STANDARDS FOR INTERVENTIONAL ELECTROPHYSIOLOGY STUDY AND CATHETER ABLATION IN ADULTS

Joseph de Bono on Behalf of BHRS Council, April 2020

1. INTRODUCTION

This document replaces the previous British Heart Rhythm Society (BHRS) document "Standards for interventional electrophysiology study and catheter ablation in adults" issued in 2016. It has been compiled by a group of interventional cardiac electrophysiologists, cardiac physiologists and specialist arrhythmia nurses drawn from both secondary and tertiary centers and approved by the Council of the BHRS in April 2020. This document will be reviewed by BHRS Council no later than April 2022.

The purpose of the document is to facilitate the provision of high quality, evidence-based electrophysiology (EP) assessment and intervention to all patients who may benefit. This includes the identification of patients with indications for intervention, a broad description of the range of procedures available and the means by which to provide them, patient and procedure follow up, data collection, storage and submission.

It includes the best available evidence and expert opinion on current practice. The source material for this evidence is listed in the reference section.

It is recognised that competency can only be defined effectively in terms of patient outcome. Numbers given in this document are indicative and should not be taken in isolation as evidence of competency or the ability to provide a safe, high quality service. This document is not intended to disrupt or disenfranchise existing, successful electrophysiology services. It should be regarded as a template for developing best practice when starting *de novo* and a recommendation to enable successful but inadequately resourced services to develop.

This document is not intended to replace Trust policies and other legislation e.g. data protection and codes of conduct that should be adhered to in addition to the recommendations of this document.

In summary, this document aims to:

- Deliver the highest possible standard of care for patients with arrhythmias

- Encourage strong links and active collaboration between primary care, secondary care EP units and tertiary centre EP units

- Ensure that procedures are performed by appropriately skilled operators in a suitably staffed and equipped environment achieving nationally acceptable success rates with minimal complication rates

- Ensure that patients have 24/7 access to specialist arrhythmia care and advice at regional level

2. DEFINITIONS

The following definitions are used within this document. For the purposes of this document, as some Trusts cover multiple sites, an electrophysiology centre is taken to mean a single hospital site where invasive electrophysiology procedures are performed rather than the Trust as a whole. It is accepted that operators may work at more than one centre but each centre should conform to the standards within this document. Furthermore, as more non-cardiac surgical centre's develop in-house interventional electrophysiology capabilities, it is appropriate to describe the scope of practice as *standard* catheter ablation and *complex* catheter ablation.

In addition many centers are developing specific expertise in the use of Single shot techniques for ablation of atrial fibrillation (Currently largely cryoballoon ablation but also LASER ablation. More technologies will become available in the future). These ablation techniques require a different skill set from either standard or complex ablation and are classified separately. BHRS recognizes the difficulty in defining absolute requirements for this artificial distinction between intervention types and acknowledges that locally available systems of care and expertise will contribute critically to the scope of locally available electrophysiology practice.

Standard EP study / catheter ablation:

- Invasive electrophysiology study
- Ablation of the atrioventricular node
- Ablation of atrioventricular nodal reentrant tachycardia
- Ablation of accessory pathways
- Ablation of cavo-tricuspid isthmus dependent atrial flutter

Single shot ablation for atrial fibrillation

Complex catheter ablation:

- Ablation of atrial fibrillation (AF) using a 3-dimensional mapping technique

- Ablation of non-cavotricuspid isthmus-dependent atrial tachycardia
- Ablation of ventricular tachycardia (VT) including idiopathic focal ventricular tachycardia
- Ablation of atrial or ventricular arrhythmias via the pericardial route
- Modification of the sinus node
- Ablation in patients with complex congenital heart disease (see BHRS document "Cardiac Rhythm management in patients with congenital heart disease").

***Operator*:**
The first operator is the clinician who is the main individual performing the case, especially at the time of the ablation. The first operator will normally be scrubbed or control the delivery of ablation energy, with the exception of some cases where the majority of the procedure is conducted robotically. A second operator is another clinician present throughout and normally also scrubbed. Either first or second operator can be an accredited electrophysiologist or a trainee. In cases when two operators have performed an equal part in the case, they can each be 'joint' first operators. This would apply particularly to complex cases (e.g. VT ablation) that may otherwise require an individual operator to be scrubbed for several hours. The responsible consultant should be an accredited electrophysiologist supervising the case, who can also be one of the actual operators. For the purpose of recording procedure numbers, a clinician can "count" procedures conducted in any of these three roles, though those where he/she was not physically operating should be enumerated separately.

***Training centres*:**
At present, there is no mechanism for designation of Training Centres in the UK although it is likely that a process of departmental accreditation in Training and Practice will be developed in the future. However, the Joint Royal College of Physicians Training Board (JRCPTB) Speciality Training Curriculum for Cardiologists (August 2010)[1] specifies that centres offering advanced rhythm training should have at least 2 electrophysiologists who spend the majority of their time practicing electrophysiology. Centres should perform ≥100 EP studies and catheter ablations per year and have availability of complex mapping and ablation technologies.

3. TREATMENT INDICATIONS

Catheter ablation is primarily a therapy that improves quality of life although in certain situations may improve prognosis. The various indications for catheter ablation are clearly described in numerous international guidelines and consensus statements[2-4] and the National Service Framework for Coronary Heart Disease chapter 8 with some aspects of catheter ablation already examined and approved by NICE[5-7]. It is not the purpose of this document to reinterpret peer reviewed, published guidance. It is recognised, however, that such guidance may not cover all patient groups and may not be appropriate in certain situations. Furthermore, clinical judgement based on published evidence should be used for indications not yet considered by NICE. It is

important to demonstrate compliance with best practice and regular audit of procedure indications and outcomes is strongly recommended. It is essential that all interventional EP centres ensure accurate and timely procedure data submission to the national CRM database.

For complex ablation, the development of a multidisciplinary approach to patient selection, management and follow up is recommended. Involvement of physicians (interventional electrophysiologists, imaging and heart failure specialists), physiologists, and specialist arrhythmia nurses to aid in assessment of suitability for ablation and follow up may lead to improved patient outcomes. BHRS recommends that the appropriate international guidelines be used to inform practice and that the reasons for practice outside well established and accepted guidelines and consensus statements be clearly justified.

4. REQUIREMENTS FOR PERFORMING CATHETER ABLATION

Safe invasive electrophysiology assessment and treatment requires the appropriate environment, equipment, trained personnel and culture[8]. BHRS recommends that all centres and cardiologists performing EP studies should also have competency to proceed safely to catheter ablation if necessary including access to the left atrium and great vessels if required. All electrophysiology studies and ablations should be performed in units that meet or exceed the quality standards, with a minimum of two active consultant cardiac electrophysiologists per centre, one of whom should ideally hold BHRS, EHRA or IBHRE certification. Formal arrangements for handover, in-hours and out-of-hours expert cover and on-going care should be in place.

Cardiac arrhythmias are a major source of morbidity and mortality for patients with Adult Congenital Heart Disease (ACHD). BHRS has produced a separate standards document for cardiac rhythm management in these patients[9]. These procedures should not be performed in non-specialist centres or by individuals without the appropriate expertise in adult congenital heart disease and electrophysiology.

4.1 CARDIOLOGISTS – training requirements

This section refers to cardiologists performing standard and complex catheter ablation procedures.

a. Trainees should have achieved a CCT in cardiology and completed a recognised EP training program in a Deanery-designated training centre or equivalent. The programme should include at least 2 years of subspecialty training in heart rhythm management with dedicated time within that programme specialising in electrophysiology and ablation

b. Trainees should have completed a log book of procedures

c. Trainees should have been actively involved with at least 200 standard

ablation procedures and performed 50 as first operator

d. Trainees should have completed training in transseptal puncture and performed >20 transseptal punctures as first operator.

e. Trainees may also elect to train in more complex ablation techniques, the requirements for which may be more exacting than for standard ablation. To achieve the minimum standard for training, trainees should have performed:

   - For complex atrial arrhythmias, to have been actively involved with at least 100 complex atrial ablation (primarily AF and left atrial tachycardia) with 50 as first operator

   - For ventricular arrhythmias in structural heart disease or involving 3D electroanatomic mapping – been actively involved with 20 ablations with 10 as first operator

   - For complex congenital heart disease – been actively involved with 20 ablations with 10 as first operator

   - For epicardial ablation, been actively involved with 10 "dry" pericardial punctures and to have performed 5 "dry" punctures as the first operator

f. Trainees should not be permitted to perform procedures unsupervised until they have received a certificate of completion of specialist training. BHRS recognises that the level of supervision will appropriately vary according to the expertise of the individual trainee

g. Trainers should spend at least 70% of their working time involved in heart rhythm management. Trainers should have at least 1 hour a week dedicated to supervision of each of their trainees in addition to their clinical workload

h. Trainers should be actively involved in heart rhythm audit and research

i. Trainers should achieve the standards required for maintenance of competence

j. Trainers should be aware of the recommendations by the professional bodies pertaining to the specialty, have annual appraisal and maintain a CPD diary

4.2 CARDIOLOGISTS – maintenance of competence

a. There should be a minimum of 2 active interventional cardiac electrophysiologists per centre (one of whom should ideally be BHRS, EHRA or IBHRE certified), with formal support from larger centres

encouraged for centres establishing de novo invasive EP services. Although it is possible to perform catheter ablation in a centre with one competent specialist, this is not a sustainable model of care for the development of a high quality, comprehensive heart rhythm service

b. Complex ablation should not be performed in single operator centres

c. All interventional electrophysiologists should perform at least 50 catheter ablation procedures per year as an "operator" (as defined above). For those undertaking complex ablation, a minimum of 25 procedures should be complex, however, 50 is desirable. Those undertaking less than 25 AF ablations per year have a demonstrably higher complication rate[10]. Similarly an operator performing standard ablation should perform at least 25 standard ablations a year, whilst operators performing single shot atrial fibrillation ablation should be performing a minimum of 25 ablation using that technique each year. The association between complications and case volume is acknowledged by BHRS and is the justification behind these minimum basic requirements[9]. BHRS recognises the changing case mix encountered during both training and consultant practice and encourages all electrophysiologists to maintain their skills and knowledge in both standard and complex cases.

d. If a cardiologist does not perform this number of procedures per year then competence should be independently assessed in accordance with current specialty training guidelines* (a structured report should be obtained from the trainer/assessor on competency for "sign off." This report should include the number of cases performed and the level of competency as assessed by the trainer/assessor. Assessment should consist of successful completion of 6 DOPS in catheter ablation at level 3 by at least 2 assessors)

e. All cardiologists performing catheter ablation must undertake appropriate CPD in electrophysiology including implications for driving.

f. All electrophysiologists must audit their personal complications and share these within their centre at least quarterly and through the national CRM database for clinical governance purposes. If an operator's complications were to exceed accepted limits, practice should be reviewed locally by the appropriate clinical governance structures already in place and if necessary, advice sought from elsewhere within the UK. For consultants engaged in a supervising role, complications occurring during a procedure will be ascribed to the consultant responsible for the patient for the purposes of data returns.

* Operators performing fewer than 50 procedures per year may need to average their figures over 2 years to account for random variation, however, the necessity to do this should be seen as an exception

4.3 CARDIAC PHYSIOLOGISTS / HEALTH CARE SCIENTISTS (HCSs)

a. There should be at least 2 cardiac physiologists / HCSs actively involved in interventional electrophysiology where these procedures are performed

b. Each physiologist / HCS must have had appropriate training in the execution of electrophysiology studies and catheter ablation

c. At least 1 physiologist / HCS should have current accreditation in catheter ablation and electrophysiology (BHRS, EHRA or IBHRE)

d. All physiologists / HCSs must undertake appropriate continuing professional development in catheter ablation and resources made available for them to do so

e. Each physiologist / HCS should be actively involved in at least 30 electrophysiology procedures per year. If a physiologist / HCS does not perform this number of procedures in a 12 month period then competence should be independently reassessed in line with local governance procedures.

4.4 SPECIALIST ARRHYTHMIA NURSES

a. Hospitals delivering specialist cardiac arrhythmia care are expected to develop the role of Cardiac Arrhythmia Nurse Specialist/Arrhythmia Advanced Nurse Practitioners as an appropriate (and sustainable) level as recommended in the NSF Chapter 85. Ideally, at least 2 nurses per centre should be denoted as Specialist Arrhythmia Nurses or Arrhythmia Advanced Nurse Practitioners to allow continuity of care during periods of absence and can be achieved if necessary by nurses taking up dual or part time roles

b. Cardiac arrhythmia nurses should receive training appropriate to their involvement in the CRM team and should work according to protocols developed within their centre and nationally

c. Nurses should undertake appropriate CPD in heart rhythm management and resources made available for them to do so. Nurses should be encouraged and supported to undertake BHRS certification

d. Where nurses are running outpatient clinics independently, they should have same day direct telephone access to a consultant and the opportunity to meet with the supervising consultant at least fortnightly to discuss clinical cases.

4.5 CENTRES

In order to comply with the requirements for individual operators, centres

performing catheter ablation procedures should undertake a minimum of 100 ablations per year. Centres undertaking catheter ablation for AF should also perform a minimum of 50 AF ablations per year. Whilst the evidence for outcomes associated with centre volume is largely derived from studies of atrial fibrillation, it is likely that similar factors apply to other ablations. Thus centres undertaking complex ablation should perform at least 50 complex ablations per year (which may include ablation of atrial fibrillation using 3d Mapping), whilst centres performing standard ablation should perform at least 50 standard ablations per year. This should be regarded as a minimum and for centres offering advanced training in cardiac rhythm management, it would be expected that they would undertake significantly more procedures.

Basic requirements – standard ablation:

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

a. Wards with bedside cardiac monitoring equipment including effective rhythm alarm systems and capable of storing 24 hours of continuous ECG data

b. Nursing staff experienced in care and management of patients with cardiac arrhythmias

c. Facilities for cardiopulmonary resuscitation, temporary and permanent pacing. Staff should hold recognized qualifications in resuscitation (ALS for operators and lead staff responsible for sedation, ILS for other members of the clinical team)

d. A catheter laboratory equipped with modern X-ray equipment and the appropriate patient and operator radiation monitoring systems in place

e. Facilities for anaesthesia and ventilation within the laboratory in the event that they are needed

f. A modern digital electrophysiology recording and storage system and haemodynamic monitoring; a programmable stimulator; a radiofrequency generator specifically for EP procedures

g. Equipment for pericardiocentesis

h. Echocardiography

Additional requirements – complex ablation:

For centres undertaking complex ablation procedures, BHRS advises that there should be on site access to emergency cardiothoracic surgery or arrangements in place for immediate transfer. While acknowledging that this will be rarely employed, as the scope increases of complex left atrial,

ventricular and epicardial procedures, it is crucial that optimum patient safety measures are in place to manage rare but severe complications. 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. Centres undertaking complex ablation should have ready access to the following in addition to those described above:

a. Electroanatomic mapping hardware

b. Haemodynamic assist devices (intra-aortic balloon pump, mechanical assist devices) for VT ablation in structural heart disease

c. Intensive Therapy Unit availability for planned high-risk cases

Additional requirements – single shot atrial fibrillation ablation:

For centres undertaking single shot atrial fibrillation ablation procedures, BHRS advises that there should be on site access to emergency cardiothoracic surgery or arrangements in place for immediate transfer. While acknowledging that this will be rarely employed, as it is crucial that optimum patient safety measures are in place to manage rare but severe complications. 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. Centres undertaking single shot atrial fibrillation ablation should have ready access to the following:

a. Equipment for single shot atrial fibrillation ablation

b. Wards with access to bedside cardiac monitoring equipment including effective rhythm alarm systems and capable of storing 24 hours of continuous ECG data where necessary

c. Nursing staff experienced in care and management of patients with cardiac arrhythmias

d. Facilities for cardiopulmonary resuscitation, temporary and permanent pacing

e. A catheter laboratory equipped with modern X-ray equipment and the appropriate patient and operator radiation monitoring systems in place

f. Facilities for anaesthesia and ventilation within the laboratory in the event that they are needed

g. Equipment for pericardiocentesis

h. Echocardiography

5. POST PROCEDURE FOLLOW UP STANDARDS

Standard ablation

All patients who undergo catheter ablation should be followed up at least once in a clinic with direct links and feedback to the operator to allow audit of the outcomes of the ablation performed. Some centres may choose to do this using remote follow up either through local clinics with remote supervision from the referring center or by telephone of video clinics, but time must be set aside to talk to patients, examine their follow up data (ECG/Holter arranged locally) and log the outcome in a database. Follow up must also be consistent with national database requirements.

Complex ablation and single shot atrial fibrillation ablation

BHRS endorses the 2017 HRS/EHRA/ECAS expert consensus statement on catheter and surgical ablation of atrial fibrillation[4].

Some points deserve special mention:

a. ECG confirmation of the diagnosis of AF is mandatory prior to recommending catheter ablation as a treatment

b. Cardiac imaging to assess cardiac structure and function is recommended prior to catheter ablation

c. Anticoagulation is recommended following catheter ablation, tailored to the stroke risk of the patient rather than to the anticipated effect of ablation on the frequency of atrial fibrillation. The CHA2DS2VASc scoring system should be used in preference to the CHADS2 score

d. Following successful catheter ablation, patients should be followed up for at least 1 year in the outpatient setting

e. Patient related outcome measures (PROMS) should be collected following catheter ablation of AF

f. Patients who have undergone ablation should be provided with a contact number at the ablating centre and advised to report symptoms occurring within the first six weeks following ablation. Atrial oesophageal fistula is likely under-reported and fatal if not recognised and treated early[11,12]. Diagnostic delay following post-procedure presentation to a non-ablation centre can be reduced by early communication with the ablation centre. Protocols should be in place for the diagnosis and management of this rare but catastrophic complication. It is recommended that specific information relating to atrio-oesophageal fistula (such as that offered by Arrhythmia Alliance) is provided to patients following catheter ablation of AF.

6. AUDIT

Complications associated with catheter ablation typically occur at the time of the procedure or shortly thereafter i.e. within six weeks. There are also occasional advice and safety notices from manufacturers and the MHRA which necessitate timely action.

a. All ablation centres must collect data on their patients, procedures and follow-up which is immediately available and facilitates audit. It is mandatory that all hospitals performing catheter ablation submit accurate and timely procedural data to the national CRM database. This is a national quality requirement and is audited by the Care Quality Commission

b. In addition, the audit data should be presented and discussed in a multidisciplinary team meeting at least quarterly. Attendance should be mandatory for trainers and trainees alike.

REFERENCES

1. Speciality Training Curriculum for Cardiology. Joint Royal College of Physicians Training Board August 2010

2. Josep Brugada, Demosthenes G Katritsis, Elena Arbelo, Fernando Arribas, Jeroen J Bax et al. 2019 ESC Guidelines for the management of patients with supraventricular tachycardia. The Task Force for the management of patients with supraventricular tachycardia of the European Society of Cardiology (ESC): Developed in collaboration with the Association for European Paediatric and Congenital Cardiology (AEPC). *European Heart Journal*, ehz467

3. Edmond M. Cronin, Frank M. Bogun, Philippe Maury, Petr Peichl, Minglong Chen et al. 2019 HRS/EHRA/APHRS/LAHRS expert consensus statement on catheter ablation of ventricular arrhythmias. Heart Rhythm 2019

4. 2017 HRS/EHRA/ECAS/APHRS/SOLAECE expert consensus statement on catheter and surgical ablation of atrial fibrillation. Hugh Calkins, Gerhard Hindricks, Riccardo Cappato, Young-Hoon Kim, Eduardo B. Saad et al.

5. Department of health coronary heart disease team: National service framework for coronary heart disease - chapter eight: Arrhythmias and sudden cardiac death. 2005

6. NICE. Interventional procedure guidance 168: Percutaneous radiofrequency ablation for atrial fibrillation. 2006:9

7. NICE. Interventional procedure guidance 427: Percutaneous balloon cryoablation for pulmonary vein isolation in atrial fibrillation. 2012:7

8. Campbell RWF, Charles R, Cowan JC, et al. Clinical competence in electrophysiological techniques. *Heart*. 1997;78:403-412

9. Lowe M et al. Cardiac Rhythm Management in Patients with Congenital Heart Disease Standards of Care for patients undergoing catheter ablation and device implantation. British Heart Rhythm Society, 2016

10. Cheng EP, Liu CF, Yeo I, et al. Risk of Mortality Following Catheter Ablation of Atrial Fibrillation. J Am Coll Cardiol 2019;74:2254–64

11. Deshmukh A, Patel NJ, Pant S, et al. In-hospital complications associated with catheter ablation of atrial fibrillation in the united states between 2000 and 2010: Analysis of 93,801 procedures. *Circulation*. 2013;128:2104-2112

12. Cappato R, Calkins H, Chen SA, et al. Updated worldwide survey on the methods, efficacy, and safety of catheter ablation for human atrial fibrillation. *Circ Arrhythm Electrophysiol*. 2010;3:32-38