The Cardiac Society of Australia and New Zealand

# Guidelines for advanced sub-specialty training in Cardiac Implantable Electronic Devices (CIEDs): selection, implantation and follow-up

**These guidelines were reviewed and revised by Dr Gerald Kaye (Chair), Professor Andrew McGavigan, Dr Justin Mariani, Dr David Heaven, Dr David O'Donnell, Dr Rajiv Mahajan, Dr Richard Hillock and Dr Waheed Ahmad on behalf of the CSANZ Heart Rhythm Council Writing Committee. No authors have any relevant Conflict of Interest to disclose.**

**The committee wish to acknowledge previous training guidelines prepared and chaired by Dr Angus Hamer in 2006 and Dr Hugh McAllister and Professor Andrew McGavigan in 2013.**

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## GLOSSARY OF TERMS:

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|---|---|
| ACC | American College of Cardiology |
| CIED | Cardiac implantable electronic device |
| CRT | Cardiac resynchronisation therapy |
| CSANZ | Cardiac Society of Australia and New Zealand |
| EP | Electrophysiology |
| HRS | Heart Rhythm Society US |
| ICD | Implantable cardiac defibrillator |
| ILR | Implantable loop recorder |
| PPM | Permanent Pacemaker |

## INTRODUCTION

Implantable cardiac electronic devices (CIEDs) such as pacemakers and defibrillators are an accepted and proven therapy in patients with cardiac arrhythmias. Australian and New Zealand guidelines for training of physicians in CIED prescription and implantation were initially written in 2006. The updated 2013 guidelines outlined a detailed requirement for both training as well as maintenance of skills and were based upon prevailing clinical expertise as well as contemporaneous guidelines published by the American Heart Rhythm Society (HRS), the American Heart Association (AHA) and the European Society of Cardiology.

The present writing committee recognise that the past ten years has witnessed major innovation and technological advances which has increased the complexity of the specialty, both in terms of appropriate device prescription as well as implantation and follow up. As a result, there is a move, particularly in the US and Europe, for device therapy to become a sub-speciality in its own right. The committee recognises that trainees should be offered a modular approach to training allowing flexibility in future career planning. In addition, the guideline reflects specific and unique issues related to Australia and New Zealand such as geography and the organisation of health services, particularly in remote areas for which allowance has been made, with recognition of patients' desire to be treated locally with the availability of local expertise. Further, the committee is aware of issues concerning implant volume against complication rate, and these issues should be addressed based on robust outcome data increasingly expected by government and providers to base reimbursement and funding decisions.

The current guidelines define appropriate training and maintenance of skills, provide a framework for future development to encourage high quality training centres within Australia and New Zealand and define a minimum uniform practice. With predictable advances in technology the guidelines need to be adaptable to future change. Ultimately guidelines must be seen to support what is best for our patients, and be based on good clinical practice and evidence based medicine.

The current guidelines are based upon a synopsis of relevant published data and guidelines of the Heart Rhythm Society (HRS) and European Society of Cardiology [1-6]. The recommendations have been modified for local conditions.

## DEFINITION OF A CARDIAC IMPLANTABLE ELECTRONIC DEVICE (CIED) SERVICE

CIEDs include pacemakers, implantable cardioverter defibrillators (ICD), cardiac resynchronization devices (CRT) and implantable loop recorders. Centres that provide specialised training in cardiac pacing and ICD implantation and follow up should have a well-defined service.

## KEY POINTS

Any service/training centre should include the following:

- A minimum of two physicians/cardiologists (and/or surgeons) who are specialists in device implantation. It is recommended that all services should include a specialist in cardiac electrophysiology, or in cases where this is not possible, have established links to an EP centre.
- Appropriate nursing and technical support personnel (at least one paramedical professional who works regularly in CIED).

- Pertinent equipment, including pacing system analysers and programmers from multiple manufacturers.
- An institutional case load of at least 50 device implantations per year, with a mix of types of device implants, including single and dual chamber pacemakers, ICDs and resynchronisation devices, depending on local expertise and training.
- Facilities for computer storage of data and a standardised database for storage of implant and follow up.
- Ability to implant and follow up more than one manufacturer's devices.
- Departmental organisation capable of dealing with the increasing use of device remote monitoring – adequate and timely receipt of remotely transmitted CIED data and clinical support to deal appropriately with such data [7].
- Regular Mortality and Morbidity (M&M) meetings of complications related to CIED implantation and follow up.
- Regular attendance at national and international conferences devoted to implantable device management.
- A training centre should also satisfy the following criteria:
    - Include at least one Cardiac Electrophysiologist.
    - Perform at least 100 device implantations per year (see below), with a mix of types of device implants, including single and dual chamber pacemakers, ICD's and resynchronisation devices.
    - Run a complex CIED follow up service including a well-defined remote monitoring programme.
    - Implant a mix of multiple manufacturers' devices.
    - Have a described training programme and a named training director.

## CIED PRESCRIPTION, FOLLOW-UP AND IMPLANTATION TRAINING REQUIREMENTS

These guidelines have been modified to suit the Australasian working environment. All training should be under the guidance of an experienced mentor/operator who participates in a recognised CIED service and fulfils the criteria outlined above.

## TRAINING

Training is designed in a modular fashion allowing trainees to develop to chosen levels within the specialty: Track I and Track II training.

Track I training allows non implanters to follow up devices and this is particularly pertinent for patients in remote areas where implantation is not performed but local follow up represents a more cost effective service delivery as well as taking into account patient preferences. Individuals completing Track I training are not involved in CIED implant training. However, it is recognised that as technology progresses and device remote monitoring becomes more widespread, Track I training alone might become obsolete in future years. Track I training may be attained via a dedicated CIED or combined CIED/Cardiac Electrophysiology Fellowship or alternatively with additional training within or subsequent to completion of advanced training in cardiology.

Training in Track II includes surgical implantations and management of any resultant complications as well as ongoing follow up of CIEDs [17]. The committee recognise that although training in Track II CIED management may most easily be attained within the confines of a dedicated CIED Fellowship, similar training could be achieved by a combined Cardiac Electrophysiology and CIED Fellowship, through special training during a sabbatical leave or under the auspices of a recognised mentor in private practice. Regardless of training venue, the trainee and mentor should keep a log and submit case lists for review to document fulfilment requirements. The mentor should be willing to attest that the trainee is technically competent at the completion of their training.

A further track (Track III) for highly advanced techniques such a lead extraction is recognised but not discussed further as there are separate guidelines for these. These track levels are based upon a modification of HRS/AHA guidelines updated in 2015 [18].

Regardless of the training taken and successful completion of the requirements within a specific training track (see below), the mentor/director of the training program must be willing to attest to the trainee's competence.

It is also recognised that volume of procedures generally is related to lower mortality and complications and although there are no internationally agreed figures for the volume of CIED implants it is generally accepted from published data that minimum numbers are definable [8-16]. This guideline makes recommendations on minimum numbers both for training and maintenance of competency. It should be stressed that these are minimum numbers and do not necessarily reflect best practice.

## Track I

***Training Requirements*** (Usually completed during advanced training, but may be completed post completion of advanced training)

1. Acceptance into, or completion of, advanced training in either cardiology or cardiothoracic surgery.

2. Demonstration of competency in all pacing principles in Table I. Specifically, the trainee should have a thorough understanding of the indications and contraindications for pacing and defibrillation therapy, the pre-implantation evaluation of the patient and interpretation of all information applicable to the patient's pacing history, such as capture threshold measurements, strength-duration thresholds and curves, sensing threshold measurements, unipolar and bipolar electrograms and impedance measurements. The trainee must also be able to interpret electrocardiograms in patients with CIEDs to determine whether function of the CIED system is normal or abnormal. The trainee must be able to determine the interaction between the patient and the CIED system and be competent to fine tune that interaction for optimal patient benefit. A full understanding of pacemaker and ICD function and programming during and after general surgery is required including advice and support to surgical colleagues. Specific knowledge of pacemaker behaviour during bipolar and monopolar diathermy is required.

3. Participation, during initial training, in at least 150 follow-up visits of patients with implanted arrhythmia control devices, of which the trainee should be the primary evaluator in at least 100. The trainee must demonstrate knowledge of the approach to routine follow-up and troubleshooting of implantable devices. Hands-on assessment should include interpretation of paced and non-paced electrocardiograms, interrogation and programming of devices, evaluation of pacemaker dependency and interpretation of telemetry data. Active participation in diagnosis, prescription and management of 50 patients who require CIED implantation is desirable. Trainees should have exposure to remote monitoring of CIEDs.

### *Maintenance of Competency Requirements*

1. Completion of training requirements as detailed above.
2. Follow up of a minimum of 50 active CIED patients per year.

## Track II

***Training Requirements*** (completed post FRACP or FRACS advanced training) – table II

1. Completion of all requirements described for track I.

2. Training in electrophysiology (as it applies to cardiac pacing), detailed understanding of anatomy relevant to cardiac pacing, pathology, selection of patients and devices, surgical technique, management of complications, CIED electrocardiography and follow-up and cardiac pharmacology as it relates to pacing and defibrillators.

3. Supervised instruction in the surgical techniques required for venous dissection and cutdown. The trainee should be exposed preferably to a number of different vascular approaches including

subclavian and axillary vein puncture as well as cephalic vein cut-downs. This should include experience handling venous dilators and introducers, catheter manipulation within the heart including cannulation of the coronary sinus and passing leads into epicardial coronary veins, intra-operative electrographic recordings and threshold determinations and post-operative care.

4. Participation in at least 100 initial implantations of trans-venous CIEDs as the primary operator with a further 25 as the sole operator[9] all under the direct supervision of a recognised mentor. This should include exposure to CRT devices and implantable defibrillators. For surgeons, some allowance should be made for epicardial implantations completed (n=25). However, since the state-of-the-art for CIED is a transvenous approach, it is essential that the bulk of the training experience be with trans-venous devices. Cardiovascular surgery trainees should be given exposure to trans-venous implantation of pacemakers in training centres where these devices are implanted by cardiologists. Surgeons should also be involved in the correct clinical indication and follow up of CIEDs including management of complications and understanding of appropriate programming.

5. With increasing device complexity the trainee should have detailed knowledge of appropriate device selection for individual patients and knowledge of complex programming for multiple clinical situations

6. Participation in at least 25 revisions of CIED systems. This experience should include replacement of pulse generators, revision and replacements of CIED leads.

7. Preferably the trainee should have exposure to lead extraction techniques (track III). Lead extractions are difficult and require a great deal of experience to perform safely. It is recognised that not every training centre will have expertise in lead extraction. If lead extraction techniques cannot be learned during the training period and trainees want to perform this procedure at a later date, they should seek this experience with an individual expert in these techniques [4].
    - The committee recognises that exposure to lead extraction may be limited in some areas. However it is encouraged that all trainees looking to become full time device implanters are exposed for some periods during their training to the procedure of lead extraction in order to better understand the complexities of the procedure which would enhance their understanding of the potential long term complications during an implant.

8. Throughout training, responsibilities should include the emergency treatment of patients with pacemakers and defibrillators. This will allow the trainee to obtain experience in dealing with acute pacemaker and ICD related problems, including those arising from temporary pacing, the use of emergency trans-cutaneous pacing techniques and management of multiple ICD shocks.

9. ICDs and CRT have traditionally been prescribed, implanted and followed up by cardiac electrophysiologists. With the expanding indications and demand for ICD implantation there has been a move towards non-electrophysiology trained cardiologists prescribing and implanting ICDs for primary prevention indications. The basis of this move is the assumption that appropriate device selection, implantation and follow-up in this group requires less training and experience than in the case of secondary prevention ICD implantation. There is little evidence to support this approach. Indeed, there are data to support improved outcome when ICD and CRT procedures are performed by experienced implanters5. However, there may be instances where a non-electrophysiology trained individual may implant ICDs and CRT. We would recommend that in addition to the training requirements above, participation in at least 15 CRT and 20 ICD procedures be performed as primary operator under direct supervision of a recognised mentor (see appendix 1).

### *Maintenance of Competency Requirements*

All surgical procedures imply a balance between volume of procedures and outcome and safety both an individual implanter and also with a training centre. The committee also recognises that for some patients great distances are involved and local implanting centres may not be able to achieve high volumes compared to some Metropolitan centres. There is a balance between these parameters particular if local access for patients is considered important. These numbers for maintenance of skills are set as a minimum and although may not be ideal reflect a balance between outcome and safety and practicality of service delivery.

1. Implantation of a minimum 25 new trans-venous device implantations and 5 revision procedures per year. Low volume of CIED implantation is associated with high rates of perioperative complications, including vein access, lead stability and wound problems [10].

2. ICD implantation only to be performed by experienced implanter of CIEDs – minimum of 35 implantations of CIEDs per annum and at least 100 in previous 3 years. To maintain competency in ICD, it is recommended that ideally >20 ICD procedures are performed per year. We also recommend that a CIED service where ICDs implanted should include a minimum of one electrophysiologist for decision support and troubleshooting.

3. Cardiac Resynchronisation therapy (CRT) – As it is recognised that CRT implantation is technically more challenging in respect to left ventricular lead placement and troubleshooting in order to maintain competency, it is recommended that ideally >12 procedures are performed per year [18]. A full understanding of the latest developments in both coronary sinus lead technology and delivery systems should be maintained in addition to an understanding of the potential complications and their management with particular reference to CRT and coronary sinus lead delivery.

## FUTURE CONSIDERATIONS

There is a worldwide trend recognising the increasing complexity of device prescription and implantation and CIED therapy is being promoted as a specific sub-specialty. The current guidelines include future planning for further discussion:

- *Mandatory* data collection, audit and procedure outcome
    - Each individual implanter should be expected to keep a regular log of their procedures and outcome which should be submitted to a standardised centralised database in a timely manner
    - A database of device implant rates and complication is currently being developed which the society supports and encourages. An anonymised central database of procedural outcomes both acute and chronic should be considered in the future.
- It is proposed that a centralised training document including training videos be developed and made available on either the CSANZ website or via the HeartOne website which can be accessed by trainees and recorded as completed. Modules would be developed in specific areas such as cardiac anatomy related to pacing, implants techniques etc. It is felt that this would expose the trainees to an accredited, minimum consistent level of training.
- Future technological advances, for example, leadless pacing and His bundle pacing etc, should be initially trialled only in recognised high volume implant centres prior to more widespread dissemination to the general implanting community.
- It is proposed at some stage to develop specialised training centres within Australia and New Zealand similar to those currently under discussion and development by the European Heart Society whereby training fellows will be able to train for a year of two, at experienced high volume centres under recognised accredited implanters and to enable access to new and future devices and technological advances. Such centres would be endorsed by the Heart Rhythm Council of CSANZ.
- These guidelines should be considered for revision every two to three years to accommodate the rapid changes occurring in the field

## TABLE I

- **History:** Symptoms that suggest a pacing system complication, e.g. pacemaker syndrome, extracardiac stimulation, inappropriate rate response and loss of capture. Understanding interactions of pacemakers with drugs and implantable cardioverter defibrillators.
- **Physical Examination:** Physical signs of pacing system complications. Expected appearance of pacemaker pocket and incision. Anatomical complications and recognition of rare complications such as occlusion of the superior venous and thoracic veins.
- **Chest Radiography:** Assessment of pacing system, i.e. lead and electrode placement, lead integrity and pulse generator orientation and identification.
- **Electrocardiography:** Thorough understanding of normal and abnormal pacemaker function and of magnet function.
- **Mode Codes:** Understand the accepted nomenclature for pacing modes.
- **Indications:** Understand the current guidelines for CIED indications. Proper prescription of, contraindications for, and understanding of complications of single chamber, dual chamber, rate adaptive and anti-tachycardia devices.
- **Telemetered Pacemaker Data:** Programmed data, measured data, rate histograms, electrograms and other diagnostic data.
- **Device:** Understanding of basic pulse generator design and function. Physiology of electrical stimulation and the genesis of the endocardial electrogram.
- **Programming:**
  - Sensing threshold.
  - Stimulation threshold.
  - AV conduction assessment.
  - VA conduction assessment.
  - Assessment of chronotropic incompetence.
  - Optimisation of physiological function.
- Initiation and management of pacemaker-mediated tachycardia.
- Uses of available programmable pacing modes: rate programming, output programming, sensitivity programming, refractory period programming, rate adaptive parameters, mode switching, rate drop function.
- Complications of programming: rate changes, oversensing, undersensing, cross-talk, noncapture.
- Differential diagnosis of device and lead malfunction.
- Non-invasive programmed stimulation.

[For further details on specific training requirement refer to: 2015 ACC/AHA/HRS Advanced Training Statement on Clinical Cardiac Electrophysiology (A Revision of the ACC/AHA 2006 Update of the Clinical Competence Statement on Invasive Electrophysiology Studies, Catheter Ablation, and Cardioversion). Zipes DP, Calkins H, *et al*; JACC 2015;66(4):2676-2712]

## TABLE II

- To understand in detail the basic principles of pacing both electrically and the engineering involved
- To understand pacemaker lead construction and characteristics
- To understand the published guidelines for implantation of pacemakers and clinical indications
- To understand in detail the implantation procedure, and the cardiac and thoracic anatomy, the cardiac conduction system and its disease processes.
- To master safe sterile technique for all procedures, appreciating sterility and antibiotic usage
- To have detailed knowledge of the programming of modern pacemakers following implantation including troubleshooting
- To demonstrate appropriate skills in correct patient selection.
- Safe implantation of single and dual chamber pacemakers via the cephalic, subclavian and axillary approaches.
- To demonstrate safe and competent intravascular catheter manipulation
- Surgical skills in opening, manipulating and closing wounds.
- Managing acute and late complications e.g. cardiac tamponade, cardiac laceration etc
- In the insertion and care of temporary pacing wires including detailed and safe approach to cephalic, subclavian or internal jugular venous access.
- Competent Programming of pacemakers and troubleshooting including the programming of sensors, and newer anti-atrial tachycardia algorithms
- To work closely with other health care professionals as necessary: e.g. cardiac technicians, Cardiologists, Infection control, Care of the elderly, Neurologists
- To appreciate the psychological impact of the patient's arrhythmia illness on the patient and their family, and manage it sensitively.
- Understand the principles of ICDs and the published guidelines for ICDs.
- To carry out specialist investigation and treatment of patients who may benefit from ICD implantation
- To understand the implantation procedure, and the cardiac and thoracic anatomy and master safe sterile technique for all procedures
- To be able to implant single and dual chamber ICDs, and recognise and treat complications which may occur during and after implantation
- To be able to program ICDs, provide zones for ventricular tachycardia of various rates, algorithms for discrimination between ventricular and supraventricular tachycardia, appropriate use of antitachycardia pacing algorithms, and appropriate shock therapy.

- To be able to "trouble-shoot" ICD problems, including the recognition of; drug-device interactions, appropriate and inappropriate shocks, device and lead complications, and problems that may require specialist intervention such as ablation (for both supraventricular and ventricular arrhythmias)
- To appreciate the role CRT plays in the management of patients with CHF.
- To undertake implantation of CRT devices with a high probability of success.
- To recognize and deal with complications of implant or device behaviour.
- To be able to optimize therapy delivery.
- To be able to programme the devices appropriately, and to advise on optimisation using recognized techniques, including echocardiography, electrocardiographic approaches and newer haemodynamic techniques.

[For further details on specific training requirement refer to: 2015 ACC/AHA/HRS Advanced Training Statement on Clinical Cardiac Electrophysiology (A Revision of the ACC/AHA 2006 Update of the Clinical Competence Statement on Invasive Electrophysiology Studies, Catheter Ablation, and Cardioversion). Zipes DP, Calkins H, et al; JACC 2015;66(4):2676-2712]

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# APPENDIX 1

Procedures Numbers*

| | CIED procedures |
|---|---|
| CIED implantation | 100 |
| Pacemakers | 40† |
| ICDs | 60† |
| CRT pacemakers or ICDs | 25‡ |
| CIED replacement/revision | 30 |
| CIED interrogation/programming | 200 |
| CIED interrogation/programming, pacemakers | 100 |
| CIED interrogation/programming, ICDs | 100 |
| Remote device interpretation§ | 50 |

*Actual numbers that should be performed and/or interpreted successfully to achieve competence are intended as general guidance, based on the educational needs and progress of typical CCEP trainees. †Of which at least 20 should be dual chamber. ‡Also count as pacemaker or implantable cardioverter-defibrillator implants. §The remote interrogations can be included as CIED interrogation/programming number requirements [18].

[ACC/AHA/HRS Advanced Training Statement on Clinical Cardiac Electrophysiology (A Revision of the ACC/AHA 2006 Update of the Clinical Competence Statement on Invasive Electrophysiology Studies, Catheter Ablation, and Cardioversion). JACC 2015;66(4):2676-2712]