

CLINICAL STANDARDS AND GUIDELINES FOR THE FOLLOW UP OF CARDIAC
IMPLANTABLE ELECTRONIC DEVICES (CIEDs) FOR CARDIAC RHYTHM
MANAGEMENT

June 2022

INTRODUCTION

This document replaces the previous British Heart Rhythm Society (BHRS) document “Clinical Guidance for the Follow Up of Cardiac Implantable Electronic Devices (CIEDs) for Cardiac Rhythm Management” published in 2020.

It has been co-produced by a group of cardiac clinical scientists/cardiac physiologists, specialist arrhythmia nurses, cardiac electrophysiologists and cardiologists with a specialist interest in CIED therapy, with experience across tertiary, district general hospital and clinical academic settings. The document had been approved by the BHRS council in May 2022 and will be reviewed by the BHRS council on a biannual basis. A list of contributors can be found at the end of the document.

The purpose of the document is to facilitate the safe delivery of high quality, evidence based CIED follow-up to all patients and services which may benefit. It has been developed to support services, teams and individuals involved in CIED follow up. It includes the best available evidence and expert opinion on current practice with the source material for this evidence listed in the reference section.

This document is not intended to disrupt or disenfranchise existing, successful CIED follow up services. It should be regarded as a template for developing best practice. 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.

It must also be recognised that increasingly new device technology is introduced which may be introduced between guideline review dates.

DEFINITIONS

The following definitions are used within this document. For the purposes of this document, as some Trusts cover multiple sites, a CIED follow up services is taken to mean a single hospital site where CIED follow ups are performed rather than the Trust as a whole.

Cardiac Implantable Electronic Device (CIED)

CIEDs encompass a range of devices including single and dual chamber bradycardia devices, implantable loop recorders, atrial tachycardia devices, implantable cardioverter defibrillators (ICDs), cardiac resynchronisation (CRT) devices and newer technologies including leadless pacemakers, subcutaneous ICDs and devices capable of physiological pacing.

In Person Evaluation (IPE)

It is defined as a face-to-face device follow up.

Remote Monitoring (RM)

Is defined as the automated transmission of data based on pre-specified alerts related to device functionality and clinical events which provides the ability for rapid detection of abnormal device function and/or arrhythmia events¹.

Remote Interrogation (RI)

Is defined as routine, scheduled, remote device interrogation planned to mirror an in-office check, planned to save an in person evaluation^{1,2}.

CRM Cardiac Clinical Scientist

A person registered as a clinical scientist with the health care professions council (HCPC) specialising in cardiac sciences trained in cardiac rhythm management (CRM). Some clinical scientists may be involved in advanced practice with specialist roles defined by local policies and service need. Typical routes include cardiac sciences scientist training program (STP) graduates and cardiac physiologists who have achieved STP equivalence.

Highly Specialised Cardiac Physiologist

A person qualified as a cardiac physiologist/cardiac healthcare science practitioner with the appropriate academic qualifications and experience (BSc Clinical Physiology, BSc Healthcare Science (cardiac physiology) or MSc Clinical Science (Cardiac Science) or equivalent) with the knowledge and skills equivalent to Agenda for Change band 7, eligible to register or registered with the RCCP/AHCS clinical physiology register or with healthcare science practitioner registration.

Cardiac Physiologist

A person qualified as a cardiac physiologist/cardiac healthcare science practitioner with the appropriate academic qualifications and experience (BSc Clinical Physiology, BSc Healthcare Science (cardiac physiology) or equivalent) with the knowledge and skills equivalent to Agenda for Change

band 5/6, eligible to register or registered with the RCCP/AHCS clinical physiology register or with healthcare science practitioner registration.

What is new?

- Recommendation that all patients are offered remote follow up
- Alert based follow up may be used
- Annual in person follow up is not required
- Consent for remote data transmission is recommended
- Clarification of remote device follow up competencies should be the same as in person competencies.
- BCS & BHRS MDT recommendations incorporated
- Box change patients should be carefully evaluated.

CIED FOLLOW UP

Cardiac implantable electronic devices (CIEDs) have evolved significantly over the last decade with a wide range of devices available and indicated to treat patients with symptomatic bradycardia, patients at risk of sudden arrhythmic death, and those with worsening heart failure (HF).

The challenge in treating patients with CIEDs lies not only in the implantation of the device, but more so with the device follow up which is a fundamental step in the management of patients with CIEDs³ and is a lifelong commitment and requirement for patient care.

CIED follow up is complex. Advancements in technology have seen the development of multiple programmable features and algorithms and growth in a vast array of stored diagnostic information which combined with an aging population with multiple co-morbidities contribute to this complexity.

CIED follow up involves regular technical review of device function including battery and lead integrity. In addition, it involves monitoring of patient symptoms, disease states and management of new and progressively changing conditions. These include but are not limited to management of atrial fibrillation (AF), ventricular arrhythmias and HF.

Traditionally device follow up has been performed as an in-person evaluation (IPE) 'face to face'. Depending on the device type and previous IPE results, follow up frequency may range between 3 months and 2 years.

Remote follow up

Remote monitoring (RM) technology has become increasingly intuitive and easy for patients to set up and use, and a large body of research has demonstrated a clear advantage of continuous RM compared to intermittent in-person evaluation. However, despite RM being a Class 1 recommendation in international expert consensus statements (Slotwiner, et al., 2015), the uptake has been modest, limited by the structuring of financial incentives, the need for significant changes in workflow and training, and lack of specific targets and guidance.

In other aspects of their lives, people see the benefits of digital technology, but for many CIED patients the experience of follow-up remained unchanged until the Covid-19 Pandemic intervened. The Pandemic has greatly accelerated the utilisation of RM but also exposed inequalities in its implementation (Nouri, et al., 2020). During the pandemic, cardiac physiologists have adopted innovative ways of continuing to make best use of their skills and experience to benefit our patients, but these changes need to become embedded to support recovery and longer-term challenges: to build on what we have learned during the pandemic to transform the delivery of CIED services.

STRUCTURING AND FREQUENCY OF FOLLOW-UP

Current CIED follow-up strategies include a mixture of calendar-based and unscheduled in-person evaluations, remote follow-up and remote monitoring with periodic downloads and automatically triggered alert transmissions. Structuring of the traditional follow-up of CIED patients at 3, 6 or 12-month intervals is a legacy from >2 decades ago - when regular manual threshold tests, battery tests and capacitor reforms were needed, and remote monitoring technology was in its infancy. These tests are now largely obsolete or can be automated effectively – most modern implantable pulse generators are equipped with algorithms that provide reliable pacing threshold management.

Periodic calendar- based follow-up has significant limitations - problems are unlikely to be tied to the scheduled time points, and periodic evaluation results in a low frequency of actionable events with only rare capture of device malfunction [10]) among a large volume of evaluations conducted. Clinically silent problems present a challenge: asymptomatic time-critical issues must wait until the next scheduled clinic visit or scheduled download for evaluation but may pose an immediate risk to the patient. Despite the advent of remote monitoring using automatic alerts, calendar-based follow-up persists in practice and has influenced the structuring of remote download transmissions (7). Calendar-based interrogation is vulnerable to compliance failure (13,14) and is time intensive to troubleshoot (15), defeating the intent of remote care. Replacing calendar-based IPEs by simple remote interrogations at identical intervals merely replicates the limitations of the existing model of care. Remote follow-up without continuous monitoring of alerts has limited early detection capability (17). Persevering with this structure generates enormous clinic workloads but may not be the most effective strategy for achieving core follow-up objectives with limited resources.

Recent European guidelines have recognised that annual in-person evaluation is not necessary for all CIED patients.

ALERT BASED FOLLOW UP

Remote monitoring was introduced as complementary to quarterly remote interrogations. Alert-based monitoring enables truly early (<48 h) detection of actionable events, overcoming limitations of periodic interrogations (either in-person or remote) (8,18). Remote monitoring without periodic follow-ups is effective in its own right – a recent study demonstrated that an alert-driven follow-up model, asynchronous to any calendar-based schedule, was effective and efficient (19). However, rather than reduce clinic workload, remote

monitoring as it is currently structured generates considerable “invisible” clinic work because it has not replaced the model of periodic evaluation. Despite its clear advantages, adding alert-based remote monitoring to the existing model of regular scheduled downloads for already saturated clinics, has resulted in a disappointing rate of adoption and adherence of this model of care (11).

EQUALITY AND DIVERSITY

The patient-device-manufacturer-hospital interaction involved in maintaining on-going RM is complex, and patient compliance can be challenging. The pandemic has shone a brighter light on health inequalities (ref) including the provision of remote monitoring. Cardiac departments should ensure that they reduce unwarranted variation in access to remote monitoring and that they address inequalities in access, experience and outcomes.

They should develop processes that maintain effective communication with a diverse range of patients, including proactively reaching out to individuals who are clinically and socially vulnerable, including those with learning disabilities and dementia. We ask that the care home sector allows remote monitoring for care home patients (more efficient, reduces spread of infection).

RECOMMENDATIONS

1. All appropriate patients should have remote monitoring
2. Alert-based remote follow up should be considered as standard care for CIED patients who consent to it, including those with pacemakers
3. Cardiac departments should reduce unwarranted variation in access to remote monitoring, ensuring that the benefits are extended to a diverse range of patients
4. Consent for remote monitoring should be included as part of the general consent for device implantation
5. Appropriate alerts should be programmed on in patients with wireless-enabled devices
6. CIED follow-up can be structured in a variety of different ways depending on local circumstances and patient factors.
7. Annual in-person evaluation is not mandated for all CIED patients
8. Periodic in-person evaluation may be necessary and desirable for all patients
9. Alert-based remote monitoring alone (without periodic downloads) may be appropriate for some patients
10. Actionable alerts should be responded to in an appropriate timeframe
11. Local follow-up arrangements should be audited regularly to ensure they are safe and effective
12. Action on data which points to heart failure decompensation is recommended

Competencies

Performing a remote clinic review requires the same accreditation as an individual performing an in-person clinic review. Lone / home workers need the support of departmental colleagues in the event of a device or patient problem. It is important that departments have plans to allow rapid means of

communication allowing sharing of data and conversations. BHRS remote monitoring survey suggested the individual on remote clinic was potentially more vulnerable due to isolated working and due to the uncertainty of content of the download if alert-based download, and yet seems a lesser grade of person was often responsible for the remote clinic than in person clinic.

It is important that significant changes in device function or patient's health are detected and acted upon. Examples would include a significant increase in ventricular pacing, new onset atrial fibrillation, reduction of biventricular pacing or changes suggestive of development of heart failure. Pattern recognition of potential under-reporting from the device of significant changes is important.

Device follow up

In the United Kingdom the majority of device follow up is performed by cardiac clinical scientists, cardiac physiologists/cardiac clinical practitioners and in some cases by specialist nurses. These specialists work mostly autonomously with expert knowledge and experience to provide CIED follow up services to all patients implanted with a CIED. These follow up services encompass an approach to device management and clinical management of patients with a complex range of conditions.

Regardless of the method adopted, the increasing complexity to CIED follow up combined with the ability to alter a patient's therapy or "prescription" by reprogramming a device means that standards that provide for this to be done safely and effectively are essential. Inappropriate or incorrect use of device features, failure to recognise symptoms and worsening conditions or other errors with aspects of device programming may result in serious harm to the patient.

It is therefore essential that standardised procedures are carried out by appropriately qualified personnel and there are appropriate levels of training and standards in place to ensure clinical governance with clearly established lines of clinical responsibility for all follow-up services.

Although CIED services are run by clinical scientists/cardiac physiologists, device follow-up remains the ultimate responsibility of the clinician in charge. For most services at present this tends to be an appointed cardiologist (consultant physician with specialist interest) but in the future may fall under the responsibility of a consultant clinical scientist. The clinician responsible for providing such a service must have the required knowledge to do so and it is therefore recommended that the clinician in charge has a recognised CRM device qualification such as BHRS, European Heart Rhythm Association (EHRA) or International Board of Heart Rhythm Examiners (IBHRE) certification.

CIED FOLLOW UP CLINIC OBJECTIVES

Put simply, the objective of CIED follow up, in line with the BHRS mission is:

“To improve and extend the lives of people with CIED therapy”

All the activities of a device follow-up service should align with this objective, and a wide range of activities may contribute to achieving it, including personalised evidence-based programming, vigilance in identifying and addressing complications and system failures, responsive remote monitoring and disease surveillance, appropriate and timely referral to other specialties and services, provision of education, counselling and support services.

It is important to advise patients and their general practitioners that the device is functioning appropriately, to advise the patient to report wound problems, and advise them to seek cardiological advice if symptoms deteriorate.

CIED follow up clinic objectives

To identify any abnormalities in the implanted CIED system and complications of the therapy in order to ensure prompt treatment. This includes utilising device diagnostics to trouble shoot arrhythmias and abnormalities in the CIED system

To recognise the potential development of new onset atrial fibrillation and be aware of risk scoring (e.g., CHA2DS2- VASc scoring) to assess the risk of thrombo-embolism to patients and refer, as per local protocol, for confirmation of atrial fibrillation and management which may include consideration of anti-coagulation, ablation or cardioversion.

To assess battery status to predict end-of-life of the pulse generator in order to permit timely elective generator replacement

To ensure that safe and accurate measurements are made of device and lead function and that accurate records of each visit are kept. Staff leading the clinic must be able to recognise problems and complications and make the appropriate changes or recommendations.

To identify patients who may be suitable and benefit from an upgrade to CRT or ICD in addition to those who may benefit from downgrading of a system e.g., CRT-D to CRT-P.

To enable modifications to CIED parameters in line with the requirements of each individual patient.

To maximise clinical safety and efficiency in line with clinical governance

requirements.

To recognise pacemaker syndrome and minimise unnecessary right ventricular (RV) pacing where appropriate in order to reduce the risk of developing pacing induced heart failure.

To regularly review appropriate patients in line with local, manufacturer and national guidelines.

To implement relevant advisories from device manufacturers and the Medicines and Healthcare products Regulatory Agency (MHRA) guidelines and advice and notify the MHRA and manufacturer of any problems arising with devices or leads.

To be able to identify relevant clinical problems and refer patients for immediate or deferred medical care appropriately in line with local policy.

To provide accurate and complete communication about patient-device interaction and appropriate functionality to GPs and other relevant health professionals.

To optimise the system to provide delivery of optimal therapy for the individual patient needs whilst maximising generator life. Safety must be paramount whilst manufacturer guidance and BHRS recommendations should also be taken into account.

To identify any abnormalities in ICD/CRT systems and any complications of the therapy in order to ensure prompt treatment.

To assess arrhythmia burden and refer patients where appropriate for further specialist management .There should be a protocol in place for this.

To ensure that ICD therapy zones are appropriately programmed to minimize the risk of inappropriate therapy being delivered and to ensure that effective and appropriate therapy is provided using evidence-based strategies and programming guidelines (see section 7.2)

To assess and maximize left ventricular (LV) pacing (biventricular or LV fusion) in CRT devices in order to maintain effective resynchronisation and to be able to provide optimisation of the device.

To recognise signs of worsening HF and follow a local protocol for referral of patients for HF assessment.

To provide patient and family support and education together with any other healthcare professionals involved in the patient's management.

To monitor the device implant site and watch for any evidence of infection and educate patients about the signs of wound problems. Patients under remote follow up require education on wound problems, advice on what is abnormal.

Standardised protocols are useful for common problems e.g., asymptomatic ventricular tachycardia, atrial high rate episodes

Physiological pacing (His bundle /Left bundle branch pacing) follow up clinics

Patients with left bundle branch (LBB) and direct His bundle pacing need specific and appropriate follow up. This will usually require a 12 lead ECG during threshold checks. Follow ups should only be undertaken by those who have been trained to recognise direct/selective & non-selective His bundle capture, and can program devices appropriately, recognising that specific His bundle devices are not currently available, and some device algorithms may not be appropriate in this context.

There should be clear documentation that the lead is implanted in the conduction system. Patients should be enrolled in research studies or registries where possible to ensure on-going evaluation of this emerging area. Centers not routinely following up conduction system pacing patients should develop sufficient awareness of this type of pacing in order to recognise these patients if they are admitted via A/E or other routes.

CIED SERVICE REQUIREMENTS

There should be a clearly defined protocol documenting the lines of communication and support between the lead cardiac scientist/physiologist for the CIED follow-up service and the consultant cardiologist responsible for the onsite service to ensure that clinical governance requirements are met. The lead cardiac scientist/physiologist for pacemaker follow-up services at non-implanting hospitals must also have clear links with the lead cardiac scientist/physiologist and consultant cardiologist at the implant center.

The lines of clinical responsibility must be clearly defined in the local Trust policy. Trusts delivering CIED follow-up services have a responsibility to ensure appropriate arrangements are in place to cover clinic activity (elective or urgent).

It is recommended that services provide all staff involved with CIED follow up with access to a regular formal multidisciplinary team (MDT) meeting where specific device and patient concerns can be discussed.

In centers implanting and following up patients with ICDs and CRTs there should be a 24hr emergency service available to deal with patients admitted for multiple shock delivery or non-delivery of appropriate therapy. This should consist of an appropriately trained cardiac clinical scientist/physiologist and an appropriately

trained cardiologist, either on site or with clearly defined, documented and

agreed protocols with alternate implanting centers to transfer patients to a centre offering 24hr emergency service. Magnets should be available in all emergency departments to stop shock therapy in an emergency.

Cardiac scientists/physiologists competent in and regularly performing CIED follow up in patients with ICD/CRT devices should have knowledge of using manual delivery of anti-tachycardia pacing (ATP) in the event of a failure of automatic therapies for VT and knowledge of overdrive therapy for termination of atrial flutter in patients who have developed this and who are appropriately anti-coagulated to support such services and provide best patient management.

All follow-up centres should have provisions for emergency ICD deactivation (even if this is with a magnet only) to account for the range of patients with devices which may attend unexpectedly.

All follow up centers should have provisions for perioperative management of patients with CIEDs.

CIED follow up services should have access to psychological support and counselling services. Staff involved in the care of patients with ICDs should be able to provide pre-ICD implant, typical day to day advice and education in clinic and through 'helplines' to patients with ICDs. It is recognised however that 'counselling' a patient if they are severely struggling psychologically following cardiac arrest, ICD implant, from shock therapy or other reasons falls outside the skill set of most cardiac scientists/physiologists and specialist nurses. Consequently, it is recommended that there are local procedures and policies in place to help recognise and support this group of patients which should include guidance on referral to appropriate services.

Patient support groups are encouraged where possible as many patients find this helpful.

Staffing requirements

All device implants and device follow up centres must have a designated clinical head of department (HoD). The HoD may either be a specialist registered physician or a clinical scientist/highly specialist cardiac physiologist.

The clinical head of department (HoD) should hold BHRS certification (or equivalent e.g., EHRA, IBHRE), have at least the knowledge and skills equivalent to those required for an agenda for change band 8 (at least band 7 if head of service) and should be on one of the following accredited registers.

The Academy of Healthcare Science (AHCS)

The Registration Council for Clinical Physiologists (RCCP)

Registration as a clinical scientist with the Health and Care Professions Council (HCPC)

It is recommended that all cardiac clinical scientists/cardiac physiologists performing CIED follow-up should be on an accredited register.

Depending on the clinic throughput, it is recommended that device follow up clinics must be undertaken with a minimum of two physiologists immediately available, of which the senior physiologist must have the clinical expertise and responsibilities of a Highly Specialist Cardiac Physiologist / cardiac clinical scientist with BHRS certification (or equivalent).

Cardiac clinical scientists/cardiac physiologists who undertake unsupervised device follow-up should hold BHRS certification (or equivalent) and have the knowledge and skills equivalent to Agenda for Change band 7.

Cardiac clinical scientists/cardiac physiologists undertaking device follow up clinics must hold a current ILS certificate as a minimal resuscitation requirement.

All members of staff performing device follow-up must undertake and record CPD continually throughout their working life in order to maintain, improve and develop their knowledge and skills.

Recommended CIED follow up numbers

Below are recommendations including minimal number of follow ups cardiac clinical scientists/cardiac physiologists should perform on an annual basis. It is recognised that competence can only be defined effectively in terms of patient outcomes. Numbers are indicative and should not be taken in isolation as evidence of competence. Senior staff must provide oversight to ensure the safety of patients and junior staff. Evidence that competence and maintenance of competence is met should be recorded taking note of recommendation 'd'.

Cardiac clinical scientists/Cardiac physiologists performing bradycardia only follow up should perform a minimum of 100 bradycardia pacemaker system follow-up review procedures per year.

Cardiac clinical scientists/Cardiac physiologists performing bradycardia only follow up should attend the local implant center regularly and not less than twice per year to remain familiar with evolving technology (this applies to physiologists leading follow-up clinics at non-implant hospitals)

Cardiac clinical scientists/Cardiac physiologists performing ICD/CRT follow up should perform a minimum of 100 follow-up review procedures per year.

All cardiac clinical scientists/cardiac physiologists should have annual direct observations of procedural skills (DOPS) or Peer to Peer review documented to evidence competency requirements are met and maintained.

Staff records

The department should maintain a comprehensive up-to-date list of its staff and records of their training activities, professional qualifications, registration status, training courses attended, and certificates of competence with identification of designated responsibilities and authorisation to carry out specific follow-up tasks. There should be regular review of performance, and assessment of competence. This might include direct observation/peer review, retrospective audit, and appraisal. Staff should be allowed protected time to engage in continuous professional development activities and to undertake improvement initiatives. Staff must comply with locally defined mandatory training and registration status should be confirmed annually (e.g., at appraisal). Tailored induction, training and supervision programs should be available specific to each role. Examples include programs for staff taking on new roles, locum staff, those returning to work following career breaks and students. Departments should collaborate with education institutions for education and training support to meet current and predicted workforce needs.

Facilities and environment

The facilities and environment provided should be fit for purpose. Design of clinical areas must consider the need to ensure patient confidentiality, privacy and dignity, emergency evacuation and manoeuvring of patients, and ready access to water supply for handwashing facilities. The space and environmental conditions must assure the quality, safety and efficacy of the services provided.

There should be sufficient suitable space to deliver the activities and associated functions of a device follow-up service; adequate space for patient, carer/chaperone/interpreter, staff, trainees/students, programmers, PCs, emergency equipment, consumables, and other items necessary to perform follow-up. Where possible, access to the clinical room should be limited/controlled to include only the patient and clinical staff conducting the follow-up.

There should be appropriate access for users and staff who use wheelchairs, trolleys/beds, have impaired vision and hearing loss or other needs. Safety notices and signposting should be clear and unambiguous. Reception, waiting and changing facilities should be sufficient, and appropriate seating should be provided for all patients - to include space for people waiting in wheelchairs, on trolleys, bariatric patients, and those waiting for hospital transport. Adequate and appropriate security systems should be in place for the protection of patients and staff e.g., access control, alarms systems, cctv etc. Sufficient and appropriate changing

facilities should be provided for staff including those with disabilities with access to safe storage for personal items, access to toilet facilities and drinking water. Space for staff activities such as a rest area, a space for staff meetings, education and quiet study should be provided.

Equipment

A wide range of equipment is essential within the CIED follow up clinic or immediate vicinity of the clinic area with access to further cardiac investigations (which need not necessarily be on site). These are listed below:

Equipment essential in the CIED follow up clinic (or in the immediate vicinity):

- 12-lead electrocardiogram (ECG) machine with real time recording
- An appropriate range of manufacturer programmers
(with appropriate documentation for use of each specific model)
- Emergency "crash" trolley and defibrillator with integrated pacing function
- Magnet
- Wound treatment pack
- Telephone and/or arrest call button
- Data management system/patient notes
- Sharps box
- Oxygen, suction and relevant adjuncts
- Computer in the clinic room for access to device database

There should also be access to MHRA CIED adverse incident reporting online.

Investigations to which the cardiac physiologist should have referral access:

X-ray facilities
Ambulatory ECG recording
Echocardiogram
Phlebotomy

Cardiac investigations to which it may be desirable to have referral access:

Exercise stress testing

Access for rapid referral of any patient needing urgent admission should also be available.

Suggested device follow up procedure

A procedure for device follow-up should include the following where possible:

- Recording of an ECG rhythm strip to verify device function and monitoring this throughout the check
- Maintenance of device function throughout check
- Identification of the device and leads from the patient records
- Assessing the clinical condition of the patient and identifying any changes in status from previous visits including recognition of atrial fibrillation either as new onset or an increased burden and identifying the associated risk factors (there should be a local protocol in place for handling this situation)
- Initial interrogation of the device and recording of any relevant information
- Assessment of device battery status and comparison with previous records
- Safe testing of device and lead status including thresholds for sensing and capture as well as impedance measurements
- Assessment of diagnostics, events and appropriate counters/histograms for rate assessment and appropriate function
- Appropriate troubleshooting for complications/problems using other investigations where necessary
- Appropriate reprogramming of the device to ensure that optimal settings for clinical outcomes are provided for each individual patient
- Recording all of the above
- Checking final settings and ensuring that any changes have been fully and appropriately documented and checked to ensure patient safety
- Appropriate scheduling of the next appointment or referral
- Ensuring that device registration has been undertaken and that all patients have their registration/ID cards and all appropriate information.

A computer is recommended in rooms used for cardiac device follow up for access to cardiac device databases and for generating reports.

Reports

There should be a locally agreed structure/template for device follow-up reports, including those shared with GPs and other departments. Ideally these should be developed in consultation with referrers and stakeholders.

Every CIED follow up performed should have a report generated by the cardiac physiologist / cardiac scientist performing the procedure. All parameters and clinical details should be documented in the department's database and/or the patient's pacemaker notes. All clinics should have a database on which all information about the patient and their device is

available in line with the National Institute for Cardiovascular Outcomes Research (NICOR) CRM database requirements.

An electronic report database should exist with a facility to store device reports as PDFs. Data must be submitted in a regular and timely fashion with all appropriate fields completed to the UK central cardiac rhythm management database held by NICOR.

Reports or a letter with relevant findings should be sent to the patient's general practitioner and the referring hospital where appropriate. A copy of the report and any information such as programming changes should also be given to the patient if desired.

Responsibility for signing off device follow-up reports for different types of devices and in different situations must be clearly defined, and a list of competent physiologists should be maintained.

Reports should include the following:

- The device follow-up center should be clearly identified
- The name of the reporting practitioner(s) and their position
- Indication for follow-up (e.g., routine, patient initiated etc.)
- Whether the encounter is face to face or remote
- A summary of demographics, relevant clinical and device history
- Details of the implanted system
- A description of the relevant findings/observations including any unexpected findings
- A conclusion and/or diagnosis including an estimation of how definite or likely the conclusion/diagnosis is and description of any, further appropriate diagnostic tests or steps that may be necessary
- A summary of any communication with colleagues, physicians, other healthcare professionals or technical support from the manufacturer

All reporting staff must have ready access to a second opinion. Reports should be periodically evaluated by a supervising peer, or team, with feedback to the authors of the reports.

Audit

All departments providing device follow-up should consider how they will measure performance and should agree metrics and key performance indicators to monitor and verify the effectiveness of their services. All processes should be reviewed regularly, and any necessary corrective actions are taken. Lessons learnt should be disseminated throughout the team to support service improvement, and where appropriate more widely through local and national networks. Opportunities should be provided for service users to provide feedback.

A formal quality assurance system should be in place including documented regular review meetings, regular process audits to ensure compliance with departmental and BHRS standards, annual peer to peer review and quality assurance processes of all staff involved in follow up clinics as per IQIPS departmental standards.

Patient information

Good communication is central to high-quality healthcare. Each department should develop patient-friendly information about what will happen before, during and after device follow-up visits and whilst being monitored remotely. Patient and public involvement (PPI) groups and engagement activities should be undertaken in the development and review of information.

Patient information should include specific information including the address, opening hours, contact details, access and parking arrangements for the service. Information should be accessible in a range of formats and media, and in various languages relevant to the population served.

Information should address specific aspects of care such as:

- Explanation of the purpose of device follow-up
- Explanation of what will happen during and after the appointment
- How long the appointment is likely to take
- Who will perform the follow-up?
- Access to interpreters and chaperones, if required
- Arrangements for patients who lack capacity, vulnerable adults and users with intellectual disabilities
- Communication and dissemination of results
- Explanation that the patient should notify the provider if they cannot attend and how to arrange an alternative date/time
- How the patient can provide feedback

Managing feedback and complaints

The department should have systems in place to ensure that feedback or complaints can be given in different formats and media, and that those giving feedback and or making a complaint can do so in confidence. Feedback and complaints, and actions taken should be recorded.

Regular review of the following service delivery aspects to include but not limited to:

- Choice of appointments offered
- How well their individual needs and concerns were addressed, e.g., access to facilities.
- Availability, sufficiency and timeliness of information to ensure that they were able to make informed decisions about their care

Suitability of waiting and changing areas, where applicable
Effectiveness of available communication mechanisms
Privacy, dignity, confidentiality and security
Staff conduct and behaviors.

Clinic time and appointment schedule

All device follow-up clinics should work to a standard procedure/protocol. This may be locally developed but should incorporate the minimum requirements set out in these guidelines.

The typical clinic time for cardiac device follow up including clinical assessment should be 20-30 minutes for a standard device follow up e.g., pacemaker or ICD and 45 minutes for complex device follow up e.g., CRT or physiological pacing systems (His or LBBB) (or patients requiring more detailed evaluation). This is not mandatory and may vary according to the presenting problems/complications.

Recommended appointment schedule

BHRS recommended follow up schedules are displayed as flow diagrams for pacemaker, ICD, CRT and physiological pacing and ILR device follow up in the appendix to this document. These should be followed after the post implant and first IPE has been performed.

Additional recommendations are as follows

All patients implanted with a CIED must have a post implant check within 72 hours of implant⁴. Ideally this should be within 24 hours and can include an on table check only. If an on table check only method is performed, this should follow a local protocol and be audited to ensure appropriate device programming and safe patient outcomes.

All patients with a CIED should have an evaluation 2-12 weeks post CIED implant⁴. This should include an assessment of wound healing and the patient and their carers/relatives should be given an opportunity to ask any questions they have, and adequate time should be allocated for this purpose. If they have not already received an device identity card, patients should be given one at this appointment. This evaluation may be able to be done remotely - as long as wound health can be adequately assessed (e.g. by remotely viewing the wound using digital photography and telemedicine systems or via email). RM data should be reviewed to ensure it is set up and functioning, and any necessary troubleshooting or patient education performed to ensure on-going monitoring.

After the first in-person evaluation (IPE), appointment schedules will be dependent on the type of implanted device, and the follow-up model implemented for the patient. The follow-up model (IPE only, IPE + RM, RM only) will be determined by local policies and guided by factors including (but not restricted to) - patient preference, device capabilities, effectiveness and

appropriateness of automated algorithms, and the need to adjust settings with 12 lead ECG guidance (e.g. CRT and conduction system pacing (His to confirm capture \pm LBBB area pacing). Wireless RM with automated alerts, without routine IPE, may be an acceptable model of follow-up for some CIED patients; as long as appropriate alerts are programmed, transmissions are viewed regularly, and there is a robust process for ensuring continuous monitoring.

Appointment schedules will depend on patient compliance to offered services. Patients non-compliant with remote monitoring or follow up, despite being offered a high level of help and resources to achieve an effective remote connection should be monitored with IPEs. Furthermore, there should be a robust process in place to ensure patients who fail to attend are not lost to follow up e.g. letter to GP following 2 successive failures to attend. Cardiac clinical scientists/cardiac physiologists should use their discretion for devices that require closer monitoring e.g., programming/lead issues, batteries closing in on elective replacement indicator and monitoring of arrhythmias

Provision of Remote follow up / remote monitoring

Remote follow up is recommended internationally and should be considered as integral to the provision of CIED services. Remote monitoring should be available to all patients with CIEDs who want it, including those with bradycardia pacemakers (Ref). Centers which currently do not offer RM should formulate a plan to deliver a RM service, or partner with another center in their network.

Implantable loop recorders and insertable cardiac monitors should be followed up depending on symptoms, and this may be done via remote monitoring. If the patient's problem has resolved or the device has been implanted for over 12 months, individual decisions on frequency of monitoring should be made. Remote follow up is now well established as an alternative to in-person follow up when used with robust protocols. Certain patients (e.g. His bundle pacing) are not suitable for entirely remote follow up. Periodic in-person evaluation may be necessary and desirable for some patients (such as those patients for whom analysis of the paced 12 lead ECG is important for tailoring programming – e.g. conduction system pacing)

Disease management

With the majority of CIEDs now capable of recording advanced diagnostics it is important that those performing CIED follow up able to recognise new and worsening conditions and symptoms have appropriate local pathways in place to improve patients' symptoms and prognosis, ensuring relevant and significant information is disseminated for timely action.

Atrial high-rate episodes

There should be a clear local protocol or pathway for patients with CIED detected atrial high-rate episodes, AF with symptoms and/or patients presenting with AF with a fast-ventricular response. CIED follow up staff should be aware of risk scoring (e.g., CHA2DS2-VASc scoring) to assess the risk of thrombo-embolism to patients and refer, as per local protocol, for further management (which may include consideration of anti- coagulation, ablation or cardioversion).

Patients with atrial fibrillation documented on an ECG should be reviewed regarding their risk of stroke. In the absence of ECG confirmation of AF, definitive evidence for treating patients with atrial high-rate episodes are lacking. Atrial high rate episodes are likely to represent atrial fibrillation, but most implanted devices cannot provide ECG confirmation and hence conventional confirmation is recommended at the time of writing.

Departments are encouraged to refer patients for inclusion into relevant randomised studies in this area, but where this is not practicable

there should be agreed departmental protocols for managing these patients - developed with clinician input and based on the best available evidence. It is sensible to consider face to face evaluation at the earliest opportunity & to obtain an ecg to diagnose atrial fibrillation. These should be reviewed in the light of emerging evidence.

Heart failure (HF)

There should be a clear local protocol or pathway for patients with CIEDs whom show signs of worsening HF.

It is recognised that HF management is performed by multi-disciplinary teams involving nurse specialists in hospital and community settings and as such it is recommended that CIED follow up services build relationships with local and community HF teams to develop appropriate protocols and pathways across regions for patients showing signs of worsening heart failure. The use of multiple physiological parameters detected by CIEDs is emerging as novel way of predicting HF episodes before they occur.

Ventricular arrhythmias (VA)

It is recommended that there is a local protocol/pathway to manage patients with ventricular arrhythmias and those who receive ICD therapies for ventricular arrhythmias. The centre should assess arrhythmia burden and have a *process* for referring patients, where appropriate, for further specialist management such as medication or ventricular tachycardia (VT) ablation. There should be protocols in place for this, *and for managing other common device or rhythm related issues*. Of note asymptomatic patients with LVEF >45% and non-sustained ventricular tachycardia (>3 beats for upto 30 seconds) do not appear to have a reduced longevity.

Care of patients approaching end of life

No set of guidelines can provide prescriptive guidance for every end-of-life circumstance¹⁵. But an over-arching principle of end-of-life care should be to avoid circumstances that might detract from a peaceful death¹⁶. ICD shocks are painful and distressing, and can result in fear, anxiety and depression^{17,18}. It is important that non-cardiologists can request device deactivation and that prompt response is available

ICDs that remain active in dying patients can cause unnecessary pain and distress as a result of multiple shocks: in one study¹⁹ a quarter of patients with an active ICD received shocks in the last hours of their life - one patient receiving no less than 53. In some cases, an ICD may prolong the process of dying without hope of changing the ultimate outcome²⁰. When a person's life expectancy is short, continued ICD therapy may no longer be in line with their objectives and they may wish their device to be switched off. However, not all

patients want their ICD deactivated.

A person may request withdrawal of a previously consented intervention if their goals have changed²¹. When death follows withdrawal of treatment, the person's underlying condition is deemed the cause of death, in contrast to euthanasia which involves an active intervention^{22,23,24}. Refusal or withdrawal of treatment is lawful provided that it follows from a competent person's request when fully informed of the likely consequences²⁵.

Decisions about deactivation should be made jointly with any patient with decision-making capacity - following explanation of the risks and benefits²¹. Although professionals should be involved, a competent patient should ultimately make their own decisions, without coercion or interference from others²⁶. However, patients' preferences, beliefs, and values about being involved in health-care decisions may vary depending on cultural and social norms²⁷ - some patients do not want to be told about a bad prognosis or to participate in decision-making, preferring to leave this to their doctors or relatives²⁸. Respecting such attitudes shows respect for a patient's autonomy as much as giving patient's information that they do want.

If a person lacks capacity, then a decision on withdrawal can be made via advance directives, by surrogate decision makers (power of attorney) or may be made by medical professionals in the person's best interests²². During the very last days of life, a person's decision-making capacity may fluctuate and gradually diminish, which increases the role of relatives as intermediaries between the patient and healthcare professionals²⁹.

At the end of life, patients think and act in relation to close family and friends, and as their physical and psychosocial condition deteriorates, they may not be able to fully participate in decision making without the support of relatives³⁰. At this time, many patients want close relatives to be involved in major decisions who can enable the patient to maintain their identity and to die in accordance with their values; relatives know the patient best and want to ensure that their interests are respected³¹.

Although they may not be accountable for ICD deactivation decisions, healthcare professionals performing ICD follow-up need to have a good understanding of the issues around device deactivation.

Recommendations

CIED follow up services must have a local policy for the management of patients with CIEDs towards the end of their lives.

All follow up centres (including those performing pacemaker only follow up) should have a policy in place for deactivation of ICD function in ICD and CRT-D devices.

ICD and CRT-D deactivation should be performed using a CIED programmer. Deactivation using a magnet is acceptable as a temporary measure in out-of-hours emergencies. This should be upgraded to CIED programmer deactivation as soon as is reasonably possible.

Where practicably possible centres should offer domiciliary visits. Where domiciliary/community deactivation is considered there must be robust safeguards in place for staff and patients. Risk assessment for loan workers and assessment of the suitability of the domiciliary/community setting will be required (e.g.: electrical safety, dangerous dogs and accessibility).

Device therapy termination should be a consensus between the physician normally responsible for patient care e.g., oncologist, device consultant, GP, device physiologist, the patient and where possible a representative for the patient (e.g. a relative).

Different levels of device therapy termination should be considered specific to the individual case and informed consent must be documented.

Healthcare professionals performing ICD follow-up should receive education and training that covers communicating with patients in a palliative setting and the ethical and legal aspects of ICD deactivation

Departments should be vigilant in identifying patients with significant physical or cognitive decline which may prompt conversations to establish a patient's wishes.

Departments should work with heart failure and palliative care teams to ensure appropriate management of patients towards the end of life

Device replacement

Consideration of whether device replacement is appropriate should be planned prior to the day of the procedure. Discussion with relatives about care home residents with advanced dementia are important to avoid unnecessary distress and cancelling the procedure on the day. Patients with defibrillators may no longer fulfil the criteria for device therapy. Remote devices follow up means that decisions about the appropriateness of device replacement may not be as clear if the patient is not being seen face to face. We recommend departments consider reviewing in person those patients requiring box changes by members of the multi-disciplinary team.

MDT discussion is recommended by the BHRS, BCS, BGS & BSH for the following (<https://www.bsh.org.uk/wp-content/uploads/2022/02/Heart-failure-MDM-final-revised-v2.pdf> Accessed 24 April 2022):-

- Patients with bradycardia devices who are approaching the need for a box change who may benefit from complex device implantation
- Patients who are being considered for new implants when the decision is not straightforward
- Patients who may benefit from conversion from bradycardia pacing
- Patients who require end-of-life decisions and device deactivation
- Patients where therapeutic arrhythmia ablation is a potential option

Minimum dataset for MDT

- Diagnosis

- Current clinical state and NYHA functional class
- Comorbidities and frailty status (Clinical Frailty Scale if over 65 years of age)
- Social and functional history
- Current and previous drugs
- Relevant recent blood test results
- Recent 12-lead ECG and any ambulatory ECG recordings
- Relevant cardiac imaging results

Core attendees for MDT

- MDM coordinator
- Heart failure cardiologist
- Device implanting cardiologist
- Heart failure specialist nurse
- Arrhythmia specialist nurse
- Cardiac physiologist with device expertise

Provisions for MRI

Each device follow-up centre must ensure that they have agreements and arrangements in place that allow their patient's access to magnetic resonance imaging (MRI) scanning. See BHRS guidance.

GUIDELINES ON DEVICE PROGRAMMING

Pacemakers

There are limited specific guidelines with recommendations on the programming of pacemakers. Often manufacturer guidance is used to tailor programming for individuals. Evidence from a randomised controlled trial (RCT) showed that optimal programming reduced ventricular pacing (VP) burden, improved left ventricular systolic function, preserved battery longevity and had no detrimental effect on patient quality of life³⁵. As a patients' cardiac condition changes over time, so might too the requirements of their device and the priorities regarding their therapy. At every opportunity, careful consideration should be given to the following:

The most appropriate mode selection, considering the effectiveness of rate response in each individual

Avoid RV pacing where necessary through programming of RV pacing avoidance algorithms, AV search or extended AV delays.

Optimise the base rate (50ppm where applicable) making use of sleep, rest, and hysteresis rates (40ppm where applicable).

Prolong battery life through optimising device outputs including minimum automated outputs. Consider benefits of auto threshold testing algorithms where appropriate considering each manufacturer algorithm.

Factor in appropriate upper tracking rate (UTR) based on patient age, activity levels and co-morbidities

ICDs

The core objective of ICD programming is to provide patients with appropriate device therapy in the form of a shock or ATP when a life-threatening ventricular arrhythmia presents. Therapy should be delivered within an appropriate time frame, not too soon to allow the arrhythmia time to self-terminate and not too late that the patient loses consciousness. At the same time programming must be tailored to avoid inappropriate therapies which have a significant impact on patients physically and psychologically.

In 2015 a comprehensive expert consensus document was produced by four continental electrophysiology societies including the Heart Rhythm Society (HRS) and the European Heart Rhythm Society (EHRA)³⁶ with a further updated document produced in 2019³⁷. Both these documents provide guidelines for optimal ICD programming based on the best evidence currently available and include manufacturer specific programming methods.

The BHRS endorse the HRS/EHRA guidelines and encourage services to use these to set local protocols for programming of ICD therapies.

Services should also carefully consider the following:-

- Ensure programming and alert notifications are tailored to the need of the individual patient.
- Document where programming strategies deviate from guidelines.
- Review programming at each CIED check, after patients receive therapy and at the time of generator change. Programming strategies may require adjusting over time and with changing conditions.
- Regular assessment and updates to morphology templates where appropriate when this type of discriminator is programmed on
- Discuss ICD deactivation with patients at follow up (even if at a stage where not yet want to)
- Consider setting up weekly physiologist led VT clinics to see patients receiving tachycardia therapy with access to cardiologists, echocardiography, ecg (to look for CRT candidates), HF specialist nurses, ablation / advanced HF therapy referral, MDT discussion as per BCS & BHRS guidance. Commonly, VT can represent a deterioration in left

ventricular function requiring evaluation and medication.

CRT

There are limited guidelines on programming CRT devices beyond demonstrating electrical resynchronisation where a device is implanted for broad QRS dyssynchrony.

CRT may also be implanted prophylactically in a patient with a narrow QRS but programmed in a VVI mode to act as a back up. Specific situations where CRT may be implanted as back up include post complex surgery or in ACHD patients.

In standard CRT indications efforts should be made to maximise bi-ventricular pacing (BiVP) (biventricular or LV only) and where possible minimise atrial pacing. AF ablation / AV node ablation should be considered in patients with atrial fibrillation receiving <92% biventricular pacing. At every opportunity, careful consideration should also be given to the following:

Use of 12 lead ECG or a chest lead when assessing BiVP.

Assessment of the underlying rhythm at every check to aid programming choices

Adjustments to AV/VV timing utilising dynamic adaptive algorithms where appropriate

LV pace vector optimisation by achieving the best QRS morphology and shortest QRS is important. Selecting vectors with the longest conduction timing (Q to LV), appropriate impedances, avoidance of anodal capture and diaphragmatic pacing and true LV capture. It is recognised that there may be a difference between the best capture threshold and the best electrical resynchronisation, which requires programming specific to patient characteristics.

Aim for a dominant R wave in V1 (true BiVP) and right axis deviation (RAD) in limb leads with a -ve ECG Lead I.

Programming of a low base rate to encourage atrial sensing (AS)

Programming of appropriate UTR to ensure BiVP at higher rates in more active patients

CRT “optimisation”

There are multiple methods of adjusting devices systems intended to provide cardiac resynchronisation with the aim of improving cardiac output and patient symptoms but currently there is an absence of confirmatory trial evidence to support a particular approach. The BHRS suggest avoiding non-defined terms e.g., “non-responder”, “responder” – CRT provides “disease modification”. A review of methods used is beyond the scope of this document. However, services following up and programming CRT patients should consider the following guidance.

Follow up services should specify their goals for CRT programming (e.g., QRS narrowing)

Follow up services should have a protocol for CRT programming which may include using 12 lead ECG.

There should be a guidance on possible programming changes for patients who remain symptomatic and those who are decompensating

Cardiac clinical scientists/cardiac physiologists should thoroughly review HF diagnostic data

Cardiac clinical scientists/cardiac physiologists should have access to an MDT meeting and access to community HF teams

Patients with atrial fibrillation who are not in complete heart block should be considered for AV junction ablation and/or AF ablation (in selected patients).

Iron deficiency (TSAT < 20%) is common in patients with congestive cardiac failure and symptoms may be improved with iron infusions. A review of medications and blood tests should be considered alongside re-programming.

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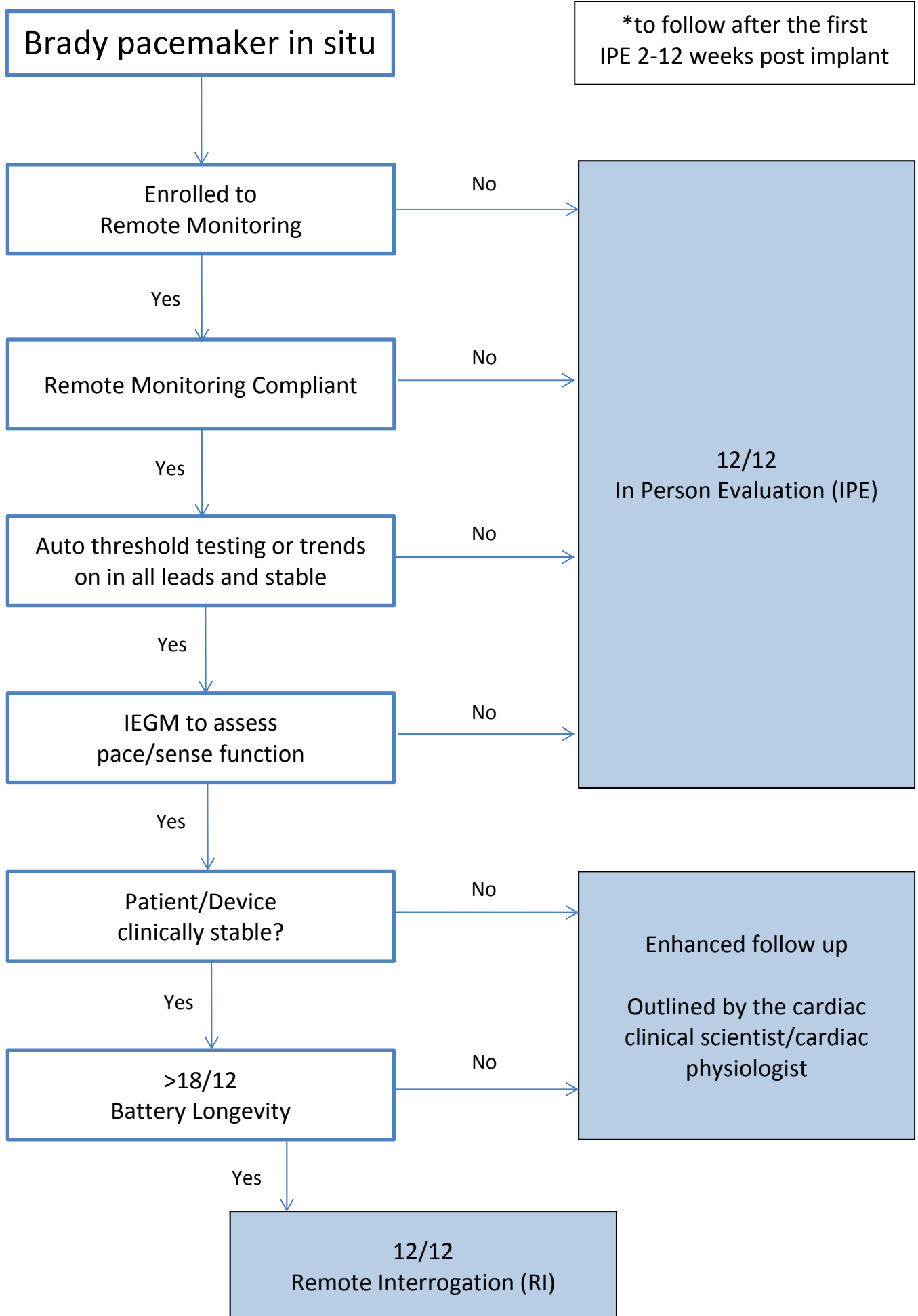
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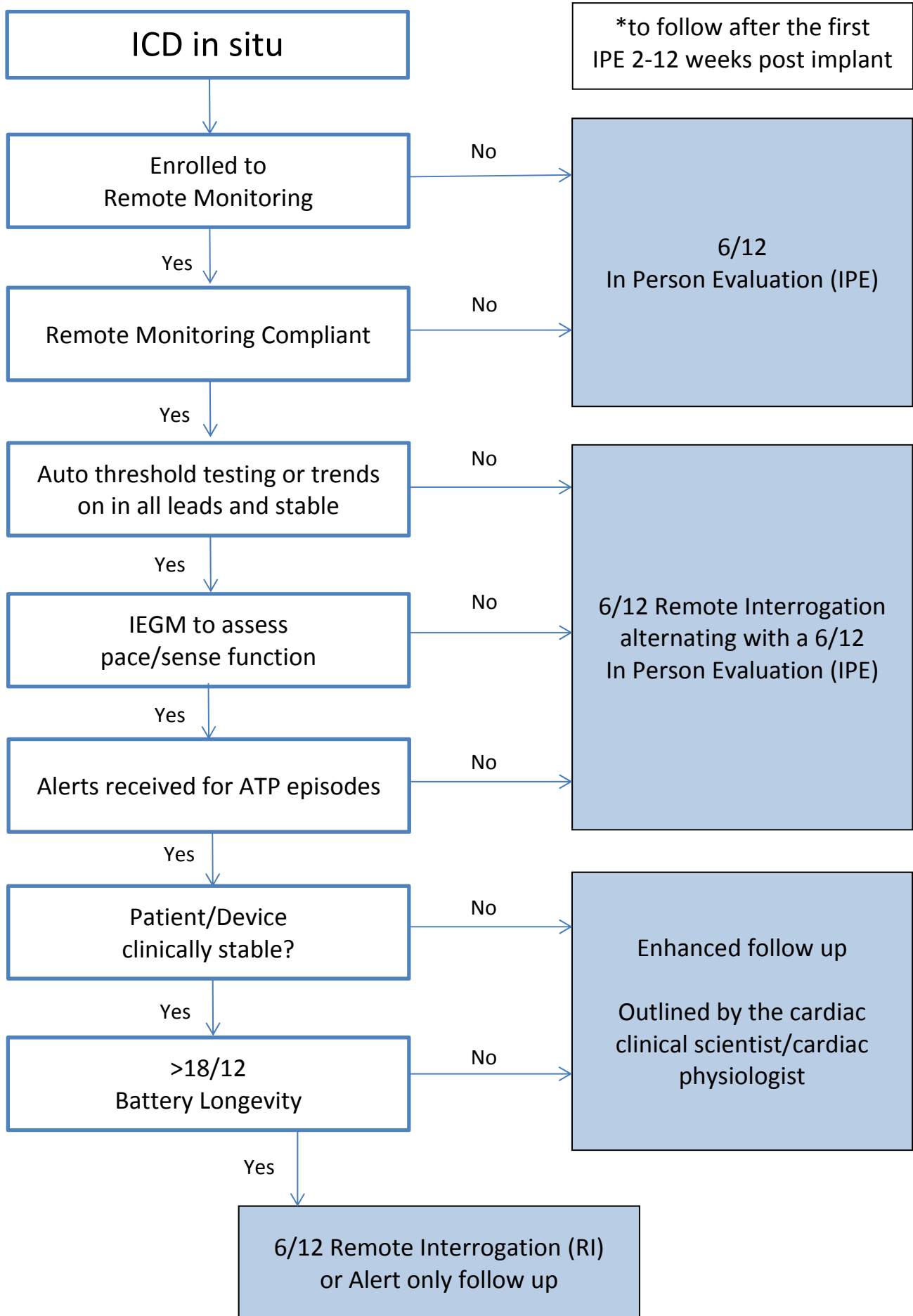
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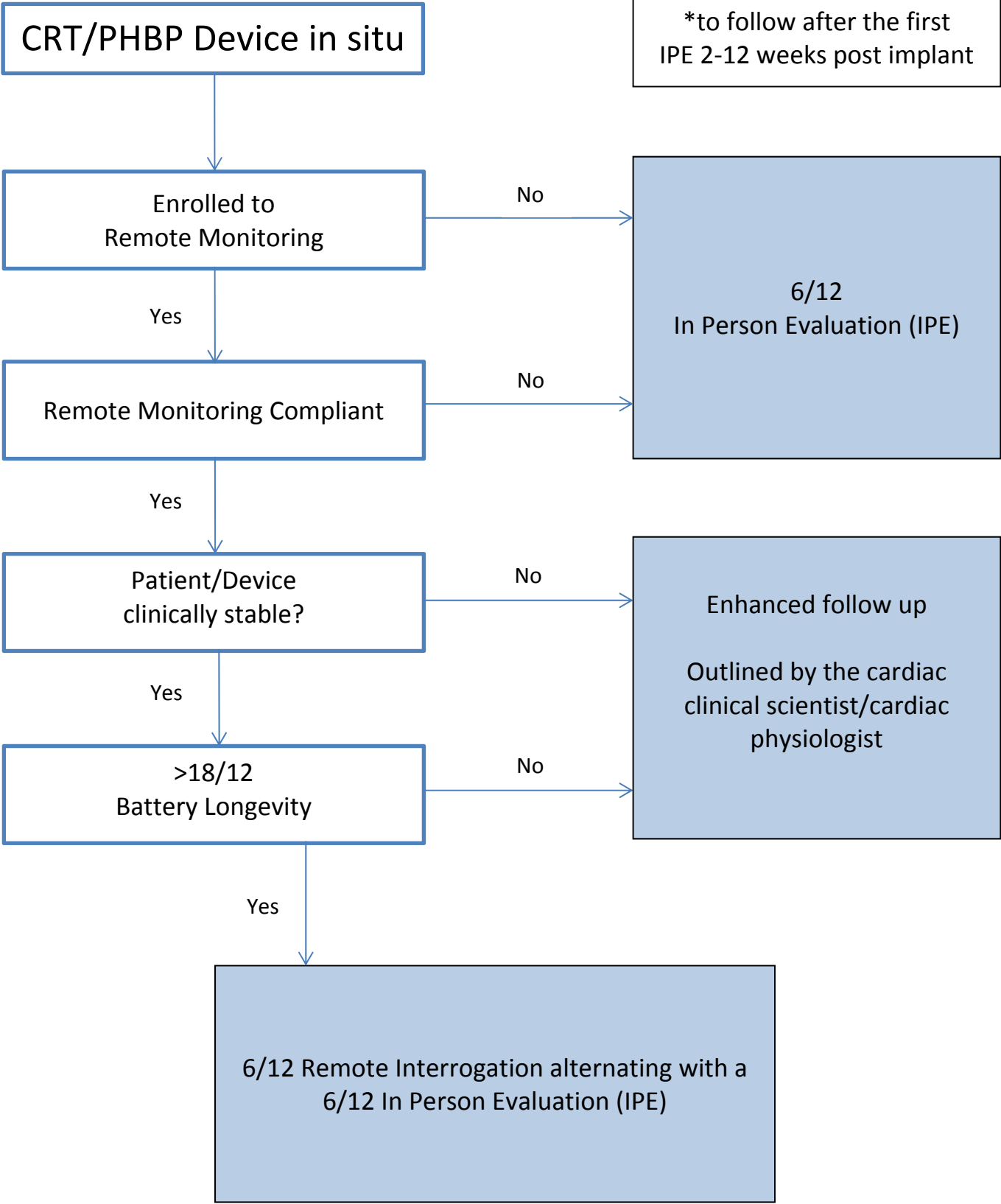
Bradycardia Pacing Device Follow-Up Pathway



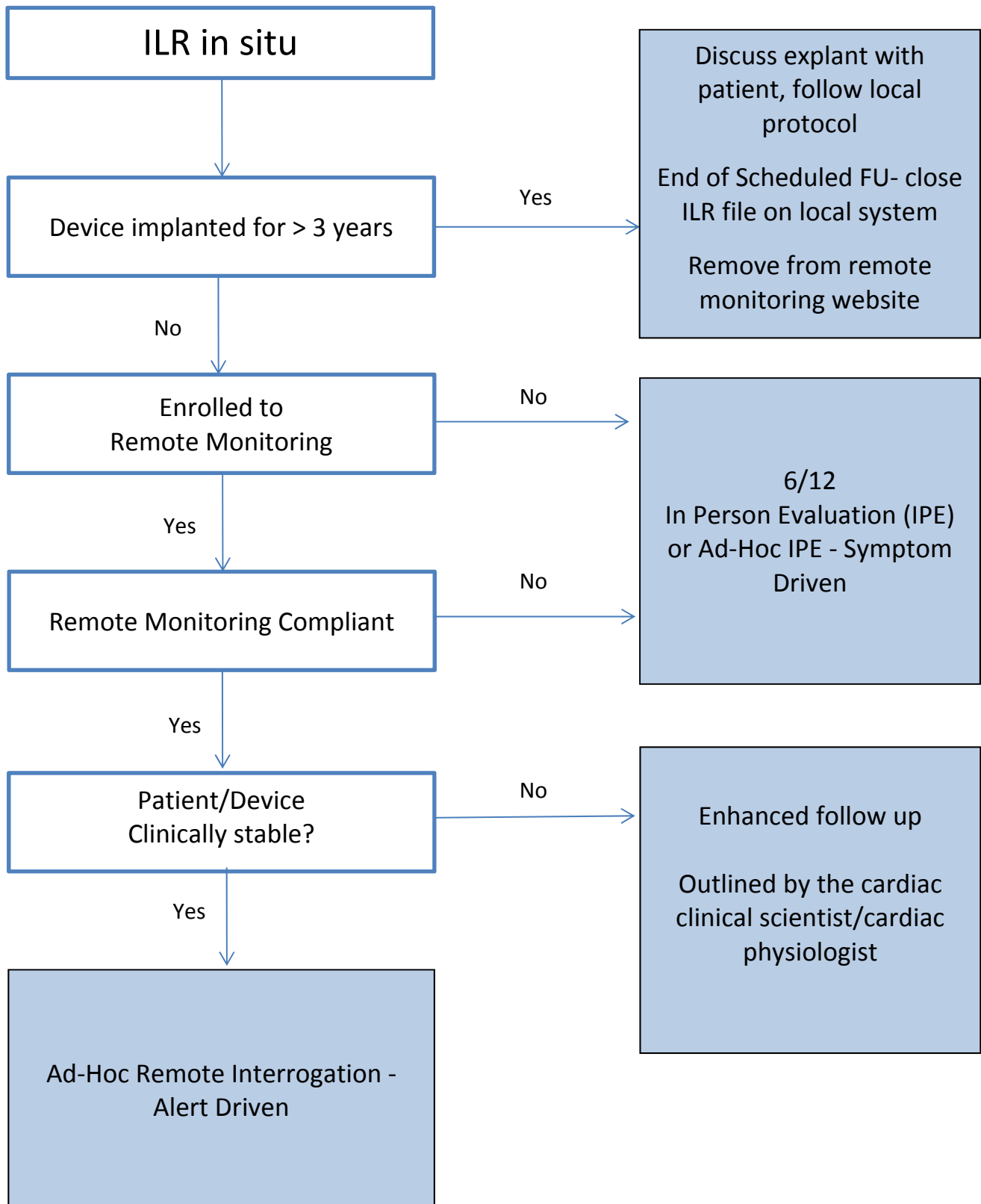
ICD Follow-Up Pathway



CRT/Physiological His Bundle Pacing Follow-Up Pathway



Implantable Loop Recorder Follow-Up Pathway



Cardiac Implantable Electronic Device Follow-Up Pathway

