Working Group of Cardiac Pacing and Electrophysiology of the Swiss Society of Cardiology

2015 guidelines update for performing cardiac implantable electronic device procedures and catheter ablation of arrhythmias

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Summary

Guidelines defining competency for performing procedures involving cardiac implantable electronic devices and catheter ablation of arrhythmias have been published by the Working Group of Cardiac Pacing and Electrophysiology of the Swiss Society of Cardiology since 2000. These guidelines have been updated in 2005 and 2011 with the evolution of procedure complexity. They define not only the requirements for baseline training, but also the procedural volume and continued medical education to maintain competency. The current update is warranted owing to the new certification standards of the European Heart Rhythm Association, publication of data on outcome linked to procedural volume, and the emergence of new technologies.

Key words: cardiac pacemaker; implantable cardioverter defibrillator; catheter ablation; implantation; follow-up; guideline

Rationale

In 2011, our Working Group published guidelines on pacemaker (PM) / implantable cardioverter defibrillator (ICD) implantation and follow-up (including remote device management), as well as on catheter ablation of arrhythmias [1–6], based upon the European guidelines defining competency for heart rhythm specialists [7]. Since the publication of these guidelines, new standards for European Heart Rhythm Association (EHRA) certification have been defined (http://www.escardio.org/communities/EHRA/accreditation) and new data and technologies have emerged, which warrant the current update.

Competency for performing procedures

The requirements for competency outlined in the 2011 guidelines remain valid unless stated otherwise in this update. Physicians must have undergone at least 1 year of specific training in a recognised teaching centre, and should be full members of our Working Group. A summary of the criteria are outlined in table 1.

Device follow-up: Physicians performing device follow-up should fulfil EHRA level 1 certification (i.e., pass the EHRA pacing exam). In addition, a logbook of the minimum number of follow-ups corresponding to the EHRA level 2 certification needs to be completed:

– 200 device follow-ups as a first operator including at least 100 high-energy devices (ICDs/CRT-D) and 50 cardiac resynchronisation therapies (CRT-D/P)

These items have to be performed within a period of 24 consecutive months (taken any time from 2 years before up to 2 years after the year of the exam) in a recognised teaching centre.

The numbers of follow-ups required to maintain competency remain unchanged compared with the 2011 guidelines (table 1). As stated in the 2011 guidelines, centres with high device follow-up volumes may employ allied professionals to perform the follow-ups under the supervision of a physician who fulfils the requirements for competency outlined in the present document.

Routine device follow-ups are medical procedures and must not be performed by industry representatives. Their services should only be requested if company-specific problems are identified which cannot be solved otherwise. Device companies that propose a programmer to physicians must receive a signed

Table 1: Minimum requirements for acquiring and maintaining competencies in device therapy and percutaneous catheter ablation of arrhythmias for cardiologists with a FMH title. Membership of the Swiss Working Group of Pacing and Electrophysiology is mandatory for all categories.

Acquisition of competency	**Minimum requirements (as first operator)**
Catheter ablation of arrhythmias	Pass the EHRA EP exam 100 diagnostic EP studies (standalone or prior to ablation) 100 catheter ablations. These must consist of: *50 standard ablations including* His bundle – maximum 5 AVNRT – 15–25 AVRT – 15–25 right atrial tachycardias – 5–10 cavo-tricuspid atrial flutter – 10–25 idiopathic VT/VPB – 5–10 *50 complex ablations,* at least 30 of which are atrial fibrillation ablation, including transseptal puncture.
Device follow-up	Pass the EHRA cardiac pacing exam (level 1 EHRA certification) At least 200 follow-ups including at least 100 high-energy devices (ICDs/CRT-D) and 50 CRT (CRT-D/P)
Device implantation	Pass the EHRA cardiac pacing exam At least 200 follow-ups including at least 100 high-energy devices (ICDs/CRT-D) and 50 CRT (CRT-D/P) Implantation logbook for primary interventions within 2 consecutive years in a teaching centre (refers to the declared competency): PMs: 45 ICDs: 25 CRTs: 30
Lead extraction	At least 40 lead extractions via different approaches, including femoral workstations
Maintainance of competency	**Minimum requirements (as first operator)**
Device follow-up	PM: 50 patients/year ICD: 30 patients/year CRT: 20 patients/year (may be cumulated with PM/ICDs) 10 hours of specific post-graduate training/year
Device implantation	PM: 20/year* ICD: 20/year* CRT: 20/year (primary implantations or upgrades) 10 hours of specific post-graduate training/year
Lead extraction	10 patients/year or 15 leads/year
Catheter ablation of arrhythmias	50 ablations/year AF: 25/year 15 hours of specific post-graduate training/year

* Includes generator changes.
AF = atrial fibrillation; CRT = cardiac resynchronisation therapy; EHRA = European Heart Rhythm Association; EP = Electrophysiology; EPS = electrophysiological study; ICD = implantable cardioverter defibrillator; PM = pacemaker

declaration by the physician (downloadable on www.pacemaker.ch and sent to our secretariat) stating that the physician fulfils the requirements for competency for device follow-up according to our guidelines.

Device implantation: Physicians performing device implantation should have completed EHRA level 1 certification and fulfil the numbers of procedures as first operator defined in the 2014 EHRA logbook requirements. The definition of a first operator relating to a trainee includes supervision by the trainer to perform at least one critical step in the procedure (e.g., venous access or lead placement). These minimum numbers should be fulfilled for the competency they wish to declare i.e., the declaration may be limited to PM or ICD implantation only.

- PM primary implantations: 45
- ICD primary implantations: 25
- CRT primary implantations/upgrades: 30

These items have to be performed within a period of 24 consecutive months in a recognised teaching centre, with a logbook signed by the trainer.

Leadless PMs and subcutaneous ICDs have just recently been introduced. Patient management involves not only device implantation but also proper evaluation for indication, alternative treatment options, risks and limitations, competency for optimal programming and device follow-up. Therefore, implanting physicians must fulfil the same minimum requirements as for standard PM and ICD implantation. In addition, we strongly recommend that physicians follow training for implanting these devices as the techniques are specific to these procedures.

At least 20 PMs and 20 ICDs should be implanted annually (primary implantations or generator changes, both as first operator) in order to maintain competency in these fields. Regarding CRT implantation (either CRT-P or CRT-D), at least 20 primary procedures or upgrades (i.e., addition of a coronary sinus lead to a pre-existing system) must be performed as first operator.

Lead extraction: The 2011 guidelines require that operators extract at least 15 leads/year, and the current update adds that competency may also be maintained by performing lead extractions in at least 10 patients annually. These criteria apply to leads implanted at least 1 year previously or to a lead, regardless of the duration of implantion, requiring the assistance of specialised equipment that is not included as part of the typical implant package, and/or removal of a lead by a route other than via the implant vein [8]. Institutions performing lead extraction must have cardiosurgery back-up and need to make sure that the patient can go on cardiopulmonary bypass within minutes in order to manage intrathoracic bleeding.

Interventional electrophysiology: EHRA has recently adapted its logbook requirements for achieving full (level 2) certification in interventional electrophysiology for the candidates sitting the exams as from 2014. As full EHRA certification in interventional electrophysiology is a requirement for competency since our 2011 guidelines, the new requirements apply to our update and are listed below:

- 100 diagnostic EP studies (stand-alone or prior to ablation)

– 100 catheter ablations as first operator. These must consist of:
  50 standard ablations including:
    His bundle – maximum 5
    AVNRT – minimum 15, maximum 25
    AVRT – minimum 15, maximum 25
    right atrial tachycardias – minimum 5, maximum 10
    cavo-tricuspid atrial flutter – minimum 10, maximum 25
    idiopathic RVOT VT/VPB – minimum 5, maximum 10
  50 complex ablations, at least 30 of which are atrial fibrillation ablations – including transseptal puncture.

The above items have to be performed within a period of 24 consecutive months – these 24 months can be taken any time from 2 years before up to 2 years after the date of the exam.

Our guidelines for competency also apply to newer technologies for nonsurgical atrial fibrillation (AF) ablation, for example, using "single shot" technology such as cryoablation, duty-cycled radiofrequency catheters, laser balloons, etc. These technologies require a full understanding of electrophysiological principles and intracardiac electrograms, not only for executing the procedure in a safe and effective manner, but also for understanding endpoints for successful ablation and handling consequences such as atypical flutter.

Electrophysiologists who wish to maintain competency in percutaneous catheter ablation of arrhythmias must perform at least 50 ablations/year. Regarding AF ablations, the current update recommends a minimum of 25 procedures/operator/year, which, according to recent data [9], has been established as a cut-off for improving procedural success and avoiding complications.

Declarations of competency

Members of the Working Growup are requested to declare their competencies on the website www.pacemaker.ch. In order to fulfil the requirements for competency outlined in the 2011 recommendations and in the current guidelines (table 1), the volumes should be attained within 3 years of starting a new activity. It is the responsibility of our members to update their competencies by autodeclaration, and to inform the Working Group in case of changes. The declarations for maintenance of competency should be based upon the volume of procedures accomplished over the previous calendar year. The Working Group may request documentation upon submission for membership, or in the case of changes or maintenance of competencies, in order to ensure that the information presented on our public website is accurate.

Table 2: Minimum annual volume of centres for maintaining competency for performing device implantation and percutaneous ablation of arrhythmias.

Activity	Minimum centre volume
Device implantation	20/year (in total, including PMs, ICDs and CRTs, primary implantations and generator changes) The operator must fully fulfil the requirements of competency for implantation outlined in the present guidelines
Ablations	50/year For AF: 25/year

Minimum volumes of procedures per centre

Procedural safety and efficacy depend not only on the competence of the operator, but also on that of the medical staff involved in the procedure, who set up the equipment, monitor the patient, perform measurements, dispense postoperative care, etc.

As concerns device implantation, an independent centre should have a minimum of 20 procedures/year (primary implantations and generator changes of PMs, ICDs and CRTs). It should be stressed that the physicians performing these procedures should fulfil competency requirements according to the present guidelines.

According to recent surveys conducted by EHRA [10, 11], Switzerland has one of the highest densities of ablation centres in the world. The current update defines the minimum number of ablation procedures for centres as being 50/year. Regarding AF ablation, the minimum annual volume per centre should be 25 procedures. A summary of the minimum annual centre volumes are listed in table 2. These volumes must be reached within 3 years of initiating an ablation or device programme.

Teaching centres and satellite centres

Teaching centres include the University Hospitals or any other institution that submits a request to the Working Group to be evaluated and recognised as such.

Electrophysiology/cardiac device therapy teaching centre requirements

– One dedicated electrophysiology/cardiac pacing laboratory
– Full cardiology service (cardiac surgery recommended)

– Regular teaching (tracing rounds/trouble shooting)
– Documentation and review of complications as part of the training
– For electrophysiology, availability of at least one 3D mapping system
– For device therapy, implantation and follow-up of devices manfactured by all major device companies present in Switzerland

Staff requirements

– Two senior electrophysiologists – both EHRA members (EHRA certification recommended)
– Programme director should have >5 years of experience in cardiac EP/CP and be a full member of our Working Group

Requirements for fellow participation

– Number of fellows in the centre should allow each fellow to fulfil the requirements of the EHRA logbook for certification in 2 years
– Fellows should be able to perform as the first operator: >50 ablations/year including complex procedures at the end of training; >50 device implants per year including ICDs and CRTs, and >100 device follow-ups per year.

Satellite centres for device implantation

Centres that fail to meet the minimum volume of device implantations may affiliate themselves as a satellite centre of a teaching centre. The affiliation between the satellite and teaching centres should be formalised, with responsibilities of each party being clearly defined (e.g., assistance/supervision of the satellite centre by the teaching centre). The Working Group should be informed regarding this affiliation, and the procedures performed in the satellite centre (with any complications) should be entered separately in the national registry (www.arrhythmia.ch), and not under the statistics of the teaching centre.

Some implanting and ablation centres are part of the same healthcare network, i.e., they involve the same administration, healthcare personnel, electronic database, etc. In this case, the Working Group should be duly informed and the statistics may be entered under the same entity in the national registry.

National CHPACEWEB registry

Our Working Group has been mandated by the Swiss Society of Cardiology to implement a national registry for device implantation and ablation procedures (www.arrhythmia.ch). The main aims of this registry are (1) to maintain quality control (e.g., in case of safety advisories, etc.), (2) to provide benchmarks for procedures in Switzerland and (3) to simplify generation of annual national statistics that provide an overview of healthcare in this field. Following a pilot phase launched in 2009, entry of procedural data in the national registry became obligatory for all centres and physicians performing device implantation and arrhythmia ablation as from the 1 January 2013. Our Working Group manages the registry independently, and strives to provide accurate data. To fulfil this task, centres and physicians may be requested to provide additional information, and quality audits may be performed.

Conclusions

The aim of our recommendations and the present update is to maintain a high quality of care that remains affordable for our healthcare system. As in other fields, proper training and adequate procedural volume [9, 12, 13] are major determinants of quality. The recommendations for acquiring and maintaining competency defined in this update are based upon EHRA criteria and on published data.

Our Working Group relies upon the collaboration of its members to declare their competencies in a transparent manner, and to provide documentation if requested in order to ensure that the information presented on our public website is accurate. We also strongly recommend that our members do not perform technical procedures outside the scope of their declared competencies, not only in the interest of patient safety and quality of care, but also in their own interest in case of legal issues. Adherence to standards and to best practise will also allow our medical community to continue to maintain its position with respect to payers and to political instances.

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References
The full list of references is included in the online version of the article at www.cardiovascmed.ch.

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