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## Practice Guidelines

# Consensus statement for implantation and follow-up of cardiac implantable electronic devices in India



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## ABSTRACT

Cardiac implantable electronic device (CIED) procedures are being done by many operators/centers and it is projected that this therapy will remarkably increase in India in the coming years. This document by IHRS, aims at guiding the Indian medical community in the appropriate use and method of implantation with emphasis on implanter training and center preparedness to deliver a safe and effective therapy to patients with cardiac rhythm disorders and heart failure.

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## 1. Introduction

In India, every year nearly 40,000 permanent pacemakers (PPM), implantable cardioverter defibrillators (ICD) and bi-ventricular pacemakers (cardiac resynchronization therapy - CRT) are implanted [1]. These devices are all together called cardiac electronic implantable devices (CIED). The burden of arrhythmias and heart failure benefitting from CIED implants, along with its recognition and therapy prescribed is increasing and projected to exponentially rise in the coming decades.

The purpose of this document is to lay outlines for availability of appropriate facilities and training of implanting physicians and

paramedical staff in order to ensure safe and effective therapy of CIED.

It should be understood that competency here has been defined as per what a core committee of Indian Heart Rhythm Society (IHRS) members feel appropriate for training requirements for CIED implantation. The numbers though quoted are indicative and not an absolute requirement; however it should be considered as bare minimum requirement as evidence of competency or the ability to provide a safe implantation.

This document intends to provide an India-specific template for CIED therapy to patients at new startup centers and also a working framework to existing centers with a successfully running device implantation program to improve outcomes.

## 2. Definitions

Definitions used in this document are used to delineate certain

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### Abbreviations

CIED	Cardiac implantable electronic devices
TPM	Temporary pacemaker
PPM	Permanent pacemaker
ICD	Implantable cardiac defibrillator
CRT	Cardiac Resynchronization therapy. CRT-P: Pacing only. CRT-D With ICD (Combo Device)
SCD	Sudden cardiac death
ILR	Implantable Loop recorder
MCI	Medical Council of India
DNB	Diplomat of National Board
Cath.	Catheterization
Lab	Laboratory
PT	Prothrombin time
aPTT	activated partial thromboplastin time.
ECG	Electrocardiogram
ECHO	Echocardiogram

criteria and are as follows:

**Physician:** A medical doctor who is in charge of taking the decision for further management based on the patient's condition.

**Center:** A single hospital site where CIED are implanted.

**Operator:** A physician who implants the cardiac device.

**Proctor:** An experienced/high volume operator, who may render his/her services on call to a center that does not have trained operators.

A physician and an operator may work at more than one center. The procedures included in this document are:

1. Temporary pacemakers (TPM) implanted for bradycardia as a bridge to permanent pacemaker or to tide over the transient cause of bradycardia.
2. Permanent pacemakers (PPM) implanted for irreversible bradycardia indications.
3. Implantable cardioverter defibrillators (ICD) implanted for secondary or primary prevention of sudden cardiac arrest (SCD) in patients at risk.
4. Cardiac resynchronization therapy (CRT) devices (bi-ventricular pacemakers) for therapy of heart failure. They include pacing only (CRT-P) or incorporated with defibrillators (CRT-D/Combo device).
5. Implantable loop recorders (ILR)

### 3. Treatment indications

Implantation of CIED's across various spectra of indications improves morbidity and/or mortality and the indications are outlined by various guidelines [2–6]. Guideline based indications of CIED device implantation aims to bring uniformity in physician advice for a given patient all across the country. However a physician and operator both need to decide the need for implantation of device based on the risk of implantation versus the benefit that implantation of device offers in a particular patient individually. It should be understood that published guidelines may not include all patient groups and may not be appropriate in all situations and therefore clinical judgment based on clinical evidence and published guidelines must be used by the physician in arriving at an appropriate safe and beneficial clinical decision. It is important however, to appropriately inform and discuss the treatment offered with the patient and his/her relatives to appropriately make them

understand the benefits, that a CIED being offered, would bring. In situations of clinical uncertainty, or when higher risk of implantation is understood by the physician and the operator, referral to, or discussion with an experienced colleague is recommended. Cost of the device also is an important consideration, especially when being provided by government sponsored schemes. Hence the advice on need of implantation of a CIED may vary occasionally across different centers based on variety of factors and individual experience. Appropriate choice of device is a must, as further upgrade of devices is not only more costly, but increases procedural time and risk of infection [7].

The indications as cited for implantation of a CIED should always hold documentation of scientific and evidence based indication as well as hold compassionate grounds taking into account the socioeconomic status into consideration and should at all times be an informed clinical decision being accepted by the patient and/or the patients relatives.

### 4. Requirements for performing CRM device implantation [8–11].

Safe and successful device implantation requires appropriate physician knowledge, operator training, facilities and equipment and trained paramedical staff.

#### 4.1. Operator

- A primary operator can be one who has undergone certified training in cardiac electrophysiology from a MCI/DNB board recognized institute in India or equivalent recognized degree from abroad.
- A primary operator can be one who has passed a cardiology training program i.e. DM Cardiology/DNB Cardiology from a MCI/DNB board recognized institute in India or equivalent recognized degree from abroad
- They should satisfy the following recommendations.
  - For Temporary Pacemakers
    - Each operator should have had appropriate training in temporary pacemaker implantation defined as either assisting or implanting under supervision at least 20 TPM.
  - For Permanent Pacemakers
    - Each operator should have had appropriate training in pacemaker implantation defined as either assisting or implanting under supervision at least 20 PPM under an experienced operator or at a high volume center.
    - An experienced operator should have performed  $\geq 60$  PPM implants in the last 2 years.
    - At least 10 atrial lead insertions should be done under supervision for the operator to be competent to implant a dual chamber pacemaker/atrial pacemaker.
    - All operators must be fully competent in pacemaker follow-up.
  - For ILR implantations
    - Operators who have been trained in pacemaker implantations can undertake ILR implantations.
  - For ICD implantations
    - ICD implantations should be done only once the operator is appropriately trained for PPM implantation.
    - Each operator should have appropriate training in ICD implantation defined as either assisting or implanting under supervision at least 10 ICD under an experienced operator or at a high volume center.
    - An operator could be considered experienced if he/she has performed 30 ICD implantations in the last 3 years.

- The operator should have understood defibrillation testing (DFT) and should be competent to do DFT when required.
- The operator should be technically competent to understand the parameters programmed and ICD hardware
- It is desirable that the operator be familiar with sub-muscular implant techniques.
- The operator should be well versed with resuscitation techniques in case of emergencies arising during the procedure.
- Follow up of ICD under supervision of at least 20 ICD cases should be there.
- The operators must be fully competent in ICD follow-up and should be able to take care of emergencies arising at the point of care.
- Presence of an anesthetist is desirable during an ICD implantation procedure.
- For CRT (P or D) implantations
  - CRT implantations should be done only once the operator is appropriately trained for PPM implantation.
  - Each operator should have appropriate training in CRT implantation defined as either assisting or implanting under supervision at least 15 CRT under an experienced operator or at a high volume center.
  - Coronary sinus cannulation either during CRT or during electrophysiology procedure in at least 15 cases should be done under supervision prior to initiation of CRT implantation independently.
  - An operator could be considered experienced if he/she has performed 30 CRT implantations in the last 3 years.
  - The operator should be well versed with complications of the procedure and know how to handle them along with the resuscitation techniques in case of emergencies arise during the procedure.
  - The operator should be technically competent to understand the parameters programmed and should be able to optimize CRT therapy on follow up.
  - Follow up of CRT under supervision of at least 20 CRT cases should be performed.
  - The operators must be fully competent in CRT follow-up and should be able to take care of emergencies arising at the point of care.
  - Presence of an anesthetist is desirable during a CRT implantation procedure.

Virtual simulator training of implantation of devices is not considered as an acceptable alternative for being eligible to do CIED implantation unless it is a new technology not introduced elsewhere, but certainly can be used to pre-train new implanters for them to understand the procedure well before they enter in actual cases of device implantation.

Proctors, who are experienced operators for implanting devices, can be called at new centers in which the primary operator is not well trained and the patient cannot be shifted.

#### 4.2. Centers

- Implantation should be performed in an appropriately prepared and well equipped cardiac catheterization (cath) laboratory (lab).
- Appropriate sterile measures should be ensured by all personal of the cath lab.
- Presence of external defibrillator is a must.
- Presence of R2 pads (subcutaneous pads) for external defibrillation is a must for ICD/CRT-P/CRT-D implantation procedure.

- Appropriate hardware for device implantation should be available readily during device implantation.
- The center should have at least 2 trained nurses and a cath lab technician assisting the procedure.
- High volume center is defined as centers
  - Which perform  $\geq 70$  PPM implants/year
  - Which perform  $\geq 20$  ICD implants/year
  - Which perform  $\geq 20$  CRT implants/year
- It is desirable to do ICD's and CRT implantations at high volume centers where experienced operators are also working.
- Center should have in-house device programmers to interrogate CIED devices in cases of emergency. A magnet should also be kept in cases of emergency.
- It is advisable that each center should maintain a database of patients with CIED's and also of their follow up and complications if any. This database should allow immediate tracing of patients with device advisories.
- It is important for a center to periodically review and audit all CIED implantations to maintain good clinical practice standards.
- Centers should encourage active training and continuous education of operators, physician and supportive staff for delivery of safe and effective therapy with CIED for those who may benefit from it.

#### 5. Implantation techniques and guidelines of preparing patient for device implantation, especially with a view to prevent device infections [9–13].

Basic implantation technique has been described, and is beyond the scope of this document. Knowledge of testing of the lead parameters for sensing and pacing is essential. This includes a basic understanding of the electrical theory for appropriate pacing and an ability to use the pacemaker system analyzer. For generator change, operators must be familiar with the special problems likely to be encountered at the time of generator change, especially the risk of damage to leads. Furthermore, it is necessary for the implanter to know about acceptable parameters/ways for connection of a new generator to old pacing leads.

Preparation of patient should be like a surgical preparation. Shaving from neck to umbilicus and also groin shaving should be done preferably using electric clippers rather than razors. 4% Chlorhexidine/Povidone Iodine bath with sterile drape after the bath should be done preferably the day prior to the procedure. 2 venous accesses, one on each hand is preferable as it will help to deliver drug therapy and also to take venous angiogram, if required, with ease. Antibiotic should be administered preferably within half an hour of skin incision. Choice of antibiotic is based on local institute practice.

The air requirements specified for cardiac catheterization laboratories is at least 15 air changes/hour, but 25 air changes/hour as recommended for operating theatres, is ideal. All cath lab staff should be identified prior and minimum number of staff required for the procedure should be allowed entry thereafter. All staff should wear appropriate cath lab dress and cap and mask and appropriate cath lab footwear. It is desirable that the operating team should remove hand/wrist jewelry, artificial nails and nail polish before procedures. Patient should be in appropriate clothing and with a cap and mask, when taken in the cath lab. ECG leads should be attached at sites which are easy to access.

Temporary pacemaker implantation should be done with aseptic precautions. Venous angiogram is desirable to be done pre-draping as venous anomalies can be diagnosed and further choice of site of implantation can be made and also serves as a roadmap for puncture.

The scrub nurse and operator should employ standard hand

washing techniques till the elbow and should wear the gown using sterile techniques. Double gloves preferably should be worn by the scrub nurse and the operator using sterile techniques. The scrub nurse should then prepare the trolley. Sterile Image intensifier cover should be placed then. Local site preparation with at least 4% chlorhexidine solution or Povidone iodine in alcohol or other antiseptics should be done according to the prevailing practices. Neck to axilla to Xiphi-sternum should be included in the scrub. A minimum contact time of 30 seconds should be given and the solution should not be allowed to pool at a place. No sticking material or unclean area should be visible by the end of scrubbing.

Draping should be done in such a way that only local site where incision is to be made is exposed. Use hole (fenestrated) towels/disposable sheets. It is desirable to use two layers of drape to cover the area (especially the part on the table) and cover from head to toe. The patient should be able to breathe properly and appropriate measures to be taken to avoid claustrophobia in case the towels are placed over the patient's head. The exposed local site should be covered preferably with an adhesive film so that only the site of incision is exposed. Procedure is done with care to avoid infection using standard techniques. Use of cautery is preferable to avoid bleeding and avoid post procedure hematomas. Local instillation of antimicrobials or antiseptics has not shown to be of benefit to prevent infections. The assistance of a trained surgeon should be obtained if required.

Post implantation of pacemaker, the drapes should only be removed once the skin has been closed and that the pacemaker leads are stable in place. The venous access on the same side of the pacemaker should be preferably removed to avoid any future thrombophlebitis and local infection. The patient then can be shifted out of the cath lab. Paramedical staff should be instructed to employ sterile techniques while giving intravenous medications. Post implant antibiotics, though not necessary, can be given as per institute protocol.

## 6. Implantable device follow-ups [9,14,15]

Unlike many other medical implants, the CIED implants need a regular and life-long follow-up check and appropriate programming to improve patient outcomes. After a successful CIED implantation, patients require timely follow-up checks, on out-patient basis with the help of programmers. These programmers can read the device performance and one can program various features to optimize its functioning [16]. Operators or the physician should actively follow-up patients and programming of devices should be done under their supervision with an aim to deliver optimum therapy in the safest possible way and to recognize device and patient related issues at the earliest. If physician is not versed with the programming then he/she should refer patient to persons who do the device follow up. Implanters should undergo regular training and update themselves with the newer algorithms in devices for programming. Majority of current MRI compatible CIEDs, need manual programming change before and after the MRI procedure [17].

- For Pacemakers after implantation, device interrogation and clinical follow up should be done at the time of discharge and then at 1, 3 and 6 months. Thereafter in patients with no associated cardiac disease, device follow up can be done once a year till the time of battery approaches 75% of battery status or near elective replacement indicator (ERI) or device demonstrates sudden changes in parameters. Nearing ERI, follow up should be maintained according to the expected life of the device. Device checks include battery voltage, lead impedance, pacing thresholds, sensitivity and evaluation of clinical events if any.

Appropriate changes in the programmable parameters should be done actively in order to increase device longevity along with maintaining patient safety.

- For ICD and CRT after implantation, device interrogation and clinical follow up should be done at the time of discharge and then at 1, 3 and 6 months. Thereafter follow up every 6 months is advisable till the time of battery approaches elective replacement indicator (ERI). Nearing ERI, device follow up should be maintained according to the expected life of the device. Device checks include battery voltage, lead impedance, pacing thresholds, and sensitivity. Appropriate and inappropriate ICD therapies should be analysed and device re-programming should be done as necessary. Fluid overload indicators and ST segment indicators need to be clinically correlated and therapy changed accordingly. Clinical evaluation, ECG and Echocardiogram should be done on follow up of the patients having CRT in order to monitor ejection fraction. In cases when the response to treatment by CRT is inadequate, a thorough evaluation of concomitant therapies, device programming along with echocardiographic optimization and/or opinion of experienced operator should be taken to ensure best possible outcomes.
- Remote monitoring of devices should be encouraged especially in patients residing far away from implant centers or hospitals/clinics that perform these device checks and in high-risk patients, who are likely to require frequent device follow up checks. These monitoring systems have significantly reduced the burden of routine personal visits by the patient and simultaneously have shown to improve clinical outcomes by an advanced alert system due to any device or medical issue [18]. For patients with remote monitoring, in-person follow up visit may be necessary at least once a year, to evaluate the overall clinical status. Physicians taking responsibility of remote monitoring should be appropriately trained to manage patient follow up.
- Centers should ensure appropriate training of paramedical staff and nurses to facilitate and channelize the CIED follow up. IHRS is of the view, that there is a need to create a pool of specially trained 'Cardiac Rhythm Device Specialist' technicians who are available on request of cardiologists to help with device programming and troubleshooting in their presence. This includes programming during non-cardiac surgery, and during MRI scans. IHRS will help in training and certification of these technicians.
- Resuscitation equipment should be available during follow-up checks. Any change in parameters should be done only in consultation with electrophysiologist or a cardiologist trained in CIEDs. A final parameter interrogation printout should be preserved in patient records. It is encouraged that the follow-up center preserve and maintain all such records.
- All patient and/or relatives should be appropriately informed regarding the device status and future dates of follow up. Intervention if required due to any device related issues should be discussed amongst the operator, physician, device company representative, clinical staff and/or cardiac surgical team if required and plan of management should be discussed thoroughly in the best interest of the patient.
- Development of CIED follow-up clinics should be encouraged at all implant/follow-up centers, with a team comprising of implanting cardiologist/electrophysiologist, technicians/nurses trained in device interrogation, device industry engineers and junior/trainee/assistant cardiologist [19].
- It is recommended that the implanting physician, residents in cardiology/electrophysiology training, CIED technicians/nurses and the device industry personnel/engineer undergo proper

training and regularly update themselves with the device features and programming options.

## 7. Role of device industry engineer/technician for CIED follow-up checks

At present no legal regulatory framework or formal recognition of the role of paramedical personnel (physician assistants, nurses, technicians, etc.) in device follow up exists in India and as such, any role played by them must be under the direct supervision of a responsible physician. The role of the industry employed allied professional (even if qualified as a paramedical) is limited to the provision of information and technical support, as well as updating on device-related advisories and recalls, always under the direct supervision of a responsible physician. Specifically, the practice of using the services of industry employed allied professionals for long-term direct technical support for routine follow-up is not desirable. Under no circumstances should CIED follow up (especially ICD and CRT) be done by industry employed allied professionals alone, who have little or no knowledge of clinical condition.

- The device industry engineer or technician may do the follow up check, if requested by the cardiologist/physician. However, any device interrogation, programming or troubleshooting should be done only in the presence of the doctor and in a hospital or clinic setting.
- IHRS is against the practice of industry having paid service agreements with patients for CIED follow-up checks. This is on assumption, that when a CIED is sold to the patient, the manufacturer is bound by warranty and service contract for the service life of the device.
- The company should be approachable for information regarding the device, warranty obligations, and help during recall or advisories. However, IHRS objects to the practice of patients being contacted by the industry/helpline services for scheduling follow-up visits. Even when approached directly by patients for device programming, industry representatives should only help to connect them with implanting cardiologist/electrophysiologist. Industry representative should not organize and conduct a follow-up except under the instruction of a physician. Inability to follow this protocol will make the industry liable for any adverse outcome.

## 8. Concluding remarks

This document was prepared with the purpose of establishing standard CIED implant guidelines for safe and effective CIED implantation and follow up in order to improve patient outcomes. IHRS realizes the need for rigorous follow up and monitoring of CIED implants and creating a registry data of all CIED implants to understand better the pitfalls of this therapy in the Indian context and devise better guidelines. A systematic approach to CIED implantation and follow up, and engagement with governmental health regulators and the device industry should help improve the standard of care in CIED implants.

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