under review by NICE. In the meantime Heart Rhythm UK recommends the use of ablation in carefully selected patients with *persistent AF* as per the 2010 guidance.

Atrial flutter – this pattern of heart racing is closely linked to atrial fibrillation (it has many of the same causes). ablation results in a >90% long-term success. It is difficult to treat with medication and with high levels of ablation success, ablation is recommended for any individual with recurrent atrial flutter or a high likelihood of recurrence after a first clinical event.

Supraventricular tachycardia (SVT) affects over 200,000 people in the UK and most commonly presents between the age of 10 and 50 years. Typical symptoms are a sudden onset of a rapid heart beat (generally 150-200/min) with or without dizziness, shortness of breath or chest pain. Treatment can be with medication or by ablation. Many patients prefer ablation as a first line treatment as they find taking

medications difficult (particularly with side effects) and at best only partially effective. With cure rates of >90%, ablation provides an option to avoid medication and symptomatic heart racing. As these individuals are active in their working lives ablation provides a benefit in being able to continue working normally, without time off work. ablation treatment is recommended as a first line treatment for SVT in Chapter 8 of the NSF, by Heart Rhythm UK (<u>http://heartrhythmuk.org.uk/guidelines</u>) and by the American College of Cardiology / American Heart Association / European Society of Cardiology. <u>http://www.escardio.org/guidelines-surveys/esc-</u> guidelines/GuidelinesDocuments/guidelines-afib-FT.pdf

Ventricular preexcitation arises from the presence of an accessory pathway (an additional electrical pathway between the chambers of the heart). This may be asymptomatic or cause symptomatic SVT (Wolff-Parkinson-White syndrome). Accessory pathways can be ablated with a high rate of cure in symptomatic patients. There is also a risk of sudden death in patients with pre-excitation. This probably arises from the development of atrial fibrillation which is conducted very rapidly to the ventricles through the accessory pathway with degeneration of the heart rhythm into ventricular fibrillation.

The latest guidelines recommend diagnostic electrophysiological studies in most patients with WPW, whether symptomatic or not, for risk stratification purposes, followed by curative ablation if appropriate.

Ventricular Tachycardia - in contrast to most supraventricular arrhythmia, **ventricular arrhythmia** (ventricular tachycardia – VT, and ventricular fibrillation – VF) are serious and life threatening. These arrhythmias are most common shortly after acute myocardial infarction (AMI) but they also occur remote from AMI and in young individuals with apparently normal hearts in whom the prevalence is approximately 0.1% of population.

Patients who have experienced ventricular arrhythmia or who are at risk of ventricular arrhythmia require careful expert clinical assessment by an electrophysiologist. Patients require treatment of their underlying heart condition and risk stratification for the development of future life-threatening arrhythmia. Patients at high risk of these arrhythmia usually require an implantable cardioverter defibrillator (ICD).

Ablation therapy is used increasingly in the management of patients with ventricular arrhythmia though its use remains less frequent than in patients with SVT. ablation may be used as the primary treatment for VT (usually in patients with a normal or near normal heart) but in patients with structural heart disease it is usually adjunctive therapy to an ICD. Patients who experience repeated ICD shocks due to recurrent VT suffer a high level of morbidity and VT ablation is also valuable in the management of this patient group. ablation is recommended in the recent consensus statement on Ventricular Arrhythmias published in 2009. (http://europace.oxfordjournals.org/content/11/6/771.short)

There is a wide range in technical complexity of catheter ablation procedures depending on the rhythm being treated and whether or not there is underlying

structural heart disease. In this document ablation therapies are classified as standard and complex procedures (see below).

Definitions

Standard catheter ablation includes:

- Electrophysiological study
- Ablation of the atrioventricular (AV) node (with pacing)
- Ablation of atrioventricular nodal reentry tachycardia
- Ablation of accessory pathways
- Ablation of right atrial isthmus dependent atrial flutter
- Ablation of regular sustained atrial tachycardia
- Ablation of focal ventricular tachycardia in normal hearts

Complex catheter ablation includes:

- Ablation of atrial fibrillation
- Ablation of left atrial tachycardia
- Ablation of non-sustained regular atrial tachycardia
- Ablation of ventricular tachycardia in patients with structural heart disease
- Ablation of arrhythmia in patients with complex congenital heart disease

Service provision

Due to the need for specialist equipment and facilities and the limited number of trained healthcare professionals (doctors and cardiac physiologists), Electrophysiology (EP) and ablation services are provided in tertiary cardiac centres and larger secondary care centres. There is some variation in ablation provision across the UK, with best access in the south-east of England. All centres submit data to the National Institute for Cardiovascular Outcomes Research (NICOR). There has been a significant increase in the number of ablation procedures performed in the UK over the past 10 years.

The recent increase in ablation numbers is mostly due to the advent of ablation treatment for AF, but also an increased use of ablation therapy for heart rhythm problems in patients with underlying heart disease. These advances have been made possible by the introduction of computerised 'navigation' systems – rather like 'sat navs' for ablation. The steady increase over the past decade would be predicted to continue as services are developed.

There are no recommended 'numbers' for ablation, but it should be offered to symptomatic patients. Currently there is significant regional variation in ablation provision related to the development of local networks and regional ablation services.

Expert UK consensus recommends that an appropriate service should provide a minimum of:

• AF ablation – 100 per million

- SVT ablation 100-150 per million
- Ventricular tachycardia ablation 20 per million

It should be emphasised that these numbers represent a minimum and that well developed services with appropriate patient identification will identify much higher numbers of patients.

References

Clinical guideline (CG)36 Atrial fibrillation: National Institute for Health and Clinical Excellence (NICE) guideline 28 June 2006. www.nice.org.uk

Camm AJ, Kirchhof P, Lip GY, et al. Guidelines for the management of atrial fibrillation: the Task Force for the Management of Atrial Fibrillation of the European Society of Cardiology (ESC). European Heart Rhythm Association; European Association for Cardio-Thoracic Surgery, *Europace*2010;12(10):1360-420.

McKenna C, Palmer S, Rodgers M, et al. Cost-effectiveness of radiofrequency catheter ablation for the treatment of atrial fibrillation in the UK. *Heart* 2009;**95**:542–549.

Hunter RJ, Berriman TJ, Diab I, et al. Long-term efficacy of catheter ablation for atrial fibrillation: impact of additional targeting of fractionated electrograms. *Heart* 2010;**96**:1372-1378.

Gunawardena R, Furniss S, Shepherd E et al. Outcomes following catheter ablation of atrial fibrillation in the UK – a single-centre cohort analysis Br J *Cardiol* 2010;17(6):271-6.

2. Scope

2.1 Aims and objectives of service

Aims

The aim of the service is to provide timely diagnosis and appropriate specialised treatment to patients affected by symptomatic fast heart rhythms to reduce morbidity and for a cohort of patients reduced mortality

Objectives

EP and ablation services are designed to provide the following services in order to fulfil this aim. High quality EP and ablation services should provide the following:

• Assessment of patients with heart rhythm problems to establish whether or not the condition is life-threatening, and therefore whether urgent treatment is

needed.

- Following this initial assessment, immediate treatment of any potentially lifethreatening conditions with medical therapy, ablation or ICD therapy.
- For non-life threatening conditions, most patients are treated with medication on an initial basis (Nb. even at this stage specialist treatment can be critical as many of the medications if used incorrectly have the potential to provoke life-threatening heart rhythm problems).
- For symptomatic patients either not controlled with medication or experiencing side effects from medication, EP ablation services provide an assessment about the suitability of ablation.
- Perform EP / ablation procedures with ongoing audit of performance.

Patient groups / conditions

The patient groups served by EP ablation services are diverse and it is not possible to define a single group or a single pathway that patients will travel. Patients vary from young children with normal hearts, to children with congenital heart disease, otherwise healthy young to middle aged adults with palpitation but structurally normal hearts, through to the very elderly with or without structural heart disease or coronary artery disease. It is important to note however that the majority of individuals with SVT and many with AF are of a working age leading active lifestyles in good health apart from their heart rhythm problem, which can often be cured by ablation. It is therefore not possible to describe one demographic for those affected by heart racing problems.

The core objective of EP ablation services is to take a patient with symptoms (that are often severely debilitating, cause them enormous concern and can be life threatening) and find an effective solution. This can be with ablation to fix the problem or by a combination of medication, ablation and sometimes pacemakers, to control the problem. These treatments all have the same aim of providing significant improvements to the patient's quality of life, and on occasion quantity of life.

2.2 Service description/care pathway

It is important that EP and ablation is commissioned as an entire service – that is with outpatient assessment, diagnostic testing, the procedure and then follow-up.

The preferred model is at least one pre procedure consultation. The number of follow-up appointments is dependent on the procedure, SVT ablations normally only have one follow up while AF ablations require three or more.

Discharge is generally to General Practitioner (GP) or referring cardiologist however a small number of patients will require longer follow-up by the EP ablation service where symptoms persist.

Access to ablation services is from all areas.

• Primary Care – some primary care physicians, who are familiar with the benefits

of ablation, refer directly to ablation services. Referrals are based on symptoms and / or concerns about a possible life-threatening heart rhythm problem.

- Secondary Care the majority of ablation referrals come from secondary care. Most are seen as outpatients following assessment and treatment by a cardiologist in secondary care. Less commonly, referral is as an inpatient transfer when the symptoms are severe or the heart rhythm problem possibly life-threatening. Referral guidance, for the UK, is available from Chapter 8 of the NSF. Although the European Society of Cardiology, and the American societies (ACC and AHA) have published guidance on the management of heart rhythm problems there are no referral guidelines.
- Tertiary Care patients undergoing treatment by interventional cardiologists or cardiac surgeons may have heart rhythm problems and be referred for ablation.

The access criteria to ablation services are deliberately wide. ablation services provide specialists assessment for any individual with any of the following:

- Documented heart rhythm problems causing significant symptoms
- Documented heart rhythm problems that could be life-threatening
- Symptoms suggestive of a serious heart rhythm problem (note sometimes symptoms are infrequent and hard to document on an electrogardiogram (ECG))

Importantly, Chapter 8 of the NSF highlights that 'for many NHS professionals awareness and understanding of cardiac arrhythmias is low'. This is the barrier that patients face when trying to access effective treatment for their heart rhythm problems via ablation services. This is a key reason why access criteria should be wide. Chapter 8 of the NSF highlights the nature of access required to specialist ablation services. This can be seen in its first two quality requirements:

Quality requirement one: Patient Support

People with arrhythmias receive timely and high quality support and information, based on an assessment of their needs.

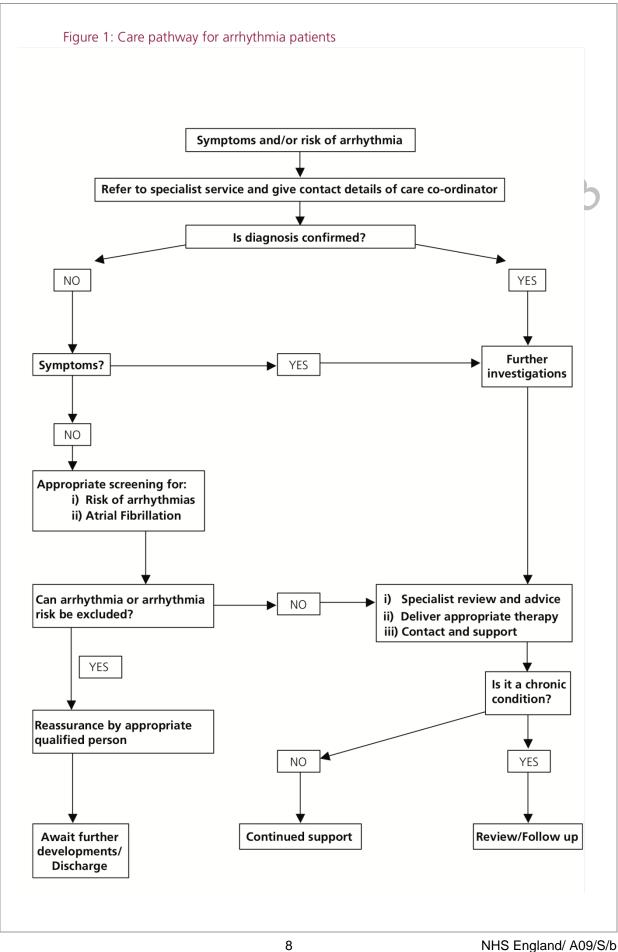
Quality requirement two: Diagnosis and Treatment

People presenting with arrhythmias, in both emergency and elective settings, receive timely assessment by an appropriate clinician to ensure accurate diagnosis and effective treatment and rehabilitation.

The patient pathway recommended on the following page is centred around "Specialist Review and Advice". This is what ablation services provide. Within the UK, unlike most European countries and the USA, heart rhythm problems are often managed by non-experts. There are therefore no international guidelines on referral as there is an expectation that all such patients would be referred.

Ref: Chapter 8 National Service Framework for Coronary Heart Disease

http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Healthcare/Longtermc onditions/Vascular/Coronaryheartdisease/Nationalserviceframework/index.htm



Outpatients

Assessment by EP ablation services is normally by outpatient referral. A smaller number of individuals with severe, extremely frequent or life threatening problems are referred as inpatients. It is worth noting that the point at which any individual requires access to EP ablation services is highly variable. Some people will want immediate assessment because of the severity of symptoms / desire to avoid longterm medication / personal anxiety. Others will need assessment only at a later stage having tried medication unsuccessfully, or having developed side effects in the longer term. Others may be more scared of a potential procedure to correct the problem than the issue itself, and this can delay referral.

There is still a barrier to referral, however, in some areas. Often the referral is initiated by a patient request and therefore less knowledgeable patients may well be placed at a disadvantage in terms of referral. There are clear guidelines for referral in the Map of Medicine for SVT and from NICE for atrial fibrillation. http://guidance.nice.org.uk/CG36/Guidance/pdf/English

There are Heart Rhythm UK and international body guidelines on patient suitability for EP ablation procedures. These documents highlight suitability but do not set referral criteria.

The service should allow a simple referral process from primary and secondary care to EP ablation services. Chapter 8 of the National Service Framework for Coronary Heart Disease recommends assessment by an 'appropriately qualified person'.

http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Healthcare/ :_Longtermconditions/Vascular/Coronaryheartdisease/Nationalserviceframework/in dex.htm

This does not have to be an EP ablation specialist but should be a cardiologist with an interest in heart rhythm problems, familiar with ablation treatment and with a proven referral pattern (a major inequity in the care of heart rhythm problems is that some cardiologists rarely refer patients for ablation). A patient representative body, called Arrhythmia Alliance, has identified that many patients who contact them suffer with symptoms for 3-4 years prior to referral to an EP ablation specialist.

There is a map of medicine pathway available for both atrial fibrillation and 'tachyarrhythmias' (Heart racing). These cross-reference each other. These can be accessed via <u>http://www.mapofmedicine.com</u>. These pathways however, are management guides and do not provide clear guidance on referral.

Heart rhythm problems present in many different situations. The key principles of presentation and management will be summarised below.

Significant symptoms

Those presenting with significant symptoms (chest pain, syncope, shortness of breath, palpitations) will often present to a hospital Emergency Department for treatment, or to an urgent GP consultation.

In the setting of significant symptoms hospital care will nearly always be required.

Following treatment of the acute episode consideration will need to be given as to the likelihood of recurrence and this guides the treatment required at that point in time. Most patients with heart rhythm problems will get recurrent symptoms.

Many patients with significant symptoms from AF are started on a drug called amiodarone, which has a number of severe side effects, especially in the longer-term. Specialist input from an EP ablation service is recommended in such a situation.

Minimal/absent symptoms (or symptoms settled as problem intermittent)

The most common heart rhythm problem to present this way is AF. The normal presentation is to Primary Care. Hospital treatment is not required urgently in this situation. Although general cardiology input is recommended for initial investigation, including echocardiography, it is likely that the patient will not require specialist EP ablation services unless significant other issues, such as structural heart disease, are discovered during further investigation.

For those with intermittent problems, where symptoms are significant, further assessment by an EP ablation service may be required. This can improve diagnosis, risk assessment and treatment (sometimes an EP study is the only way to diagnose the problem as recording intermittent symptoms on an ECG can be very difficult). Referral can be made directly from primary care or after further assessment in secondary care.

Elective inpatient care

Within cardiology, and in other medical specialties, there are clear examples of increased volume being associated with improved outcomes. Therefore this document has set out some *minimum* numbers required to establish some skill and maintain competence.

It is possible to perform standard ablation in a centre with one specialist competent to perform catheter ablation however it is important that formal arrangements must be in place to cover out of hours emergencies by accredited heart rhythm specialists. This may be done at a regional level.

Cardiologists performing complex ablation will do so in a centre where at least one other specialist accredited to perform complex ablation is practicing. Although this may require the cardiologist and their patients to travel to another centre rather than have their procedure locally, Heart Rhythm UK (HR UK) believes that colleague support and oversight is critical for delivering procedures of high safety and quality. The need to meet this requirement will stimulate local training and appointment of heart rhythm specialists.

The cardiologist will have completed appropriate training in standard catheter ablation and undergo retraining as a consultant if ablation has not been performed for \geq 12 months

All cardiologists performing catheter ablation will undertake appropriate CPD in catheter ablation

Each cardiologist performing standard catheter ablation will perform \geq 50 catheter ablations / year as first operator (performing complex ablation can be included in this number for those physicians performing both standard and complex ablation)

Cardiologists performing catheter ablation will audit their procedures including their complications and share these in an anonymised form. If a cardiologist's complications were to exceed accepted limits practice will be reviewed and advice sought from within the centre or elsewhere). Procedural audit data must be submitted to NICOR.

Operators performing fewer than 100 catheter ablations/ year will need to average their outcome figures over 2 or more years to account for random variation.

Centres Performing Only Standard ablations

Centres performing catheter ablation procedures will have a minimum set of equipment to safely carry out these procedures. These will include:

- Wards with bedside monitoring equipment with effective alarm systems and capable of storing ECG data
- Nursing staff experienced in care and management of cardiac arrhythmias
- Facilities for haemodynamic monitoring in the ward and cardiac catheter laboratory
- Facilities for cardiopulmonary resuscitation, temporary and permanent pacing
- Pacemaker and implantable defibrillator programmers
- Modern X-ray equipment capable of imaging with radiation doses comparable with the majority of X-ray systems currently used in the UK
- Facilities for anaesthesia and assisted ventilation within the catheter laboratory
- A digital electrophysiological recording system with at least 16 intracardiac channels and a programmable stimulator
- Radiofrequency generator systems capable of temperature control
- Equipment for pericardiocentesis
- A computerised database capable of submitting data to the Central Cardiac Audit Database (CCAD)

11

• Echocardiography

Centres performing complex ablation:

Access to emergency cardiothoracic surgery. Where not available on-site an agreed written protocol will be in place with the local cardiac surgical centre, and local ambulance service, to provide emergency surgical cover. In addition, the time taken for a patient to thoracotomy should be of a similar order to that possible with on-site surgical facilities where a surgical team is not on stand-by.

- Intra-aortic balloon pump (VT ablation)
- Bedside anticoagulation monitoring (e.g. Activated Clotting Time (ACT))
- 3D mapping and navigation systems
- Facilities for cardiac catheterisation
- Transoesophageal echocardiography
- Access to MRI/CT scanning

Training centres

Training centres will be expected to meet the standards for a centre performing complex ablation. In addition the following would be expected:

- At least two full time cardiologists (or equivalent part-time) performing catheter ablation as their primary specialty
- The training centre will be integrated into a tertiary cardiac centre performing complex pacing, coronary angioplasty, cardiac surgery and heart failure management.
- Centres that do not have all of these facilities can take part in a training program but will not be the sole training centre in a training program
- The training centre will be performing sufficient case numbers to have a reasonable chance of exposing a trainee to enough cases over a two year fellowship. This will mean that for one trainee at least 200 standard and 100 complex ablations will need to be performed. For two trainees this number could be the same because first operator and second operator status can be taken by trainees for the same procedure.
- Training centres will not allow trainees to perform unsupervised procedures until they have received a certificate of completion of specialist training and have completed their minimum training for the procedure they undertake (a trainer may allow an experienced trainee to perform some of the procedure, e.g. EP study, without supervision but the procedure will never be completed without direct supervision of a trainer).

Paramedical staff

Cardiac physiologists

- There will be at least two cardiac physiologists actively involved in catheter ablation in each centre
- Each physiologist will have had appropriate training in assisting with catheter ablation and the use of the equipment required for catheter ablation and resuscitation.
- At least one physiologist will have accreditation in catheter ablation and

electrophysiology (HRUK/Heart Rhythm Society (HRS) or International Board of Heart Rhythm Examiners (IBHRE))

- All physiologists will undertake appropriate continuing professional development in catheter ablation and resources made available for them to do so.
- Each physiologist will be actively involved in ≥ 30 catheter ablations / year

Specialist arrhythmia nurses

The role of specialist arrhythmia nurses varies considerably across the UK. However there remain some common quality standards that will be met regardless of the nurse role:

- Arrangements will be made that at least two nurses are denoted as specialist arrhythmia nurses/centre. This is important to allow continuity of care during periods of absence and can be achieved if necessary by nurses taking up dual or part time roles.
- Nurses will undertake appropriate continuing professional development in heart rhythm management and resources made available for them to do so.
- Where nurses are running outpatient clinics independently they will have the opportunity to meet with a consultant with a special interest in heart rhythm management at least once a fortnight to discuss cases and protocols.
- Audit will be carried out on a regular basis.

Catheter ablation follow-up standards

All patients who undergo catheter ablation will be followed up at least once in a clinic supervised by the operator to allow audit of the outcomes of the ablation performed.

Some centres may choose to do this using remote follow up but time must be set aside to talk to patients (even by phone), examine their follow up data (Electrocardiogram (ECG)/Holter arranged locally) and log the outcome in a database.

For ablation of atrial fibrillation where symptoms may not be an accurate marker of success, extended Holter monitoring or transtelephonic monitoring should be available for use in those patients where asymptomatic AF may be important (e.g. asymptomatic AF associated with heart failure). Outcomes and complications should be recorded and reported to NICOR.

2.3 Population covered

The service outlined in this specification is for patients ordinarily resident in England*; or otherwise the commissioning responsibility of the NHS in England (as defined in Who pays?: Establishing the responsible commissioner and other Department of Health guidance relating to patients entitled to NHS care or exempt from charges).

13

Note: for the purposes of commissioning health services, this EXCLUDES patients who, whilst resident in England, are registered with a GP Practice in Wales, but INCLUDES patients resident in Wales who are registered with a GP Practice in England

As described above, patients with heart rhythm problems represent a varied group. Ablation is an option in any individual with symptoms related to heart racing. Ablation is a technique that greatly improves quality of life and is indicated for symptomatic heart racing, no matter how infrequent. Ablation is also used even when symptoms are improved by medication if the patient has a desire to avoid long-term medication, or struggles with side-effects.

Within the UK individuals undergoing ablation treatment range in age from about_10 years to 90 years of age. Many patients undergoing ablation are otherwise fit and healthy, but increasingly patients with significant underlying cardiac_conditions are also having ablation.

It is, therefore, not possible to define one population who are covered by ablation services.

2.4 Any acceptance and exclusion criteria

Catheter ablation is primarily a therapy for symptoms/quality of life although it may improve prognosis in selected cases (e.g. ablation of accessory pathways in patients with pre-excited AF and in patients with malignant ventricular arrhythmia resistant to anti-arrhythmic therapy). The indications for catheter ablation are described in numerous international guidelines and the National Service Framework for Coronary Heart Disease chapter 8. Catheter ablation in some forms has also been examined and approved by NICE.

Referral acceptance criteria

The service will accept inward referrals from secondary care clinicians.

Referral criteria

Catheter ablation of AF is part of tiered therapy and is considered after initial rhythm control strategies with drugs have failed. Selection of patients for catheter ablation of persistent AF should be done with care. The principal indication for the procedure is for symptomatic benefit and the operator should feel that there is a reasonable (>60%) chance of long-term restoration of sinus rhythm, within a limited number of procedures. The procedure is also indicated in other patient groups.

Specifically, this includes patients who the cardiologist considers to have a high likelihood of an improved prognosis by the restoration and maintenance of sinus rhythm, and patients for whom effective rhythm control by antiarrhythmic medication has resulted in improved quality of life or recovery of left ventricular

function.

First line therapy for all regular SVT that are either causing symptoms or which have the potential to produce tachycardia cardiomyopathy.

Second line therapy for symptomatic atrial fibrillation (AF).

Second line therapy for VT or ventricular ectopy that is either causing symptoms or has potential to produce tachycardia cardiomyopathy.

Second line therapy for asymptomatic atrial fibrillation that has the potential to produce or be associated with tachycardia cardiomyopathy – ablation therapy for this indication may be directed purely at ventricular rate control (AV node ablation and permanent pacemaker insertion) or at rhythm control ablation.

Heart Rhythm UK in liaison with commissioners has developed guidelines on patient selection for ablation for a specific group of patients with AF and decisions on other conditions are based on international guidelines. http://heartrhythmuk.org.uk/position-statements

2.5 Interdependencies with other services

EP ablation services are mainly located in major Cardiology centres. EP and ablation procedures are performed in a cardiac catheter laboratory which allows invasive monitoring of the patient and X-ray (fluoroscopic) imaging to allow catheter manipulation and placement. In addition specialist equipment is needed. The electrical signals from inside the heart are recorded on a specialised EP system. All major centres also have 'advanced navigation' systems. This allows a map of the heart to be built using the electrical signals from inside the heart and allows the doctor to see the catheters without the use of X-ray. These mapping systems greatly improve the ability to diagnose and treat more complicated heart racing problems with a higher degree of success.

Co-located services

Complex ablation services invariably also provide complex device therapies. Heart Rhythm UK recommends that in general complex ablation services are colocalised with cardiac surgery services

Access to invasive and interventional cardiology services is mandatory for centres undertaking VT ablations

Interdependent services

Close links with secondary care in local hospitals is important to encourage appropriate referrals.

Related services

Increasingly links with primary care are resulting in referrals of patients with symptomatic AF for ablation

3. Applicable Service Standards

3.1 Applicable national standards e.g. NICE, Royal College

CORE STANDARDS

It is possible to perform standard ablation in a centre with one specialist competent to perform catheter ablation however it is important that formal arrangements must be in place to cover out of hours emergencies by accredited heart rhythm specialists.

Cardiologists performing complex ablation will do so in a centre where at least one other specialist accredited to perform complex ablation is practicing.

Each cardiologist performing standard catheter ablation will perform \geq 50 catheter ablations / year as first operator.

There will be at least 2 cardiac physiologists actively involved in catheter ablation in each centre.

Each physiologist will be actively involved in \geq 30 catheter ablations / year.

Arrangements will be made that at least 2 nurses are denoted as specialist arrhythmia nurses/centre.

RECOMMENDED STANDARDS

Operators performing fewer than 100 catheter ablations/ year will need to average their outcome figures over 2 or more years to account for random variation.

NICE has issued guidelines and a number of IPGs related to AF and cardiac ablation that may assist clinicians:

- NICE Clinical Guidelines: CG36 Atrial fibrillation. (2006) <u>http://guidance.nice.org.uk/CG36/Guidance/pdf/English</u>
- Chapter 8 of the National service Framework for Heart disease Arrhythmias. <u>http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Healthcare/Longtermconditions/Vascular/Coronaryheartdisease/Nationalserviceframework/index.</u> <u>htm</u>
- The European Society of Cardiology (ESC) has a number of guidelines ESC guidelines for the management of atrial fibrillation (2010) <u>http://www.escardio.org/guidelines-surveys/</u>

Heart Rhythm UK Competency Standards for EP and ablation – September 2010.

http://heartrhythmuk.org.uk/guidelines

- EHRA/HRS Expert Consensus on Catheter ablation of Ventricular Arrhythmias (2009). <u>http://europace.oxfordjournals.org/content/11/6/771.full.pdf</u>
- Heart Rhythm UK position Statement Catheter ablation for Persistent AF (2010) <u>http://heartrhythmuk.org.uk/files/file/Docs/Position%20Statements/HRUK%</u>

20Position%20Statement%20Catheter%20ablation%20for%20Persistent% 20AF-%20Nov%202010final.pdf

- NICE Interventional Procedure Guidelines (IPGs): there are several that apply to the treatment of AF.
- IPG 123 Cryoablation for atrial fibrillation in association with other cardiac surgery.
- IPG 184 High intensity focused ultrasound ablation of atrial tissue for atrial fibrillation as an associated procedure with other cardiac surgery
- IPG 122 Microwave ablation for atrial fibrillation in association with other cardiac surgery.
- IPG 294 Percutaneous (non-thoracoscopic) epicardial catheter radiofrequency ablation for atrial fibrillation.
- IPG 295 Percutaneous (non-thoracoscopic) epicardial catheter radiofrequency ablation for ventricular tachycardia.
- IPG399 Percutaneous endoscopic catheter laser balloon pulmonary vein isolation for atrial fibrillation.
- IPG 349 Percutaneous occlusion of the left atrial appendage in non-valvular atrial fibrillation for the prevention of thromboembolism.
- IPG 168 Percutaneous radiofrequency catheter ablation for atrial fibrillation.
- IPG 121 Radiofrequency ablation for atrial fibrillation in association with other cardiac surgery.
- IPG 286 Thoracoscopic epicardial radiofrequency ablation for atrial fibrillation.
- The Society of Thoracic Surgeons (SCS) Statement on atrial fibrillation (2007).

UK national data is collected by NICOR. At present data submission is highly encouraged but not mandatory for EP ablation procedures. Good information on numbers of procedures and acute success rates can be gained from this database. Currently the database is being redesigned to include more long-term data and information on patient reported outcomes (PROMS). The main aim of EP ablation is to improve quality of life.

In the future we would encourage a mandate that all catheter ablation centres submit accurate data to NICOR for the purposes of national audit. It is however also required that formal audit of various aspects of catheter ablation are performed, presented and discussed in multidisciplinary team meetings locally at least once every six months. This allows trainees who are attached to a centre for one year to complete an audit cycle and see the effects of this audit cycle.

4. Key Service Outcomes

Ablation services are focused on treating symptomatic heart racing. The key outcome is effective relief of symptoms. For a minority of patients ablation is used for life-threatening heart racing. The key measures are therefore that procedures are safe and that patients feel better afterwards.

All ablation centres contribute data to NICOR and there has been rigorous assessment of acute ablation success rates and complications over the past 10 years. However, there is little formal assessment of quality of life indices related to outcomes. There is ongoing work in collaboration with NICE on developing patient reported outcome measures (PROMS) following ablation. In addition some centres are using disease specific and generic quality of life tools in patient assessment before and after AF ablation.

The NICOR database for Cardiac Rhythm Management (CRM) is currently being redeveloped to enable the collection of ablation-specific quality of life outcome measures. This process will be completed by April 2013. Detailed gathering of quality of life measures, however, is labour intensive and we recommend that when services are commissioned that appropriate consideration is given to this issue.