Pathways for training and accreditation for transvenous lead extraction: a European Heart Rhythm Association position paper

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Background and aims

Introduction

The European Heart Rhythm Association charged the present writing committee with the task of producing a consensus document on training and accreditation for transvenous extraction of chronically implanted pacing and defibrillator leads.1,2 The core curriculum for the European Heart Rhythm Specialist includes implantation of heart rhythm devices but does not specifically mandate learning and accreditation for extraction techniques.3 The lack of such recommendations is related to the limited number of extractions available for training purposes and attaining competency. The present document focuses on the rising burden and the increasing complexity of techniques of lead extraction with an emphasis on the critical issues of training, accreditation, and documentation of results. There is also an educational component felt necessary to include by the Task Force in view of the specialized and emerging nature of this field. Where appropriate, a European perspective is presented and paediatric aspects are treated separately. The aim is to complement two recently published documents, one from the Heart Rhythm Society (HRS)4 on facilities, training, indications, and management of transvenous lead extraction and the other from the American Heart Association on device-related infections.5 The indications for lead extraction have not changed since these publications and are therefore not covered in this present document.

Need for lead extraction/removal—a European perspective

Due to improving recognition of clinical need and wider indications, the implant rate of Cardiovascular Implantable Electronic Devices (CIED) continues to rise in most countries.6,7 The number of leads per patient is increasing with cardiac resynchronisation therapy—pacemaker/defibrillator, upgrades and a higher proportion of dual vs. single-chamber devices. As life expectancy has risen, so have the number of generator and lead changes despite advances in technology. Product advisories are inevitable despite overall improvements in reliability and have led to surges in extraction.8–10

Currently, infection accounts for approximately two-thirds of all extractions.2,11–15 Lead revisions and generator changes carry a greater risk of infection than new implants. Ageing patients are more likely to be immuno-compromised, to have sepsicaemia16 and to be on anti-thrombotic agents and anticoagulants. These potential risk factors for CIED complication are becoming more prevalent with time along with the risk of hospital acquired infections. The rates of CIED infection are growing out of proportion to the rise in new implants.17 Clinical manifestations of cardiac device infections may be local or systemic, and primary or secondary to sepsicaemia, particularly with staphylococcus.18–20 Although the majority present as a pocket infection or erosion in the absence of sepsicaemia,11,19 the intravascular portion of the lead is usually culture positive.5,21 Superficial skin infection overlying but not

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doi:10.1093/europace/eur338
adherent to the pocket, that responds rapidly to antibiotics, may not require further action. This is in contrast to the treatment needed for pocket infections or erosions. Erosion may be caused by infection or mechanical factors or a combination of the two. Adherence of the generator or leads to the skin often precedes erosion.

Most CIED national databases or registries do not detail the number of extractions, may underreport infections and do not identify or separate out erosions. Where data are available on complications and their treatment, the usual estimate is of prevalence using the number of new implants as a denominator. True incidence calculated from the number of complications expressed as a proportion of the time of exposure to the risk, in this case lead exposure, has rarely been calculated. Local extractions rates will vary on case mix and in-house expertise. Reports from specialized centers are often biased towards more complex systems and include external referrals. The majority of extraction procedures are transvenous and performed by cardiologists and/or cardiac surgeons. Taking all these considerations and limitations in mind, the Task Force has attempted to calculate the total transvenous extraction need based on 1.5 times the prevalence of reported infection in patients implanted with a CIED (Table 1). This broad approximation holds out the possibility of assessing trends and national differences in extraction requirements. The incidence of both infectious and non-infectious cases appears to be rising. It is assumed that the ratio is stable, but in future, the proportion of extractions that are for non-infectious causes may increase reflecting greater extractor experience and confidence. The prevalence of infection from registries and national databases varies widely but mostly within the range of 1–4%.

Details of the criteria of clinical and technical success in lead extraction have recently been reviewed. All leads should be extracted if the indication is infection. However, residual lead tips or conductor coils, in the absence of insulating materials, rarely prevent full recovery from a CIED infection.

### Pathophysiology affecting lead extraction

A full appreciation of the pathophysiology of CIED implantation is critical to understanding of the risks and the training required for successful lead extraction. At the time of implantation of transvenous leads, trauma may occur to the lead and to the route of passage. Rarely, lead parts may be positioned outside the venous system, either due to migration, or placement via or through abnormal structures. Acute thrombus formation and venous occlusion are not uncommon but it is unusual for this to be evident clinically. Leads may suffer from intrinsic malfunction due to shortcomings in design and production. Such malfunction may exist at implant or develop later. Despite meticulous preparation of the skin, bacterial contamination of the generator occurs in up to one-half of all implants. Subsequent clinically relevant infection is uncommon, is more often delayed than acute, and may first become evident years after the implantation.

During the chronic phase of lead implant, thrombus may organize, leading to subtotal or total occlusion along the venous route, and formation of fibrous bridges or tunnels containing the pacing lead at points of adherence.

The commonest binding sites are located at the venous entry, especially under the clavicle, at the brachiocephalic and/or upper caval vein, the right atrium, by adherence to the tricuspid valve or passage through the papillary muscle network, and finally at the electrode–cardiac interface. Binding may also occur between leads, and is more likely if the surface is irregular, most noticeably with implantable cardioverter defibrillator (ICD) lead coils. The fibrous tissue becomes covered with endothelium and sometimes calcifies. These chronic responses to lead implantation are usually progressive, and occur more readily in younger patients. Beyond 1 year from implantation this process directly affects the complexity and risks of extraction.

### Definitions

The Task Force has adopted the definitions as recommended by the HRS:

- **Lead removal**: Removal of a pacing or defibrillator lead using any technique.
- **Lead explant**: Lead removal using simple traction techniques from venous entry site (i.e. no locking stylet, telescoping sheath, or femoral extraction tools).
- **Lead extraction**: Removal of a lead that has been implanted for >1 year, or a lead regardless of the duration of implant requiring the assistance of specialized equipment that is not included as part of the typical implant package, and/or removal of a lead from a route other than via the implant vein. Implantable cardioverter defibrillator leads may require specialized extraction equipment even when implantation duration is <1 year.

Surgical removal, necessary for epicardial leads and also some transvenous leads, is not addressed by this position paper.

### Tools and techniques for lead extraction

The main obstacles to extraction are the tissue binding sites along the course of the lead and the interface between the lead tip and endocardium. For most there is more than one binding site, and simple traction of the proximal lead end will not be transmitted to the distal tip. In these circumstances, there is a significant risk of lead disruption and tissue rupture with all the complications that can ensue. A locking stylet within the lumen of the lead spreads the traction forces along the lead body including the tip. The strength and extent of the bridging tissue may still be too great to safely use this tool alone. Other traction devices include snares, sutures, and grasping devices. It is often necessary to use...
these in conjunction with sheaths designed to directly release bridging tissue. Devices snaring or engaging the lead externally from the femoral or internal jugular route may enable the lead to be routed forwards; this avoids or reduces the risk of catching on bridging tissues.

Lead traction: Refers to the pulling force applied on the lead.

Sheaths: Sheaths operate with simple mechanical action (non-powered) or additional power and may be used singly or housed within a second sheath to create a telescoping system. Using traction through a sheath enhances safety as well as success.

Counterpressure and countertraction: Counterpressure is performed by applying simultaneously a forward pressure on the sheath and traction to the lead. Countertraction is performed when the sheath has been progressed to the lead tip-myocardial surface; the traction applied on the lead is opposed and counterbalanced by pushing pressure of the overlying sheath on the endocardium thereby limiting myocardial invagination or avulsion.

Mechanical tip dislodgement is achieved by rotating motions of a non-powered sheath, allowing mechanical dissection of the surrounding fibrosis.

**Tools**

Locking and other extraction stylets are designed to stabilize and stiffen the lead and to provide traction near the electrode tip. If simple gentle traction fails to remove the lead a sheath system is employed.

Sheaths in combination with a non-locking or a locking stylet enable counterpressure and countertraction causing mechanical dissection, separating the lead from the adjacent tissues. Non-powered sheaths are made of various compounds, including polytetrafluoroethylene, polypropylene, and metal. The aim of powered sheaths is to advance along the lead with reduced traction and counterpressure compared with ‘non-powered’ sheaths. The excimer laser system ablates binding tissue around the circumference of the lead to a depth of 50 μm. The electrosurgical dissection sheath utilizes radiofrequency energy produced by a standard electrosurgical unit to cut through fibrous tissues. The most recent powered sheath, has a cutting screw tip operated by mechanical rotation through a hand held ratchet mounted on the sheath. The shorter version of this can be used to gain venous entry, and both are particularly useful when there is major fibrous and calcified tissue along the track of the lead.

Femoral tools are useful for leads which are not accessible from the original venous entry site because of fracture and retraction into the venous system, for free-floating ends, lead fragments or as operator first preference for intact leads. The usual approach is a long sheath introduced through the femoral vein and used in conjunction with any number of positioning and grasping tools.

**Techniques and approaches**

A detailed review is beyond scope of this position paper. Typically, if the lead is intact, extraction is first attempted by inserting a regular stylet, i.e. a non-locking stylet, to preserve the lead’s lumen, disengaging the active fixation mechanism if present, and applying steady traction. Failing this, the next step is, for most authors, to use a specialized locking stylet. If traction alone is unsuccessful, a sheath is selected; the selection will depend on the potential difficulty of the extraction, lead characteristics and history, as well as operator experience and preferences. Advancement of the sheath over the lead may be curtailed by accumulation (snow ploughing) of endovascular tissue at the tip. This is usually solved by upsizing of the sheath. Leads that are not intact and cannot be removed from the primary venous insertion site may require extraction from the femoral or jugular vein with a variety of tools.

Surgical extraction is usually reserved for failure of the transvenous approach, very large vegetations, and anomalous placement of leads. When transvenous extraction is deemed very high risk, an electively combined approach may be best, so that if perforation were to occur with the chosen transvenous tools, immediate surgical repair would be possible.

**Anticipated difficulty—risk of the procedure**

Transvenous lead extraction carries risk. There are very few comparative trials of lead extraction techniques and even fewer that are randomized. Most reports are of sequential use of different extraction techniques and document operator preference and experience. However, it is clear, that extraction success, for a given casemix, both technical and clinical, has increased over time. Most reports are from high-volume centres with experienced operators receiving referrals from outside their implantation catchment. For smaller centres, the success rate is likely to be less and the complication risk greater. The population requiring extraction is getting older with more complex device systems and prior procedures and more co-morbidities. For the largest published single or multicentre series, each reporting on 975 or more leads, major life threatening complications occurred in 0.4–3.5% of the patients, and death in 0–0.8%.

Complications are commonly classified as intra-procedural or post-procedural and as major or minor. Major intra-procedural complications include myocardial avulsion, cardiac tamponade, vascular tear, haemothorax, pneumothorax, and pulmonary embolism. Surgical back-up is mandatory. To minimize risk to the patient an individualized plan is required taking account of the patient’s cardiac history, the indications for extraction, co-morbidities, and the technical challenges that may be faced, as well as a plan following the extraction. The experience of the operator and the team is a major determinant of whether and how to go ahead. If the procedure would be best performed in a more experienced centre the patient should be referred.

The outcome of any individual procedure is in part unpredictable, but as a guide to the precautions and back-up required for a particular case, the Task Force reviewed reported complications and where data were lacking, reached a consensus, in order to lay down some indicators of procedural risk (Table 2).

For patients with infection, extraction has been reported to be easier. There is limited experience and reporting of extraction of coronary sinus leads; the success rate for passive leads appears to be high but implant duration so far has been short. Prior cardiac surgery may reduce the risk of tamponade due to scarring of the pericardium and mediastinum.
A history of prior surgery, however, has the potential to severely complicate emergency surgical exploration, should this be necessary.11

It may not be appreciated that the perioperative period, particularly after the extraction, is associated with significant morbidity and mortality independent of the procedure itself. Patients with sepsicaemia, endocarditis, vegetations, and other co-morbidities are at particular risk.13,19,62–65 Vegetations frequently embolize,66 but there does not appear to be any increased mortality associated with greater vegetation size.34,66,67

**Prerequisites for lead extraction**

As for all procedural techniques there is a learning curve for extraction.38 To become an independent operator for transvenous extraction requires the ability to master some, if not all of the different extraction techniques in a sufficiently large number of patients of an appropriate case mix. In an early study involving mainly laser extraction, the complication rate declined substantially during the first 30 clinical cases, with further improvements till 400 cases.33 Complete procedural success was reduced when 60 or fewer laser assisted lead extraction procedures were accomplished over the prior 4 years, even for very experienced operators.34 The severity of the complications determines the necessity for extended training and volume for these procedures in addition to sufficient prior experience with CIED implantation and revision69. The recent HRS consensus document recommends extraction of a minimum of 40 leads as the primary operator to be a fully trained extractor, and 20 leads per year to maintain competency.4 While the Task Force accepts these figures, these numbers do not specify extraction methods, indications, patient-related risk factors, or implant duration.

**Table 2 Lead extraction: factors associated with higher procedural risk**

<table>
<thead>
<tr>
<th>Factor</th>
<th>Criteria</th>
<th>Comments and references</th>
</tr>
</thead>
<tbody>
<tr>
<td>Body mass index</td>
<td>&lt;25 kg/m²</td>
<td>Related more to size than gender33,34,43,46</td>
</tr>
<tr>
<td>Co-morbidities</td>
<td>Age, poor LV function, renal failure, coagulopathy, large vegetations</td>
<td>Most of the risk is peri-procedural33,34,41,47</td>
</tr>
<tr>
<td>Venous status</td>
<td>Occluded or severely stenosed</td>
<td>Higher risk with greater lead cross-sectional area in the young,48</td>
</tr>
<tr>
<td>Venous status</td>
<td>Complex anatomy</td>
<td>Size, tortuous lead routes, shunts52,53</td>
</tr>
<tr>
<td>Congenital heart disease</td>
<td>Complex anatomy</td>
<td>More lead–lead and lead–tissue interactions43,54</td>
</tr>
<tr>
<td>Number of leads</td>
<td>Greater number of leads present or extracted</td>
<td>Active fixation safer to extract even if not isodiametric24,41</td>
</tr>
<tr>
<td>Fixation mechanism</td>
<td>Passive</td>
<td>Catching on bridging tissues41</td>
</tr>
<tr>
<td>Lead body geometry</td>
<td>Non-isodiametric</td>
<td>Greater diameter. Uneven surface11,15,54–56 unless coated57</td>
</tr>
<tr>
<td>ICD lead</td>
<td>Coils/complexity</td>
<td>Time-dependent tissue reaction to leads11,15,34,41,43,52,55</td>
</tr>
<tr>
<td>Implantation time</td>
<td>Greater than 1 year, rising further thereafter</td>
<td>Notable examples: Starfix,58 Accufix, Encore43,39</td>
</tr>
<tr>
<td>Special/damaged leads</td>
<td>Design/provoked deficiencies</td>
<td></td>
</tr>
</tbody>
</table>

Notes: Each factor listed is treated as having an independent risk. The attributed risk for each factor is based on published data and consensus of the Task Force members. None of the reported extraction series have taken all the above factors into account; in most cases the risks can only be semi-quantified. Risk arising from a given factor frequently but does not necessarily correlate with the related complexity or difficulty of the procedure.

**Recommendations on minimum training and volume for operators and centres (Table 3)**

**Lead extraction operator:**

1. A trainee for transvenous lead extractions should be fully qualified in CIED implantations.
2. Physicians to be trained in this technique should extract a minimum of 40 leads, in at least 30 procedures as the primary operator, under the direct supervision of a qualified training physician. The lead extractions should include 10 cases with multiple leads in whom 2 or more leads are extracted, 10 leads implanted for > 6 years, and 10 ICD-leads. Removal by traction without specialized tools is by definition not lead extraction and should not count. Exposure to various venous entry sites as well as femoral/jugular retrieval techniques should be included. In addition, the trainee should be exposed to the wide variety of extraction tools and techniques. Volume alone does not guarantee competency.
3. Having completed the training programme described above, a minimum number of 15 procedures and the extraction of 20 leads should be performed on an annual basis to maintain skills.
4. A supervisor/trainer should have extracted a minimum of 75 leads, performed with an efficacy and safety record that is consistent with published data. A minimum number of 30 procedures should be performed on an annual basis by the supervisor/trainer in a solo or training capacity.

**Lead extraction centre:**

1. In a non-training extraction centre, a minimum of 20 leads should be extracted annually over at least 15 procedures. Additionally, the centre should be of high volume for pacemaker
and ICD implantations. A new centre should only be established if at least one qualified operator is present in the centre and if it is predicted that these volumes will be fulfilled taking into account their own CIED volume and that of possible referral centres.

(2) A training centre should be of high volume for pacemaker and ICD implantations. At least one operator of the centre should be a supervisor/trainer. A minimum number of 30 procedures should be performed on an annual basis.

It is clear from two recent surveys from Europe and the USA that a high proportion of centres do not fulfil these criteria but these criteria are still recommended by the Task Force. The numbers listed above are the absolute minimum required for performing extraction procedures and do not guarantee the attainment of sufficient skills to obtain the results for efficacy and safety as reported from high volume centres.

**Recommendations on personnel and roles (Table 4)**

The team members should be trained so that they are familiar with the procedure, equipment and potential complications, and emergency response protocols. In each institution, there should be a written protocol for the personnel involved in the lead extraction programme clearly detailing their specific duties during the procedure and their response in case of emergency and for activation of the surgical, anaesthesiology, and operating room staff.

**Cardiac surgery support**

The presence of a cardiothoracic surgical team within the facility is mandatory. In centres where the primary operator is a CIED-trained cardiologist, a cardiothoracic surgeon must be immediately available to manage any of the life-threatening complications that may require surgical intervention. It is widely recognized that when the superior vena cava is torn or perforated, delays from the injury to having open access to the heart of 5–10 min were often associated with a fatal outcome. Rescue efforts initiated within this time period have sometimes been successful. It is strongly recommended that the cardiothoracic surgeon is aware of the procedure, especially in smaller hospitals that may not have operating rooms and support staff available at all times. This surgeon must have the necessary skills and experience to treat perforations, especially occurring above the pericardial reflection. Techniques rarely used in routine surgery may be needed.

**Anaesthesia support**

Lead extractions should be performed in an operating room, an electrophysiology or a catheterization laboratory with

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**Table 3** Recommendations on minimum training and volume for lead extractor operators and centres

<table>
<thead>
<tr>
<th>Lead extraction status</th>
<th>Minimum number of leads</th>
<th>Minimum number of procedures</th>
<th>Additional requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trainee</td>
<td>40 leads under supervision: 10 ICD leads, 10 leads &gt; 6 years old</td>
<td>30</td>
<td>10 with ≥ 2 leads</td>
</tr>
<tr>
<td>Primary operator (trained)</td>
<td>20/year</td>
<td>15/year</td>
<td></td>
</tr>
<tr>
<td>Supervisor trainer</td>
<td>75 total</td>
<td>30/year</td>
<td></td>
</tr>
<tr>
<td>Non-training centre</td>
<td>20/year</td>
<td>15/year</td>
<td>1 primary operator</td>
</tr>
<tr>
<td>Training centre</td>
<td>20/year</td>
<td>30/year</td>
<td>1 supervisor trainer</td>
</tr>
</tbody>
</table>

**Table 4** Required personnel and roles for lead extraction procedures

<table>
<thead>
<tr>
<th>Required personnel*</th>
<th>Qualification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary operator</td>
<td>A physician who is properly trained and experienced in device implantation, lead extraction, and the management of complications according to the guidelines</td>
</tr>
<tr>
<td>Cardiothoracic surgical backup</td>
<td>Where the primary operator is a cardiologist</td>
</tr>
<tr>
<td>Anaesthesia support backup</td>
<td>Specialized anaesthesia personnel</td>
</tr>
<tr>
<td>'Scrubbed' assistant</td>
<td>Physician/nurse/technician</td>
</tr>
<tr>
<td>'Non-scrubbed' assistant</td>
<td>Nurse/technician trained in respiratory support</td>
</tr>
<tr>
<td>Personnel capable of operating fluoroscopic equipment</td>
<td>Physician/nurse/technician/radiographer</td>
</tr>
<tr>
<td>Echocardiographer</td>
<td>Physician/nurse/technician</td>
</tr>
</tbody>
</table>

*Depending on the situation and the environment, one person can hold expertise in several areas and satisfy the requirements (e.g. the extractor could be the cardiothoracic surgeon), but at least four people (two scrubbed and two non-scrubbed/sedation and airway management) need to be in the room at all times with the immediate availability of additional personnel as needed.
general anaesthesia or a combination of local anaesthesia and intravenous sedation. In the event of a complication requiring further surgical intervention, for the patient to be already fully anaesthetized is a clear advantage. Immediate anaesthesia support must be available if this is not the case. The ability to manage a patient undergoing open-heart surgery is mandatory.

Scrub personnel
Lead extraction procedures often require a range of equipment and technologies. In order to safely perform the procedure, a minimum of two ‘scrubbed’ personnel must be available, the primary operator and an assistant. In centres where the cardiologist and surgeon perform the procedure together, an additional scrub nurse/tech may or may not be desired. When a third ‘scrubbed’ person is required this could be an additional physician, physician assistant, nurse, or technician.

Non-scrub personnel
Depending on the centre and location of the procedure, two or more ‘non-scrubbed’ personnel must be available during the procedure. If one of these is responsible for monitoring sedation (e.g. a nurse) a third non-scrubbed person must be immediately available (‘outside the door’) to provide equipment and assist in an emergency.

Technical personnel
Emergency echocardiography (transthoracic and/or transoesophageal) is required to rapidly diagnose a complication. In high-risk cases transoesophageal echocardiography is recommended. A member of the operating team must be capable of performing and interpreting these studies.

**Recommendations on facility and equipment (Table 5)**

Lead extraction procedures must only be performed in hospitals with full cardiothoracic surgical, angiographic, and CIED capacity. The extraction environment will vary between centres and will be affected in part by the wide differences in the systems of health delivery across Europe. Nevertheless, the following conditions should be met.

1. A full range of extraction tools should be available.

2. An operating room or procedural laboratory specifically designed for device implantation procedures. The room must be equipped with a ventilation system designed to prevent surgical infections and handle anaesthetic gases, and be of adequate size to allow for emergency intervention.

3. Equipment and instruments necessary for pericardiocentesis, chest drainage, vascular repairs, thoracotomy, sternotomy, and cardio-pulmonary bypass must be present in the room or immediately available, and in good working order.

4. High-quality fluoroscopic equipment with image storage, either as an integral part of a lab or a modern mobile C-arm, is essential for safe performance and for visualization of small lead components, sheaths, and guidewires.

5. External and transvenous temporary pacing equipment must be readied even if the patient is not pacing dependent.

**Recommendations for paediatric/congenital heart disease cases**

Due to the anticipated small numbers of extractions required for this population,4,52,53,72,73 these procedures should be performed by a physician trained in extraction, in close collaboration with a centre accredited for the care of paediatric/congenital heart disease patients. In addition to the requirements for adult patients the service should ensure:

1. Collaboration with a physician specialized in paediatric/congenital heart diseases. This physician should be on-site during the procedure and provide adequate input and assistance by any means, including being second operator.

2. The procedure is performed under general anaesthesia, in the operating room with a scrubbed surgeon present in the room and specialized personnel and equipment prepared for paediatric/congenital heart disease cardiac catheterization and surgery.

**Patient and site preparation**

**Pre-procedural preparation and work-up**

Pre-procedural preparation and work-up starts with a detailed patient history and complete physical examination. The reason...
for extraction and whether mandatory or desirable needs to be carefully considered. If desirable, the indication for proceeding needs to be balanced against the risk. Anticipated high-risk situations are listed and in Table 2. Co-morbidities, such as need for anticoagulation therapy, renal impairment, allergies, and resistance to antibiotics may affect peri-procedural care. To plan the means and route of extraction, the operator has to assess the vascular access used for implantation. Chest fluoroscopy or films are required to define the number, type, state, and location of leads, the route taken or possible pulmonary embolic complications. Chest computed tomography may be needed if extravascular coursing is suspected, but may not be diagnostic. Echocardiography should be used to look for vegetation; their appearance and size will guide the decision to perform a transvenous or surgical approach. Venography to assess vein patency may be needed if access problems are anticipated and to plan for the possibility of venoplasty. Reviewing prior implantation reports is essential and obtaining further device and lead information from the manufacturer may be helpful. The physical characteristics of each lead (insulation material, lead design e.g. coaxial, co-radial, cable, etc.) help determine the proper extraction tools to use. Antibiotic use through the period of device extraction, whether infected or not, is dealt with extensively elsewhere. Perioperative anticoagulation therapy should be the same as for heart surgery. Blood typing and crossmatch should be routinely performed. Also required is a full blood count, coagulation profile, electrolytes, liver and renal function, virology screen (Hep B, C, and for HIV), C-reactive protein, and erythrocyte sedimentation rate. Because of the high radiation exposure, a pregnancy screen is needed for young females.

The nature of the underlying rhythm will determine whether temporary pacing is required. Drugs causing bradycardia or atrio-ventricular delay, should if possible, be discontinued pre-operatively. Even if not pacing dependent, bradycardia may be provoked during the procedure and the device should be set so that this is detected (VVI 40). Tachycardia detection must be switched off to avoid rate response and shocks.

Obtaining informed written consent from the patient is part of the routine practice of participatory medicine and a medicolegal obligation.

**Site preparation**

If temporary pacing is indicated, to reduce the risk of displacement during the extraction, an active fixation lead is preferable to a passive lead. The planned entry route for the replacement system is to be avoided. To ensure the earliest warning of haemodynamic collapse, continuous pulse oximetry, electrocardiogram, and invasive arterial blood pressure monitoring are mandatory. For reliability and access, the femoral artery is preferable to the radial. Placing vascular sheaths in the femoral vein enable volume, drug, and blood administration, emergency temporary pacing and an insertion route for extraction tools. The echo equipment must be online during the whole length of the procedure. Sterilizing and draping the sternal and the subxiphoid area is a time-saving measure in case of an emergency sternotomy, thoracotomy, or pericardiocentesis. Adhesive external antero-posterior cutaneous defibrillating and pacing pads and diathermy pads are applied. The equipment required is outlined under recommendations on facility and equipment.

**Re-implantation timing, route and technique**

Prior to lead explantation, the need, timing and route for reimplantation, should be thoroughly evaluated. The original indications for device implantation may no longer be present and re-implantation may not be required. In patients with non-infectious indications for lead extraction, re-implantation can be performed either during the same session, or shortly afterwards, using the same or alternative venous routes. However, for those patients, in whom infection was present, the new system is usually inserted via the contralateral side. It may be prudent to obtain a venogram beforehand. There are no exact recommendations for the timing of the re-implantation following removal of an infected CIED. It is dependent on a number of factors including the type and extent of infection, whether all infected and fibrotic tissue has been debried, inflammatory markers, and the clinical response to treatment. For ICD patients, an alternative re-implant strategy may become available in the absence of adequate venous access, that of an entirely subcutaneous ICD system.

**Additional competences and site preparation for infection management**

Since infections account for the majority of extractions and the numbers are rising, any extraction centre must have a clear policy for the diagnosis and management of CIED infections. Testing for infection should be routine even if unsuspected. The detail is beyond the scope of this document and is well described elsewhere.

**Intra-operative protocol.**

Regardless of the pre-operative microbiological results, further sampling is necessary during the procedure. Pocket swabs are less likely to be positive than culturing of pocket tissue. Extravascular and intravascular lead segments (the pin and lead tip) are more likely to be positive than pocket tissue and more so than blood cultures. Arrangements for appropriate storage and preservation of specimens until timely delivery to the microbiology lab should be established.

**Microbiology**

Cooperation with a microbiology lab and regular consultation with a microbiologist is strongly recommended. The lab should be located in the hospital where the extraction procedure is done. Given the nature of the materials sent for examination, the results of bacteriological analyses will be semi-quantitative. For the individual patient, the aim of consultation with a microbiologist is to ensure the most effective antibiotic therapy, bearing in mind the rising prevalence of blood stream infections and of antibiotic-resistance, particularly methicillin-resistant strain. Systematic data collection and analysis of CIED infections in an entire population should enable improvements in local antibiotic policy, as well as inform at a national level.
Lead extraction registry

A full understanding of the status of CIED extraction requires key data on clinical indications, the tools and routes of extraction, complications, and success rates (Table 6). The Task Force strongly recommends establishing a pan-national registry to address this, alongside existing national registries, most of which do not address this issue. In this age of online data and transparency it is essential for the credibility of centres to report their results to independent registries and furthermore keep a more detailed local database to document the experience and competency of individual trainers and trainees on an ongoing basis. For the USA, contemporary experience of lead extraction is well below the expectations of the HRS guidelines. The same would appear to be the case for Europe, but this needs to be documented and regularly monitored.

In each extraction centre, the Task Force strongly recommends data collection for all consecutive cases, including clinical characteristics, tools and techniques used, success, and complications. Each centre has the responsibility to constantly update their database. The database will obviously differ between centres, according to the needs of the Institution and physicians, but a minimum common dataset is mandatory (Appendix 1).

A registry would enable national comparisons and requirements, improvements in care, and serve as a resource for research. The first such experience in the field of lead extraction was the US Extraction Database, a voluntary registry commercially funded. The registry has provided invaluable data regarding the success and complications rates for intravascular lead extraction. Perceptions of lead extraction safety and effectiveness and the outcomes of patients undergoing transvenous lead extraction have been based on this and following reports. This information prompted and guided the development of new extraction tools and techniques. Future developments will not only focus on new tools but on lead design features that affect the ease and safety of extraction. Regardless, lead extraction will remain high risk and require operators well versed in several methods of extraction.

It follows that the device community requires a long-term commitment to quality through the collection and review of personal and institutional outcomes for device implantation and transvenous lead extraction. Currently, data on CIED extraction are largely local. To improve standards and target training and support requires benchmarking of local to national and to international outcomes. The proposed registry needs to be accessible to all committed lead management centres, web based, and require only simple well-defined data entry points. Each centre should only be able to access their own and benchmarked summary data. Not only physicians, but also hospitals, manufacturers of implantable devices, and national regulatory bodies should be involved in supporting this registry.

**Conclusion**

There are clear shortcomings between extraction guidelines and actual practice. Lead extraction has always been a clinical requirement, but never more so than now. The systems implanted are ever more complex, numbers are increasing rapidly, and the proportion needing extraction appears to be on the rise. Alongside, lead extraction technology has also evolved and the technical expertise required to match these developments.

Apart from improving standards of practice through guidelines and establishing a registry, there needs to be a new approach to training given the limited numbers of clinical cases requiring extraction. There are few high-volume extraction centres. New approaches such as simulator training, proctorship, exchange of physicians in training, and fellow programmes are recommended to enhance proficiency. Simulators in the field of cardiology are well established for resuscitation, catheterization, percutaneous coronary intervention, cardiac resynchronization therapy implantation, and transeptal puncture. The learning curve is enhanced and competency is achieved with less patient risk and smaller numbers. A simulator programme would seem to be the most effective way to provide practical experience in the different techniques and handling of extraction tools.

**Appendix 1: Lead extraction database form: minimal mandatory fields**

<table>
<thead>
<tr>
<th>Centre ID</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient ID (guarantee of privacy)</td>
</tr>
<tr>
<td>Gender (M/F)</td>
</tr>
<tr>
<td>Date of birth (D/M/Y)</td>
</tr>
<tr>
<td>No. of leads present (prior to procedure)</td>
</tr>
<tr>
<td>Date of 1st implant of current transvenous implanted leads (D/M/Y)</td>
</tr>
<tr>
<td>No. of leads planned to remove transvenously at the beginning of the procedure</td>
</tr>
<tr>
<td>Heart disease (specify)</td>
</tr>
<tr>
<td>NYHA class</td>
</tr>
<tr>
<td>LVEF (%)</td>
</tr>
<tr>
<td>Co-morbidities (creatinine, dialysis, diabetes, BMI, decompensated HF)</td>
</tr>
</tbody>
</table>

**Procedure**

| Date (D/M/Y) |
| Anaesthesia: local, general, IV moderate sedation, IV deep sedation |
| Room: EP cath lab, operating room |
| Duration (entire procedure without reimplant or debridement) (min) |
X-ray exposure (entire procedure without reimplant or temporary pacing) (min)
Reimplant during the same procedure: yes, no

<table>
<thead>
<tr>
<th>Lead No.</th>
<th>Manufacturer</th>
<th>Model</th>
<th>(if unknown, please specify)…</th>
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<tr>
<td></td>
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<td>Pacing</td>
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<td>Defibrillator</td>
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<td>Poles</td>
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<td>Coils</td>
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<td>Fixation: active, passive</td>
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<td></td>
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<td>Insulation: silicone, polyurethane, other</td>
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</table>

Date of implant (D/M/Y)
Vein of implant (cephalic, subclavian, ext Jugular, int Jugular): R, L
Indication for removal
Previous extraction attempt: yes, no
Lead damage prior to removal: yes, no
Placement (RA, RV, LV, LA, SVC, cardiac vein, coronary sinus, other)
Tools (specify for each lead)
Standard stylet
Locking stylet
Polypropylene sheaths
Laser sheaths
RF sheaths
Rotational sheaths
Dotter Basket
Tip deflecting wire
Lasso or Gooseneck snare
Needle’s eye snare
Others (describe)
Techniques (specify for each lead)
Traction without sheath advancement
Dilatation (counter-pressure)
Countertraction (endocardial surface)
Others (describe)
Venous approach (specify for each lead)
Cephalic
Subclavian
Femoral
Internal Jugular
External Jugular

<table>
<thead>
<tr>
<th>X-ray results (specify for each lead)</th>
<th>Total success</th>
<th>Partial success (less than 4 cm retained)</th>
<th>Failure</th>
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<tr>
<th>Causes of failure (specify for each lead)</th>
<th>Extraction time (min) (specify for each lead)</th>
<th>Without sheath—from the insertion of locking stylet</th>
<th>With Sheath—sheath time</th>
<th>Clinical results (specify for each lead)</th>
<th>Success</th>
<th>Failure</th>
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Complications (by 30 days, specify)
Death: time of occurrence
Major: time of occurrence
Minor: time of occurrence

References
Training and accreditation for transvenous lead extraction

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