

# Transvenous Lead Extraction: Heart Rhythm Society Expert Consensus on Facilities, Training, Indications, and Patient Management

*This document was endorsed by the American Heart Association (AHA).*

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## Preamble

On May 15, 2008, the lead extraction community convened to critically review the prior April 2000 NASPE policy statement on Recommendations for Extraction of Chronically Implanted Transvenous Pacing and Defibrillator Leads: Indications, Facilities, Training.<sup>1</sup> This gathering was held as a co-sponsored satellite symposium\* during the Heart Rhythm Society's 29<sup>th</sup> Annual Scientific Sessions to examine ways to revise and implement effective lead management standards.<sup>2</sup>

This writing committee, appointed by the Heart Rhythm Society, is a representative group of international experts in device and lead management from North America and Europe. Each of these physicians is an expert concerning the management of leads used with cardiovascular implantable electronic devices (CIEDs) including transvenous lead extraction. We were charged with the development of a consensus document for the lead extraction community regarding standards for safe and effective lead management. Central to this effort was a focus on transvenous lead extraction, including standards for training, and standards for the evaluation of new tools and techniques. Although the

major intervention discussed in this document is transvenous lead extraction, it was strongly recommended that this document should focus on the management of the patient, and in particular the management of the leads.<sup>2</sup>

The writing group consisted of nine cardiac electrophysiologists and three cardiothoracic surgeons, who specialize in CIED implantation and extraction. This statement represents expert consensus of the writing committee based on a review of the literature, their own experience in treating patients and input from the extraction community gathered at the symposium. It is directed to all health care professionals and health care institutions that are involved in the care of patients with CIEDs.

The document represents the strong consensus of the writing committee, which was developed as a result of comments collected at the 2008 satellite symposium; as well as during a separate face-to-face all day writing group meeting, multiple international conference calls, and three web based questionnaires. In writing a "consensus" document, it is recognized that consensus does not mean that there was complete agreement among all writing group members. We identified those aspects of transvenous lead extraction for which a true "consensus" could be identified. Surveys of the entire writing group were used to identify these areas of consensus. For the purposes of this Consensus Document we defined a consensus as 83% or greater agreement by the authors of this document.

When using or considering the guidance given in this document, it is important to remember that there are no absolutes with regard to many clinical situations. The ultimate judgment regarding care of a particular patient must be made by the health care provider and patient in light of all

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the circumstances presented by that patient, the management options available as well as the relative risks and benefits. Indicated procedures are appropriate reasons for considering an intervention. This document focuses on patient and lead management, and not just lead extraction in order to place the indications for intervention in the context of the contraindications, timing, training, facilities and personnel.

## TABLE OF CONTENTS

Introduction.....	1086
Definitions.....	1086
Extraction Tools .....	1087
Outcomes: Defining Technical and Clinical Success...	1087
TABLE 1: Classification of Complications.....	1088
Personnel, Roles and Responsibilities .....	1089
TABLE 2: Required Personnel .....	1089
Physician Qualifications and Training .....	1090
Indications for Lead Removal.....	1094
TABLE 3: Indications for Transvenous Lead Extraction.....	1096
TABLE 4: Principles for CIED Replacement following Infected Removal.....	1097
Registry and Data Management.....	1099
New Devices and Techniques.....	1099
Recommendation for Clinical Evaluation of Lead Extraction Devices.....	1099
Conclusion .....	1099
Appendix.....	1100
References.....	1101

## Introduction

Perceptions of lead reliability, performance, complications and approaches to management have evolved dramatically since the inception of pacemaker and implantable defibrillator therapy. At various points since the first implantable pacemaker was placed in 1958, conductors, insulation materials, lead construction, implantation techniques, infection and venous occlusion have been the source of significant clinical problems.<sup>3,4,5,6,7,8,9,10,11,12</sup> However, not until the late 1980s was a serious attempt made to develop tools and techniques to safely remove problematic leads. Inspection of these leads after extraction contributed substantially to an understanding of clinical and mechanical failure modes. It thus resulted in iterative improvements in the design of leads and implantation techniques in the pursuit of improved patient management. The techniques of transvenous lead extraction have been detailed elsewhere.<sup>13,14,15,16,17,18</sup>

The penetration of transvenous lead extraction techniques into general use was slow due to the potential for fatal complications and the limited training in the tools and techniques. The North American Society of Pacing and Electrophysiology [NASPE, which is now the Heart Rhythm Society (HRS)] convened a policy conference on May 11, 1997, during the 18<sup>th</sup> Annual Scientific Sessions to formalize standards: for

training of physicians in extraction techniques; for equipment and emergently needed support staff at each institution; and for indications and contra-indications for lead extraction. These standards were published as a guidance document in April 2000.<sup>1</sup>

Since the publication of this document, the community of physician experts in the management of lead problems and transvenous lead extraction has grown substantially. However, the safety and effectiveness of transvenous lead extraction as well as the application of indications vary widely. The training of physicians and the extraction team still lags behind demand. It has become the consensus of the physician community that transvenous lead extraction is a central treatment in patients with pathologic lead conditions. It is also recognized that lead extraction is only one of the tools available to physicians in what is more properly identified as lead management. Lead management requires a broad understanding of the pathophysiology of the mechanical and clinical issues associated with lead dysfunction, and a primary commitment to measuring outcomes and quality.

## Definitions

Within the general category of “lead removal,” distinctions must be made between simple procedures that can be performed via the implant vein without specialized tools (“lead explant”), and removal of leads involving more complex procedures (“lead extraction”). This is necessary when designing training programs, for classification of procedures in registries and databases, for assuring a uniform definition in the literature, for determining the personnel and facilities for the procedure, as well as for the goal of appropriate reimbursement levels for the different procedures. Although leads with less than one year of implantation can sometimes be challenging to remove, it is the exception. The standards for lead extraction, including surgical backup, personnel, facilities, training and outcomes, pertain to leads implanted for at least one year or requiring the assistance of specialized equipment that is not included as part of the typical implant tool set. Even so, extreme caution should be used when removing any lead.

**Lead Removal:** Removal of a pacing or defibrillator lead using any technique.

**Lead Explant:** A lead removal using simple traction techniques (no locking stylet, telescoping sheaths or femoral extraction tools).

**Lead Extraction:** Removal of a lead that has been implanted for more than one year, or a lead regardless of 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 (ICD) leads may require specialized extraction equipment even when implantation duration is less than one year.

**Lead Extraction Approach:** Leads are usually removed via the same transvenous access by which they were inserted, termed the implant vein. However, sometimes alternative venous access is required from a non-implant vein.

Examples of alternative lead extraction approaches include from the femoral, jugular or subclavian veins.<sup>19,20,21,22,23</sup> On occasion, the leads need to be removed via a trans-atrial or via a ventriculotomy approach.<sup>24,25,26</sup>

## Extraction tools

**Simple Traction:** Manipulation of the lead so that the lead exits the vasculature via the implant vein using tools typically supplied for lead implant, with the addition of traction. These tools include such items as standard stylets (non-locking), and fixation screw retraction clips.<sup>13,16,27</sup>

**Traction Devices:** Specialized locking stylets, snares, sutures, grasping or other devices used to engage or entrap and remove the lead or lead fragments. Locking stylets are a special type of a traction device designed to hold onto the inside of the conductor coil along its length or near the distal stimulating electrode, improve tensile properties and prevent elongation of the lead body during traction.<sup>13,16,27</sup>

**Mechanical Sheaths:** Sheaths composed of metal, Teflon™, polypropylene or other materials that require manual advancement over the lead and rely on the mechanical properties of the sheath to disrupt fibrotic attachments.<sup>3,16,27,28,45</sup>

**Laser Sheaths:** Sheaths that employ fiberoptics to transmit laser light to disrupt the fibrotic attachments.<sup>3,16,27,29,30,31</sup>

**Electrosurgical Sheaths:** Sheaths that use radiofrequency energy (such as found in an electrosurgical unit) emitted between two electrodes at the sheath tip to disrupt the fibrotic attachments.<sup>3,16,27,32,33</sup>

**Rotating Threaded Tip Sheath:** Sheaths that are equipped with a rotationally powered mechanism that bore through and disrupt fibrotic attachments with a threaded screw mechanism at the sheath tip.<sup>27,34</sup>

**Telescoping Sheaths:** Any extraction sheath that can be used as a single sheath or may be paired with a second sheath. The use of two sheaths takes advantage of the flexibility of the inner sheath and the stiffness of the outer sheath to prevent kinking and to improve the effectiveness of advancement over the lead without overstressing the lead. The outer sheath is usually mechanical, even when the inner sheath uses some other technology such as laser, electrosurgical or rotating threaded tip.<sup>13,16,27</sup>

## Outcomes: Defining technical and clinical success

Transvenous lead extraction has been effectively accomplished in many centers, many operators and with various techniques. Despite the provision of standard definitions in the NASPE policy statement in 2000, the results have been variously reported.<sup>23,26,27,28,29,30,31,32,35,36,37,38,39,40,41,42,43</sup>

Problems with the interpretation of these results are related to how the cases were selected for inclusion as well as the definition of success and failure. Extraction centers from the continental United States, Hawaii and Europe voluntarily submitted data for a national registry between December 1988 and December 1999.<sup>44,45</sup> The most recently published data from 1996 included data from 226 centers, 2,338 patients and 3,540 leads; these data demonstrated major com-

plications in 1.4%, <1% for centers with >300 extraction procedures.<sup>46</sup> Although these data are not retrievable, the final public report of this registry, which was presented at the XIth World Symposium on Cardiac Pacing and Electrophysiology in Berlin and at Cardiostim, Nice, France in June of 2000, included 7,823 extraction procedures with 12,833 leads. Multivariate analysis of the data from 1994–1999 demonstrated four predictors of major complications using the definitions described in the NASPE recommendations document.<sup>1</sup> The major complication rate was 1.6%. The four predictors of major complications were: 1) implant duration of oldest lead, 2) female gender, 3) ICD lead removal and, 4) use of laser extraction technique.<sup>47</sup> Most of these data represented non-laser assisted extraction but also represented an earlier version of the laser hardware and the physician learning curve for laser use.

The prospectively collected PLEXES and early laser reported results can be used to reasonably estimate the currently reported overall safety and effectiveness of lead extraction. The PLEXES trial was a randomized prospective clinical trial comparing the first iteration of the 12-French laser sheath to a non-laser cohort in 301 subjects with 465 chronic pacemaker leads. The procedural success in the laser group was 94% with an associated major complication rate of 1.96%.<sup>29</sup> Subsequently, when the total initial experience in the United States was reported, Byrd et al.<sup>43</sup> reported on the laser lead extraction of 2,561 pacing and defibrillator leads 1,684 patients at 89 sites. The procedural success rate was 90% with a major complication rate of 1.9% with an in-hospital death rate of 0.8%.

Though most leads are removed safely and completely, some portion of the lead may be left *in situ*. In many instances the retained fragment still allows for the desired clinical outcome, which may include multiple clinical goals. The success of lead extraction is based on the achievement of the desired clinical outcome. Procedural success rate = (equals) number of clinically successful procedures/(divided by) number of procedures performed. This is calculated as complete procedural success rate and clinical procedural success rate calculated using the complete removal of all targeted leads or the achievement of all targeted clinical goals for the procedure. Failure to remove all components of intravascular leads in a patient with systemic infection is a failure to achieve complete or clinical procedural success, while the same result in a noninfected patient achieves clinical but not complete procedural success. Leaving a tip in a case of local infection is not a failure but hopefully a clinical success.

Lead clinical success rate = (equals) number of leads removed with clinical success/(divided by) total number of leads attempted.

These targeted clinical outcomes may include one or more of the following:

- Elimination of infection (pocket infection, device related endocarditis)
- Creation of venous access in an occluded vessel

- Elimination of an identified risk (perforation, arrhythmia) produced by a lead or portion of a lead
- Preservation of desired pacing mode
- Removal of all non-functional leads
- Resolution of all pocket related symptoms (i.e. pain)

**Complete Procedural Success:** Removal of all targeted leads and all lead material from the vascular space, with the absence of any permanently disabling complication or procedure related death.

**Clinical Success:** Removal of all targeted leads and lead material from the vascular space, or retention of a small portion of the lead that does not negatively impact the outcome goals of the procedure. This may be the tip of the lead or a small part of the lead (conductor coil, insulation, or the latter two combined) when the residual part does not increase the risk of perforation, embolic events, perpetuation of infection or cause any undesired outcome.

**Failure:** Inability to achieve either complete procedural or clinical success, or the development of any permanently disabling complication or procedure related death.

### Defining complications

Recording all complications is crucial for quality assessment and quality improvement. The assessment of complications requires both a time frame and a level of severity. This is complicated by the fact that several procedures may be performed on the patient in succession during the same or closely spaced hospitalizations. For example, one will typically remove a system from an infected site on one day, and implant a replacement system a few days later. Because the cause of the complication cannot always be attributed to a specific procedure, reporting consistency is needed. The standard methodology used to classify surgical complications is by the time of occurrence. The definitions for time frames are:

**Intra-procedural complication:** Any event related to the performance of a procedure that occurs or becomes evident from the time the patient enters the operating room until the time the patient leaves the operating room. This includes complications related to the preparation of the patient, the delivery of anesthesia, and opening and closing the incision.

**Post-procedural complication:** Any event related to the procedure that occurs or becomes evident within 30 days following the intra-procedural period. Extraction events are classified as major complications, minor complications, or observations, according to their severity, as described below. Examples of classifications using these definitions are shown in **Table 1**.

**Major complication:** Any of the outcomes related to the procedure which is life threatening or results in death. In addition, any unexpected event that causes persistent or significant disability, or any event that requires significant surgical intervention to prevent any of outcomes listed above.

**Minor complication:** Any undesired event related to the procedure that requires medical intervention or minor procedural intervention to remedy, and does not limit persistently or significantly the patient's function, nor does it threaten life or cause death.

### Lead management environment

The number of lead extractions that need to be performed annually continues to increase. Given the technical challenges and risk of life threatening complications, physicians should only seek training, and hospitals should only provide this service, when there is an ongoing commitment to a procedural volume adequate to maintain the skills of the physician and team. In addition to volume, it is essential that there be an upfront sustained commitment by the physician and the hospital to maintain the proficiency of the entire

**TABLE 1** Classification of complications

Classification	Examples
Major Complication	<ol style="list-style-type: none"> <li>1. Death</li> <li>2. Cardiac avulsion or tear requiring thoracotomy, pericardiocentesis, chest tube, or surgical repair</li> <li>3. Vascular avulsion or tear (requiring thoracotomy, pericardiocentesis, chest tube, or surgical repair)</li> <li>4. Pulmonary embolism requiring surgical intervention</li> <li>5. Respiratory arrest or anesthesia related complication leading to prolongation of hospitalization</li> <li>6. Stroke</li> </ol>
Minor Complication	<ol style="list-style-type: none"> <li>1. Pacing system related infection of a previously non-infected site</li> <li>2. Pericardial effusion not requiring pericardiocentesis or surgical intervention</li> <li>3. Hemothorax not requiring a chest tube</li> <li>4. Hematoma at the surgical site requiring reoperation for drainage</li> <li>5. Arm swelling or thrombosis of implant veins resulting in medical intervention</li> <li>6. Vascular repair near the implant site or venous entry site</li> <li>7. Hemodynamically significant air embolism</li> <li>8. Migrated lead fragment without sequelae</li> <li>9. Blood transfusion related to blood loss during surgery</li> <li>10. Pneumothorax requiring a chest tube</li> <li>11. Pulmonary embolism not requiring surgical intervention</li> </ol>

extraction team, and to track outcomes of both device implantation and lead extraction.

Transvenous lead extraction is a grouping of techniques primarily designed to solve cardiac pacemaker and ICD lead management problems. A commitment to lead extraction procedures requires a commitment to quality and continuous quality improvement. This commitment to clinical outcome measurement is fundamental to the performance of transvenous lead extraction, in part because it is essential to an accurate informed consent process. Only when the risks of both doing and not doing the procedure are accurately understood by both the physician and the patient can an appropriate informed decision be made. In addition, it is not enough to estimate the hypothetical risk of a procedure done by a hypothetical physician and hospital, but it is important to estimate what the risk is for this patient under the proposed conditions.

There are additional principles that are also fundamental to quality outcomes, and these principles provide the context for the remainder of this document. Examples in subsequent sections of this document include adequate initial and continuing training in both the physical and cognitive aspects of lead management, maintaining an adequate volume of device implantation and extraction activities, ongoing assessments of the adequacy of the facilities, techniques and personnel required to safely perform the procedure, as well as the systematic measurement of the outcomes with internal and sometimes external review of outcomes. The outcomes measures should include both implantation and extraction outcomes. It is essential that the reported outcomes employ standardized definitions, and should be focused in the best tradition of a local morbidity and mortality review which looks for root causes and opportunities for improvement.

Hospitals offering lead extraction and personnel participating in these programs must have a protocol for emergency response when the need arises. There should be a mechanism in place to activate a rapid operating room response team that is capable of performing emergency surgery. This “disaster plan” should be regularly tested on a scheduled basis so that each member of the team knows exactly what to do and how to accomplish their role. This plan must be recorded as part of the written standard operating procedure of every extraction laboratory or operating room.

Finally, the lead extraction team must be committed to open review of complications and continuous improvement process. If physician and institutional expertise is not available locally, it is in the best interest of an individual patient to be referred to a center with the appropriate training and expertise.

## Personnel, roles and responsibilities

The development of a successful lead extraction program requires a team approach. Each member of the team is crucial to successful outcomes, a low complication rate and the rescue of a patient should a complication occur. A successful lead extraction program requires a wide range of tools and techniques. The staff involved in these procedures must be familiar with the equipment required and its location and use. In addition, the clinical situation during an

extraction procedure can change rapidly and the team must be prepared to deal with any eventuality. This can only come with proper planning and training.

Centers planning to develop a lead extraction program should identify a team of providers, procedures, equipment and plans for emergent response. In addition to becoming familiar with the indications for and complications of lead extraction, the team must understand the operation and use of all equipment potentially required. It is essential that the team observe procedures at an experienced center prior to launching an extraction program. Industry representatives are not a substitute for appropriately trained staff and must always function under the direction and responsibility of the attending physician. A list of required personnel can be found in **Table 2**.

**Primary Operator:** The physician performing lead extraction should meet the qualifications and training described below. In some centers a single physician trained in CIED therapy (most often an electrophysiologist or cardiac surgeon) performs the extraction. However, in some centers a team approach is taken with physicians all trained in CIED therapy (again most often an electrophysiologist and a cardiac surgeon) working together, each with their individual expertise. Given that this procedure is part of the bigger picture of “lead management”, the physician should be well versed in cardiac device implantation and management.

**Cardiothoracic Surgeon:** In some centers the primary operator is a CIED trained cardiothoracic surgeon, while in others a CIED trained cardiologist and surgeon will operate together. In centers 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. In the event of a significant complication, time is of the essence. We therefore strongly recommend that the surgeon is aware of the procedure, especially in smaller hospitals that may not have operating rooms and support staff available at all times. The surgeon must be well versed in all the potential

**TABLE 2** Required personnel\*

Primary Operator: A physician performing the lead extraction who is properly trained and experienced in device implantation, lead extraction and the management of complications.
Cardiothoracic surgeon well versed in the potential complications of lead extraction and techniques for their treatment, on site and immediately available
Anesthesia support
Personnel capable of operating fluoroscopic equipment
“Scrubbed” assistant (nurse/technician/physician)
Non “scrubbed” assistant
Echocardiographer

\*Depending on the environment, one person can hold expertise in several areas and satisfy the requirements (eg. the extractor could be the cardiothoracic surgeon), but at least 5 people (1 – airway and sedation management 2 - scrubbed and 2 - non scrubbed) need to be in the room at all times with the immediate availability of additional personnel as needed.

complications of lead extraction and re-implantation, and understand the required surgical approach to each anatomic injury that is likely to occur. For example, the surgical approaches to a superior vena cava tear, right ventricular tear or coronary sinus tear are each very different.

**Anesthesia Support:** Some centers perform lead extractions in an operating room under general anesthesia. Other centers perform lead extractions in catheterization laboratories under intravenous sedation. In the event of a complication requiring further surgical intervention, immediate anesthesia support must be available. This includes the ability to manage a patient undergoing open-heart surgery.

**Fluoroscopic Support:** Given that lead extraction requires the use of fluoroscopy to guide the procedure, personnel must be present who can operate and troubleshoot the fluoroscopic equipment.

**Scrub Personnel:** Lead extraction procedures often require a variety 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 centers where the cardiologist and surgeon perform the procedure together, an additional scrub nurse/tech may or may not be desired. In other centers, an additional “scrubbed” person is required to assist during the procedure. This could be an additional physician, physician assistant, nurse or technician. These team members should be trained so that they are familiar with the procedure, equipment and potential complications and emergency response protocols.

**Non-Scrub Personnel:** Depending on the center 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 available to provide equipment and assist in an emergency. These personnel must be trained so that they are familiar with the procedure, equipment and potential complications. Most importantly for these staff members, they must know how to activate the emergency protocols and whom to call.

**Echocardiography:** Emergent echocardiography (trans-thoracic and/or transesophageal) may be required to rapidly diagnose a complication. A physician capable of performing and interpreting these studies must be immediately available. This may be the physician performing the procedure or the anesthetist involved in the case. In centers where there is not a physician skilled in echocardiography in attendance during the procedure, an additional physician must be available to perform and interpret these studies.

It is also recommended that a designated “extraction coordinator” be identified to coordinate the procurement, storage, maintenance and reordering of the extraction equipment. There should also be a person (possibly the same person) responsible for maintaining protocols in concert with the hospital’s requirements that ensure patient safety throughout the procedure.

## Physician qualifications and training

Lead extraction is an invasive procedure that requires training and experience to consistently deliver safe and effective care. Physicians wishing to perform this procedure should be properly trained in extraction techniques and management of complications.

The simple combined acts of watching an instructional video demonstration and observing an operator perform the procedure are not adequate. Other procedures with similar operator skill requirements and patient risk (e.g., percutaneous angioplasty of coronary or peripheral vessels) require at least an additional year of training. Unfortunately there are limited data available for procedural volumes required for training and ongoing competency for transvenous lead extractions. Therefore, recommendations are based on these limited data as well as data available for other intravascular procedures.

Analysis of lead extraction outcomes suggests that the frequency of complete procedural success improves dramatically after the first 10–20 procedures have been performed.<sup>48,49,50</sup> Even physicians with many years of experience have a reduced frequency of complete procedural success when 60 or fewer laser assisted lead extraction procedures were accomplished over the prior 4 years.<sup>80</sup> Lower complication rates are associated with a prior experience of 30 procedures.<sup>47,51</sup> **These studies demonstrated the steepest decline in complications over the first 30 cases. It is also important to note that the complication rate continued to decline throughout the study (up to 400 cases).** These findings are consistent with guidance documents that delineate the training requirements for the implantation of pacemakers, ICDs and cardiac resynchronization devices, which require 25 procedures of each device type.<sup>52</sup> A review of the Medicare database revealed that for ICD implantation, mechanical complications decreased after a minimum volume of 10 implantations per year, and infections were reduced for implanters performing at least 30 implants per year.<sup>53</sup> Given the relationship demonstrated between lead extraction experience and safety and efficacy, and since these techniques are much more technically demanding and are associated with a much larger opportunity for failure and complications, it was the consensus of the writing group that a volume of extraction procedures, similar to those required for device implantation, should be required.

## Simulator program

Procedures that require technical expertise can only be learned through careful training, repetition and practice. However, the ability to provide adequate “hands-on” training, especially outside of formal fellowship programs, is limited. Even within formal fellowship programs, the number of “high volume” centers where fellows or practitioners could gain adequate clinical experience is inadequate. Simulators of surgical and catheter procedures are now a part of medical training in a variety of areas. Simulation allows practitioners to make mistakes in a “risk free” environment and gain experience not

possible in actual practice. Studies have demonstrated an accelerated learning curve and a reduction in complications with simulator training.<sup>54,55,56,57,58,59,60</sup> In addition, simulation of a wide range of clinical scenarios allows for team building and enhanced response to emergent situations.

The success of a lead extraction program, as the mainstay of a lead management strategy, requires experience. These skills, for both the operator and the other members of the lead extraction team, must be obtained and maintained through repetition. Preliminary tests (n = 36) of a simulator in 6 previously inexperienced trainees, which incorporated real time feedback of extraction forces along with the use of locking stylets, extraction sheaths and fluoroscopy, produced measureable improvement in technique. Although the current experience is preliminary, it was the consensus of the writing committee that continued development and testing of lead extraction simulators with realistic scenarios is likely to become an important future component of the initial training and maintenance of extraction skills.

### Recommendations on minimum training and volume

- Physicians being trained in this technique should extract a *minimum* of 40 leads as the primary operator under the direct supervision of a qualified training physician. Exposure to various venous entry sites as well as femoral retrieval techniques should be included. In addition the trainee should be exposed to the wide variety of extraction tools and techniques. These are minimum requirements, recognizing that volume alone does not guarantee competency.
- A minimal number of procedures should be performed on an annual basis to maintain skills. This is crucial to maintain one's acquired skills and team preparedness. In addition, expertise in lead extraction is clearly developed with each and every procedure performed. We therefore recommend the extraction of a minimum of 20 leads annually per operator.
- Physicians who have already extracted over 40 leads as a primary operator and maintain the minimum volume of 20 leads extracted annually are considered as meeting the training and volume requirements.
- Training should be obtained at centers with adequate volume, experience, and expertise. The supervisor should have extracted 75 leads, performed with an efficacy and safety record that is consistent with published data.

We realize that outside of a formal fellowship training program at a high volume center, even this minimal requirement will be very difficult to achieve. However, the difficulty of receiving adequate training should not be viewed as a reason to reduce the minimum requirements. This issue highlights the need for the development of an adequate simulator that would allow for a supplemental pathway to achieve and maintain competency.

It is recognized that in the pediatric population, a very limited number of lead extractions are performed. It is therefore suggested that extractions for this population be referred to centers that have the personnel and expertise to safely and effectively manage this specialized group. It would also be beneficial to develop a partnership between a pediatric center and a higher volume adult center. This will allow a team approach to manage the issues unique to younger patients (often with complex congenital abnormalities), and at the same time provide input and assistance from a physician with more extraction experience. These patients may require the expertise of physicians with experience in congenital heart disease device management specific skills. Although the pediatric specialists may not have the opportunity to extract at least 20 leads per year on an ongoing basis due to the reduced volume of CIED implantation in this population, the experience gained as a primary operator in the extraction of 40 leads is still an appropriate expectation. In circumstances like this, extra precautions including the consistent use of a simulator to practice the actual extraction scenario might be used to augment the exposure to volume in lieu of 20 annual lead extractions. Using general anesthesia and having the surgical team in the room and scrubbed are additional advanced precautions.

- Performing a specific number of procedures does not guarantee proficiency, competency, or safety; outcomes data are necessary to assess performance. A quality-oriented database should be maintained at each institution to document procedure activities and outcomes.
- Given the acknowledged learning curve for this procedure, even through hundreds of cases, it is recommended that a staged approach be used when starting an extraction program. While one can never predict the ease of extraction in any given individual, strong consideration should be given to starting with less challenging or risky cases. Examples would include patients with prior cardiac surgery, which reduces the risk of serious bleeding but increases the difficulty of surgical rescue. Additional examples are patients with a single lead of relatively short implantation duration or patients with relatively "young" non-ICD leads. More complex cases, with multiple leads and long implant duration, should be avoided initially and referred to experienced centers. As a physician's and a center's experience grows, so can the degree of difficulty of the cases increase.

New extractors must realize that there is a community of lead extractors who are available for ongoing mentoring. Discussions around difficult clinical situations can be very valuable and allow clinicians to arrive at the most appropriate treatment approach. When beginning a new program, a mentor or mentors should be identified.

### Facility and equipment

As discussed in the above section, a successful lead extraction program requires a coordinated, team approach. In addition to appropriate and adequately prepared personnel,

a center must have the required facilities and equipment to perform lead extractions safely and effectively. There must be a commitment to ensuring the availability and functionality of all facilities and equipment on an ongoing basis. This is especially true for equipment used only rarely, but required without delay in life threatening situations.

### Facility

Lead extraction procedures must only be performed at centers with accredited cardiac surgery and cardiac catheterization programs. As stated previously, a cardiothoracic surgeon must be physically on site and capable of initiating an emergent procedure promptly. In addition, the cardiac surgery team, equipment and facilities must be readily available. Through the external review of fatal cases around the world, it was the strong consensus that when the superior vena cava was torn or perforated, delays from the injury to having open access to the heart of more than 5-10 minutes were often associated with a fatal outcome. Rescue efforts initiated within this time period have been usually successful. Procedures can be performed in either operating rooms, or procedural laboratories specifically designed for device implantation procedures. The room must be of adequate size to allow for emergent interventions such as thoracotomy and sternotomy. The room must be equipped with a ventilation system designed to prevent surgical infections and to handle anesthetic gases.

### Equipment

Below is a review of the minimal equipment and supply requirements and is by no means inclusive. With experience, active extraction centers continually add equipment they find useful in performing these procedures.

**High-quality fluoroscopy:** The value of a high-quality fluoroscopy system cannot be overstressed. Visualization of small lead components (such as fixation screws on leads with retractable screws, migrated lead fragments and pieces of elongated conductor coil) is necessary for the safe performance of lead extraction techniques. This may be a fixed fluoroscopic system or a "high-quality" mobile C-arm.

**Surgical instruments:** These include instruments appropriate for transvenous lead extraction and device implantation. In addition, surgical instruments to perform vascular repairs, thoracotomy, sternotomy and cardio-pulmonary bypass must be immediately available and in good functional order.

**Extraction tools:** There is a wide variety of lead extraction tools. While we do not promote one over the other, it is widely accepted that having a broad variety of extraction tools increases the chance of success and limits complications. Essential tools include locking stylets, mechanical "telescoping" sheaths, and "powered" sheaths.<sup>13,27,61</sup>

**Extraction snares:** In cases with "free floating" leads, an approach from other than the implant vein is required. This is also true when lead disruption occurs during the procedures. Tools for retrieval from the non-implant vein must be available. These include large sheaths (worksta-

tions) with a hemostatic valve, and a variety of grasping and snaring devices. Venous access for these snares can be from the femoral, internal jugular, subclavian or trans-atrial sites.

**CIED implantation tools:** Stylets, wrenches, fixation tools, repair kits, adapters, sterile sleeves for the programmer, pin plugs, lead anchoring sleeves, and lead end caps should be available. Also required are the standard implantation equipment including, but not limited to, a variety of introducer sheaths, guide wires, and venous entry needles.

**Transthoracic and transesophageal echocardiography:** The ability to perform both transthoracic echocardiography and transesophageal echocardiography must be immediately available. In some centers intracardiac echocardiography is employed.<sup>62</sup>

Additionally required supplies and equipment include an anesthesia cart for general anesthesia, invasive and noninvasive arterial pressure monitoring, oxygen saturation and CO<sub>2</sub> monitoring, pericardiocentesis tray, water seal/vacuum containers for chest tube drainage (2 recommended), temporary transvenous pacemaker and connectors, transcutaneous temporary pacing and defibrillation equipment, intravenous contrast agents, fluids, pressors, and other emergency medications in the procedure room and equipment for cardio-pulmonary bypass must be readily available.

### Patient preparation

Since this procedure may result in life threatening complications, it is imperative that the patient be properly and thoroughly prepared so that if emergent intervention is required there is no delay.

### History and physical examination

A complete patient history and physical exam must be obtained. Understanding the indications for the initial device implantation, and co-morbidities that may affect the pre-, intra- and post-procedure care are critical. For example, the need for anticoagulation and "bridging" around the procedure must be determined for all patients. All medications must be reviewed. All allergies must be identified, especially contrast allergies since use of the latter may be required during the procedure and premedication can be administered if the allergy is identified. A comprehensive physical examination with specific attention to anatomic details that may influence the procedure is required. The operator should look for findings that may affect the planned procedure. For example, the presence of extensive venous collaterals of the chest wall suggests central venous occlusion. This is especially important in patients scheduled for a device "upgrade" with the planned addition of ipsilateral leads. A pre-procedure venogram may be indicated to determine the patency of the implant vein and the potential need for venoplasty or lead extraction.

### Informed consent

Written informed consent, including pertinent elements of the planned procedure, should be discussed with patient, preferably in the presence of a family member. The patient and family must understand that lead extraction is a poten-

tially life threatening procedure and this must be placed into local context by informing the patient about the hospital's extraction volume and outcomes, and the operator's personal level of experience and outcomes. As extraction is often one option in a complex device procedure; all reasonable alternatives must be discussed. This is particularly important when considering extraction versus abandonment during an upgrade procedure.

### **Planned procedure and treatment**

Prior to undertaking an extraction procedure, a clear plan for management of co-morbidities, the need for ongoing CIED therapy, and how that therapy will be provided must be formulated.

### **Patients with CIED related infection**

A plan for pre-, intra-, and post-operative antibiotics must be formulated, including the type, route and duration of antibiotics. The need for additional testing, such as transesophageal echocardiography to evaluate for the presence and/or size of vegetations, must be determined as this will help determine the most appropriate approach (transvenous or open surgical) for the extraction.<sup>63,64</sup> An active fixation temporary pacing lead should be considered in patients requiring pacing support during the interval before the replacement permanent CIED is implanted.<sup>65</sup> In addition, the timing and need for device re-implantation must be determined prior to the procedure (see discussion and **Table 4** in the indications section).<sup>97</sup>

### **Device and lead location**

The vast majority of explanted leads were originally introduced transvenously and advanced to a typical pacing/sensing position in the right atrium, right ventricle, coronary sinus or cardiac veins. However, in some cases leads may have been advanced into one or both left heart chambers via a patent foramen ovale, atrial septal defect, ventricular septal defect, or arterial access.<sup>66</sup> This is most often done unintentionally; however there are some leads that are placed into the left heart chambers for the purpose of pressure monitoring or cardiac resynchronization.<sup>67,68,69</sup> Leads may also perforate the myocardium and penetrate into pericardium or be entrapped in the tricuspid valvular apparatus.<sup>70,71,72</sup> The pre-procedure chest X-ray must be examined. If there is any question about device or lead location or anatomy, additional imaging such as transesophageal echocardiography (TEE) and/or computed tomography (CT) scanning may be required for confirmation.<sup>73</sup>

### **Device, lead and adapter information (Connected and Abandoned)**

Prior to performing the procedure, the operator must be aware of **all** device and lead hardware present, including those in use and previously abandoned. Simply asking the patient is not adequate because he/she is often unaware of prior abandoned leads and current device configurations. Every attempt should be made to review prior operative reports and to obtain device registration information from

device manufacturers. The pre-procedure chest X-ray may be the only way to determine the number and location of leads. The operator should determine the models and implantation dates for all leads and the pulse generator. The operator must also be familiar with the physical and structural characteristics of each lead. For example, it is not adequate to only determine that the lead's fixation mechanism is active or passive. Some active fixation leads require special "fixation stylets" to retract the fixation mechanism [e.g., Teletronics ACCUFIX, some Guidant (Boston Scientific) ICD leads]. Knowing that a patient has one of these leads and having the appropriate tools are important to success and safety. The operator must also be familiar with the physical characteristics of each lead including insulation material and lead design (coaxial, co-radial, cable, etc.).

### **Need for pacing support during the procedure**

It is crucial to determine if the patient is pacemaker dependant and will require temporary pacing support during the procedure. Pacemaker dependent patients should have a temporary pacing wire placed prior to extraction. The temporary wire must be readily accessible during the procedure because it may be dislodged and require rapid repositioning. Patients who are not pacemaker dependent prior to the procedure may become so during the procedure. This is especially true in patients with sinus node dysfunction after the initiation of general anesthesia. It is therefore recommended, in non-pacemaker dependent patients, that the device be reprogrammed to a pacing rate below the patient's rate (i.e. VVI 40). By doing so, when the device is disconnected from the leads the operator is not surprised to find the patient has become pacemaker dependent. A venous sheath, placed in one of the femoral veins, allows for the rapid deployment of a temporary pacing wire should it be required.

### **Device interrogation and reprogramming**

All devices should be interrogated prior to the procedure. The settings and lead parameters should be documented. This will allow for reprogramming of the current device (or programming of a new device) to the appropriate settings after re-implantation. In addition, the functioning of preserved leads can be compared to the pre-procedure values to ensure that no damage to any reused ("bystander") lead occurred. It is also recommended that rate responsiveness should be turned off to prevent rapid pacing with manipulation of the device. Tachycardia devices must have detections turned off to prevent inappropriate therapies.

### **Need for ongoing device therapy**

The original indication for system implantation must be reviewed as should changes in the patient's condition since that procedure. A decision needs to be made and reviewed prior to the extraction as to the need for re-implantation and the timing, route and technique for both temporary and permanent placement.

### Procedure preparation

Direct preparation of the patient in the extraction laboratory includes the availability of baseline blood tests (metabolic profile, CBC and coagulation profile) and blood that has been typed and cross-matched. For most procedures, at least 4 units should be available, while for some "high risk" procedures some blood should be in the procedure room. Obtaining large bore (18 gauge or larger) venous access is required, and femoral venous access is strongly encouraged since it provides venous access, facilitates temporary pacing, and provides a femoral access route for extraction and delivery of fluids, blood and drugs in the advent of a vascular emergency. The patient will require continuous electrocardiographic and blood pressure monitoring. Though the blood pressure may be monitored using noninvasive methods, invasive monitoring provides faster recognition of changes and is preferred by most experts. The patient's skin should be prepared with antiseptic solution in such a manner as to allow for an emergent pericardiocentesis, thoracotomy, sternotomy and cardio-pulmonary bypass. The ability to perform transcutaneous pacing and defibrillation using pre-applied adhesive pads is essential.

### Indications for lead removal

Indications for transvenous lead removal have previously been described by the clinically framed "Byrd Classification"<sup>74</sup> (Mandatory, Necessary and Discretionary). In 2000, these were refined and published in the format established for the American College of Cardiology/American Heart Association's methodology for practice guidelines (Class I, Class II and Class III).<sup>1,137</sup> Since the original policy conference in 1997 and its publication in 2000 there has been a substantial increase in the number of CIED implants, their leads and the inevitable CIED complications.<sup>75,76,77,78,79</sup> Equally important to note is the maturation of the techniques, technologies, and experience with transvenous lead extraction and with the long-term management of these leads. This has led to an expanded understanding of lead management issues, risks, benefits, indications and contraindications, permitting a clarification and update of these indications. Unless otherwise noted, the references to lead removal in **Table 3** relate to transvenous lead removal and not to surgical techniques.<sup>24,25,26</sup>

When considering the indication for any procedure or therapy, it is important to relate the strength of the clinical indication for transvenous lead extraction to the early and the long-term value of the outcome and the risk of the intervention evaluated on an individualized patient basis. The risk of transvenous lead extraction is highly dependent on the training and experience of the practitioner and the extraction team. Even the strongest indication should be considered contraindicated when the extraction team has little experience or inadequate tools.<sup>1,46,47,80</sup> **The indications listed in Table 3 assume that the extraction environment conforms to the standards set forth in this document.** Alternative lead extraction environments such as surgical extraction by thoracotomy or median sternot-

omy, despite the obvious clear morbidity associated with these techniques, may be more appropriate approaches to lead removal in hospitals without an extraction program adhering to the guidelines in this document.

Alternative lead placements are also without sufficient data to make firm recommendations. There is a growing literature that supports that many cardiac venous leads implanted for cardiac resynchronization therapy can be safely removed.<sup>81,82</sup> However, caution should be applied to lead removal and extraction of leads that promote tissue ingrowth that are placed into the cardiac veins.<sup>83,84</sup> There are no data to address the removal of leads from the azygous vein and this and other creative approaches to lead placement need to be approached with extreme caution.<sup>85</sup>

Certain clinical situations such as patients who require cardiac surgery for another unrelated indication or those with large infected vegetations may be better served using nontransvenous techniques. Every patient's situation should be evaluated for life-long consequences, considering the implications of current decisions on the ultimate outcomes and future management of the patient. There are no specific rules for the size of a vegetation before a decision is made to remove the leads and vegetation with open surgical techniques. Vegetation size, shape, friability, presence or absence of a patent foramen ovale, ASD or VSD, other surgical indications and goals, health or hemodynamic instability of the patient, pacemaker dependency, need for ICD or LV leads and plans for re-implantation all need to be considered when making this decision.<sup>64,86,87</sup> Sometimes, a patient with a modest sized vegetation (<2 cm) still should be taken to the operating room for open removal and debridement, especially if the patient is pacemaker dependent or requires early transvenous re-implantation. Alternatively, re-implantation can be done with an epicardial pacing lead after transvenous extraction. Patients with larger vegetations (>3 cm) will more commonly require open debridement. These decisions impact the duration and type of antibiotic therapy and the time of device re-implantation. Temporary pacing and wearable defibrillators are often considerations for these patients.<sup>65,88,89</sup>

CIED associated infections are the strongest indication for complete CIED system removal; however, these patients can present with a broad range of clinical scenarios.<sup>90,91,92,93,94,95,96</sup> Infection can present with nothing more than pain in the CIED pocket. However, when an infection is identified, this produces a strong indication for removal of all components of the CIED system including the device, lead, adapters, caps, sutures and as much of the infected tissue as possible in order to consistently resolve the infection.<sup>97,98</sup> Occasionally a patient's overall prognosis will be so poor as to favor chronic suppression instead of extraction, but this is an exception.<sup>99</sup> Documentation of device related infections, although sometimes obvious with fever, bacteremia, vegetations and sepsis, is also often difficult to diagnose or to associate with the implantable device. Even in patients with documented device related infection, cultures can be

**TABLE 3** Indications for transvenous lead extraction\*

Recommendations for lead extraction apply only to those patients in whom the benefits of lead removal outweigh the risks when assessed based on individualized patient factors and operator specific experience and outcomes.

## Infection

## Class I

1. Complete device and lead removal is recommended in all patients with definite CIED system infection, as evidenced by valvular endocarditis, lead endocarditis or sepsis. (*Level of evidence: B*)
2. Complete device and lead removal is recommended in all patients with CIED pocket infection as evidenced by pocket abscess, device erosion, skin adherence, or chronic draining sinus without clinically evident involvement of the transvenous portion of the lead system. (*Level of evidence: B*)
3. Complete device and lead removal is recommended in all patients with valvular endocarditis without definite involvement of the lead(s) and/or device. (*Level of evidence: B*)
4. Complete device and lead removal is recommended in patients with occult gram-positive bacteremia (not contaminant). (*Level of evidence: B*)

## Class IIa

1. Complete device and lead removal is reasonable in patients with persistent occult gram-negative bacteremia. (*Level of evidence: B*)

## Class III

1. CIED removal is not indicated for a superficial or incisional infection without involvement of the device and/or leads (*Level of evidence: C*)
2. CIED removal is not indicated to treat chronic bacteremia due to a source other than the CIED, when long-term suppressive antibiotics are required. (*Level of evidence: C*)

## Chronic Pain

## Class IIa

1. Device and/or lead removal is reasonable in patients with severe chronic pain, at the device or lead insertion site, that causes significant discomfort for the patient, is not manageable by medical or surgical techniques and for which there is no acceptable alternative. (*Level of evidence: C*)

## Thrombosis or Venous Stenosis

## Class I

1. Lead removal is recommended in patients with clinically significant thromboembolic events associated with thrombus on a lead or a lead fragment. (*Level of evidence: C*)
2. Lead removal is recommended in patients with bilateral subclavian vein or SVC occlusion precluding implantation of a needed transvenous lead. (*Level of evidence: C*)
3. Lead removal is recommended in patients with planned stent deployment in a vein already containing a transvenous lead, to avoid entrapment of the lead. (*Level of evidence: C*)
4. Lead removal is recommended in patients with superior vena cava stenosis or occlusion with limiting symptoms. (*Level of evidence: C*)
5. Lead removal is recommended in patients with ipsilateral venous occlusion preventing access to the venous circulation for required placement of an additional lead when there is a contraindication for using the contralateral side (e.g. contralateral AV fistula, shunt or vascular access port, mastectomy). (*Level of evidence: C*)

## Class IIa

1. Lead removal is reasonable in patients with ipsilateral venous occlusion preventing access to the venous circulation for required placement of an additional lead, when there is no contraindication for using the contralateral side. (*Level of evidence: C*)

## Functional Leads

## Class I

1. Lead removal is recommended in patients with life threatening arrhythmias secondary to retained leads. (*Level of evidence: B*)
2. Lead removal is recommended in patients with leads that, due to their design or their failure, may pose an immediate threat to the patients if left in place. (e.g. Telectronics ACCUFIX J wire fracture with protrusion). (*Level of evidence: B*)
3. Lead removal is recommended in patients with leads that interfere with the operation of implanted cardiac devices. (*Level of evidence: B*)
4. Lead removal is recommended in patients with leads that interfere with the treatment of a malignancy (radiation/reconstructive surgery). (*Level of evidence: C*)

## Class IIb

1. Lead removal may be considered in patients with an abandoned functional lead that poses a risk of interference with the operation of the active CIED system. (*Level of evidence: C*)
2. Lead removal may be considered in patients with functioning leads that due to their design or their failure pose a potential future threat to the patient if left in place. (e.g. Telectronics ACCUFIX without protrusion) (*Level of evidence: C*)
3. Lead removal may be considered in patients with leads that are functional but not being used. (i.e. RV pacing lead after upgrade to ICD) (*Level of evidence: C*)
4. Lead removal may be considered in patients who require specific imaging techniques (e.g. MRI) that can not be imaged due to the presence of the CIED system for which there is no other available imaging alternative for the diagnosis. (*Level of evidence: C*)
5. Lead removal may be considered in patients in order to permit the implantation of an MRI conditional CIED system. (*Level of evidence: C*)

**TABLE 3** Indications for transvenous lead extraction\* - continued

<p>Class III</p> <ol style="list-style-type: none"> <li>1. Lead removal is not indicated in patients with functional but redundant leads if patients have a life expectancy of less than one year. (<i>Level of evidence: C</i>)</li> <li>2. Lead removal is not indicated in patients with known anomalous placement of leads through structures other than normal venous and cardiac structures, (e.g. subclavian artery, aorta, pleura, atrial or ventricular wall or mediastinum) or through a systemic venous atrium or systemic ventricle. Additional techniques including surgical backup may be used if the clinical scenario is compelling. (<i>Level of evidence: C</i>)</li> </ol> <p>Non Functional Leads</p> <p>Class I</p> <ol style="list-style-type: none"> <li>1. Lead removal is recommended in patients with life threatening arrhythmias secondary to retained leads or lead fragments. (<i>Level of evidence: B</i>)</li> <li>2. Lead removal is recommended in patients with leads that, due to their design or their failure, may pose an immediate threat to the patients if left in place. (e.g. Telectronics ACCUFIX J wire fracture with protrusion) (<i>Level of evidence: B</i>)</li> <li>3. Lead removal is recommended in patients with leads that interfere with the operation of implanted cardiac devices. (<i>Level of evidence: B</i>)</li> <li>4. Lead removal is recommended in patients with leads that interfere with the treatment of a malignancy (radiation/reconstructive surgery). (<i>Level of evidence: C</i>)</li> </ol> <p>Class IIa</p> <ol style="list-style-type: none"> <li>1. Lead removal is reasonable in patients with leads that due to their design or their failure pose a threat to the patient, that is not immediate or imminent if left in place. (e.g. Telectronics ACCUFIX without protrusion) (<i>Level of evidence C</i>)</li> <li>2. Lead removal is reasonable in patients if a CIED implantation would require more than 4 leads on one side or more than 5 leads through the SVC. (<i>Level of evidence C</i>)</li> <li>3. Lead removal is reasonable in patients that require specific imaging techniques (e.g. MRI) and can not be imaged due to the presence of the CIED system for which there is no other available imaging alternative for the diagnosis. (<i>Level of evidence: C</i>)</li> </ol> <p>Class IIb</p> <ol style="list-style-type: none"> <li>1. Lead removal may be considered at the time of an indicated CIED procedure, in patients with non-functional leads, if contraindications are absent. (<i>Level of evidence C</i>)</li> <li>2. Lead removal may be considered in order to permit the implantation of an MRI conditional CIED system. (<i>Level of evidence: C</i>)</li> </ol> <p>Class III</p> <ol style="list-style-type: none"> <li>1. Lead removal is not indicated in patients with non-functional leads if patients have a life expectancy of less than one year. (<i>Level of evidence C</i>)</li> <li>2. Lead removal is not indicated in patients with known anomalous placement of leads through structures other than normal venous and cardiac structures, (e.g. subclavian artery, aorta, pleura, atrial or ventricular wall or mediastinum) or through a systemic venous atrium or systemic ventricle. Additional techniques including surgical backup may be used if the clinical scenario is compelling. (<i>Level of evidence: C</i>)</li> </ol>
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CIED(s): cardiovascular implantable electronic device(s)

\*Legend for Table 3 can be found underneath Table 4.

Note: Assigning a level of Evidence B or C should not be construed as implying that the recommendation is weak. Many important clinical questions addressed in this document either do not lend themselves to experimentation or have not yet been addressed by high quality investigations; the authors of this document felt it was important to include all recommendations.

negative. This may occur in the setting of preoperative antibiotic therapy, but may occur even in the absence of antibiotic therapy. Delaying the definitive operation with removal of all of the components of the CIED system can be a fatal choice for the patient.<sup>100</sup> Dy Chua and colleagues<sup>101</sup> documented that the best yield for documenting the pathologic bacteria required culture of the tissue debrided from the pulse generator pocket fibrosis. However, even this yielded positive results in only 69% of the clinically infected patients. In addition, patients who present with signs and symptoms of pocket infection usually have involvement of the intravascular components of the system. Klug et al.<sup>102</sup> demonstrated that there was evidence of intravascular lead involvement in 88.4% of patients presenting with clinical pocket infections by examining the intravascular segments of the lead. The Cleveland Clinic series noted that only in the 4 patients with incomplete extraction, out of a total of 123 patients,

did recurrent infection develop.<sup>97,103</sup> This is consistent with the pathophysiology of staphylococcal bacteria, the predominant pathogen in device infections, in that they form a protective biofilm.<sup>104</sup> This biofilm, which adheres to the plastic and metal of the devices and leads, makes these infections resistant to antibiotics and the body's immune defense system. Consequently, when pocket pain is severe enough to require intervention yet there is no overt evidence of infection, it was the consensus of the writing committee that strong consideration should be made to treat the patient as if the cause is infectious. This should also include the use of antibiotics and delaying re-implantation to another day and at a different anatomic location.<sup>105</sup>

A single positive blood culture without other clinical evidence of infection should not result in removal of the CIED system. However, when there are positive cultures obtained on different days (persistent bacteremia), even

**TABLE 4** Principles for CIED replacement following infected removal\*

Recommendations for lead extraction apply only to those patients in whom the benefits of lead removal outweigh the risks when assessed based on individualized patient factors and operator specific experience and outcomes.

## Class I

1. Each patient should be carefully evaluated to determine if there is a continued need for a new CIED. (*Level of evidence: C*)
2. The replacement device implantation should not be ipsilateral to the extraction site. Preferred alternative locations include the contralateral side, iliac vein, trans-atrial and epicardial implantation. (*Level of evidence: C*)

## Class IIa

1. A new CIED system can be implanted into patients who have no valvular or lead associated vegetations but preoperative positive blood cultures, when there is no further clinical evidence of systemic infection and the blood cultures drawn within 24 hours of CIED system removal remain negative for at least 72 hours (*Level of evidence: C*)
2. A new CIED system can be implanted into patients who have no valvular or lead associated vegetations but positive lead tip cultures, when there is no further clinical evidence of systemic infection and the blood cultures drawn within 24 hours of CIED system removal remain negative for at least 72 hours (*Level of evidence: C*)
3. A new CIED system can be implanted into patients who have no valvular or lead associated vegetations but preoperative sepsis and positive blood cultures, when there is no further clinical evidence of systemic infection and the blood cultures drawn within 24 hours of CIED system removal remain negative for at least 72 hours (*Level of evidence: C*)
4. It is reasonable to delay transvenous re-implantation of a new CIED system into patients with valvular or lead associated vegetations for at least 14 days after CIED system removal. However there are options to reduce this delay including debridement of the vegetations and epicardial lead implantation. (*Level of Evidence: C*)

CIED(s): cardiovascular implantable electronic device(s)

\*Legend for Table 3 and Table 4: Classification of Recommendations and Level of Evidence are expressed in the American College of Cardiology/American Heart Association format:<sup>137</sup>

#### Classification of Recommendations

Class I: Conditions for which there is evidence and/or general agreement that a given procedure or treatment is useful and effective.

Class II: Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment.

- IIa: Weight of evidence/opinion is in favor of usefulness/efficacy
- IIb: Usefulness/efficacy is less well established by evidence/opinion.

Class III: Conditions for which there is evidence and/or general agreement that the procedure/treatment is not useful or effective, and in some cases may be harmful.

#### Level of Evidence

Level of Evidence A: Data derived from multiple randomized clinical trials or meta-analyses

Level of Evidence B: Data derived from a single randomized trial, or non-randomized studies

Level of Evidence C: Consensus opinion of experts, case studies, or standard of care

Note: Assigning a Level of Evidence B or C should not be construed as implying that the recommendation is weak. Many important clinical questions addressed in this document either do not lend themselves to experimentation or have not yet been addressed by high quality investigations; the authors of this document felt it was important to include all recommendations.

when there is no clear source of the positive culture in the heart, on the leads or from another part of the body despite a complete evaluation (occult infection), transvenous lead extraction should be strongly considered.<sup>100</sup> Superficial or incisional erythema or infection is not clear evidence of CIED system infection, but the patient should be closely followed for progression to a deeper infection, which would require extraction.<sup>106</sup> Gram-negative bacteremia is less commonly a pathogen in CIED related infections and persistence of the bacteremia should be documented past the treatment of other sources of the bacteria before extraction is contemplated.<sup>97,98,107</sup>

CIED re-implantation after removal for an infection provides little tolerance for strategic error. The implantation approaches are limited (only 2 pectoral sites) and re-implantation at the site of CIED and lead removal, when done before the infection has been eradicated, can be associated with an early or late recurrence of the infection. **Table 4** provides recommendations or principles to be followed for timing device re-implantation, but there are little published data and no firm consensus about the best approach to patient management. When there is concern for ongoing

infection, alternatives to early re-implantation (after 2–3 days) include wearable defibrillators, epicardial lead implantation and surgical debridement of vegetations.<sup>88,89</sup> However, it is clear that in the absence of intracardiac vegetations, when there is no further evidence of systemic infection, that relatively early (3 days) transvenous implantation can usually be done without concern for infection recurrence.<sup>97</sup> Although there are no clinical trials that have tested the minimal duration of antibiotic therapy or when it is appropriate to switch from IV to PO antibiotics, there is over 20 years of experience using guidelines similar to that used for non CIED related endocarditis.<sup>14,97</sup> It is generally agreed that 2-6 weeks of IV or sometimes oral antibiotics may still required depending on the microbiologic isolate, antibiotic sensitivities and clinical scenario.

Transvenous lead extraction for patients without infection is a more controversial topic. It is often possible to abandon a failed or no longer required lead and/or implant the needed leads through the same or alternative implantation route. Since it is less common for a patient to exhibit symptoms or be at risk of death from the abandonment of non infected leads, it is more difficult to calculate the risk to benefit ratio of lead extraction

in these patients. Therefore when these indications are considered, it is crucial to balance the risk of the intervention, including the experience of the lead extraction operator, with the patient's situation.<sup>108,109,110,111</sup>

There are several other important observations that favor earlier lead extraction instead of abandonment. Leads, when left behind, are more difficult to remove and when removed are associated with an increased risk of major complications, which progresses as the implantation duration prolongs.<sup>14,46,80</sup> Therefore it is difficult to anticipate how taking risk now versus later is to be best assessed. These extraction risks increase as the inter-lead fibrosis thickens and covers more of the surface of the lead, especially when there are multiple leads.<sup>3,6</sup> Also proportional to implant duration is lead fragility, which increases with the body's chemical and mechanical stresses and reduces the likelihood of complete lead removal.<sup>11,14,46,80</sup> The risks are further increased with even modest calcification of the fibrosis.<sup>6</sup> Therefore, in a 20 year old patient with complete heart block and two failed leads, implanting new leads without extracting the old ones, although feasible, is usually inadvisable. Alternatively, in a 90 year old patient with one failed lead or an occluded vessel precluding the reuse of the ipsilateral subclavian vein, it may be more reasonable to consider that failure to remove the lead would never become a clinical issue for the patient. It is also important to consider how long the lead had been implanted, the fragility or tensile robustness of each particular lead, and the ease or difficulty of extraction of the particular lead model. The indications in [Table 3](#) were developed on the basis of the complete consensus of the document writing committee, and take into account the relative safety and effectiveness of transvenous lead extraction when done in conformance with the standards in this document.

For each of the indications listed for noninfected lead extraction, there must be a clinical goal that balances the risk of removal and reasonable alternatives should be considered. Although there are no clinical trials proving the relative advantage of lead extraction, there is a literature that supports the rationale for extraction. Severe chronic pain for which there is not alternative therapy is sometimes infection related but is most commonly responsive to generator and lead removal in the experience of the authors.

Venous thrombosis alone is not an indication for lead extraction, but when there are symptoms or when the occlusion prevents the application of pacemaker, ICD or other therapies it is often appropriate to extract the leads to achieve the clinical goal.<sup>112</sup> For example, it is inappropriate to stent open a vein, trapping the pacing leads against the vein wall and preventing future safe lead extraction.<sup>110,113,114,115</sup> Other approaches such as allowing collaterals to develop over time, use of limb elevation, anticoagulation or venoplasty are effective in alleviating symptoms and should be considered prior to lead extraction. Removal of the leads can also be associated with thrombosis and

occlusion, but acute occlusions with thrombus usually responds to anticoagulation, while chronic occlusion that develops into a fibrosis does not.

Leads can sometimes induce life threatening arrhythmias, pose physical risk to a patient such as the Teletronics ACCUFIX lead with a fracture, interfere with the normal detection of arrhythmias by an ICD or get in the way of radiation therapy or required surgery.<sup>108,109,116,117,118,119,120,121,122,123</sup> Alternatives to lead extraction are sometimes available and should be considered, such as moving a newly implanted lead further from the chronically implanted lead that had caused interference with arrhythmia detection.

Magnetic Resonance Imaging (MRI) scanning is formally contraindicated in patients with pacemakers and ICDs; however not all patients with indications for MRI scanning have reasonable alternatives.<sup>124,125,126</sup> The American Society for Testing and Materials (ASTM) and the U.S. Food and Drug Administration (FDA) have classified pacemaker systems as either MRI safe, MRI condition+al or MRI unsafe.<sup>127,128</sup> Even with new pacemaker or ICD systems that are considered MRI safe or MRI conditional, there will continue to be some situations where it will be appropriate to extract leads from patients to permit appropriate scanning of patients. However, all other alternatives should be explored before choosing to extract the leads.

The removal of functional and nonfunctional leads that are not being employed for the CIED depends on the patient's clinical situation. As discussed above, there is some risk to leaving leads in, although when the risk will come into play is uncertain.<sup>129,130,131,132,133</sup> A long-term perspective is required to allow the appropriate decision to be made, since over the first few years it would be rare for the risk of leaving the lead implanted would outweigh the potential risks of lead extraction.<sup>134,135</sup> Not all abandoned leads should be removed and there must be another clinical indication for the CIED procedure to overcome the risks associated with opening the device pocket such as infection.<sup>136</sup> There should be an additional clinical indication for opening the pocket when there is a safety alert for the lead while the lead is still functional and as such does not pose a manifest risk to the patient. This is supported by the experience with the Teletronics ACCUFIX extractions.<sup>108</sup>

Finally, removal of leads when there are multiple (4 or more) leads implanted through a single vein or 5 or more through the superior vena cava is not only more difficult but also more dangerous. This appears to be most important in medium to small sized patients (body mass index < 25) who had a 3.7 times higher major adverse event rate (2.6% absolute rate) than larger patients in the Lexicon study.<sup>80</sup> This is also consistent with the 7% major complication rate in women with 3 or more leads extracted, which was also 3.7 times higher than women with one lead and 7 times higher than men with one lead extracted as reported from the multivariate analysis of the Cook voluntary national extraction registry.<sup>46,47</sup>

## Registry and data management

The lead management environment, as discussed earlier in this document, requires a commitment to quality through the collection and review of personal and institutional outcomes for device implantation and transvenous lead extraction. In addition to the local collection and review of outcomes, a mechanism needs to be developed to benchmark local outcomes to national and international outcomes. This will require a pragmatic registry with low barriers for collecting, reporting, analyzing and benchmarking the outcomes. This tool needs to be accessible to all committed lead management centers, and requires clear definitions, simplified data collection tools and transparent administration. Although the data are not primarily to be a source of research, the publication of these data is fundamental to the goal of quality. The support for this registry should include physicians, hospitals, manufacturers of implantable devices, manufacturers of extraction and lead management devices and national regulatory bodies.

It is the consensus of the writing committee that there should be a coordinated effort to make this lead management registry a reality. The effort should be supported by CIED and extraction equipment manufacturers, but should be administered by a third party such as the Heart Rhythm Society. Data collection would be done by each medical center. Use of a web based data collection tool would meet the criteria for accessibility. Each center would be able to access only their own data and benchmarked summary data from the entire dataset. These un-audited data should be supplemented with additional benchmark summary data from a set of core centers that would submit to periodic data audits. These data would then be published and serve to provide for core data elements for the evaluation of new technologies, and would advance the standards for quality measures.

## New devices and techniques

The introduction of new devices and their use is regulated in the United States by the Food and Drug Administration. The purpose of this regulation is to assure that newly released devices are safe and effective when used according to the device labeling. The successful extraction of leads associated with a CIED often requires the use of multiple tools and techniques. Therefore, it must be understood that a single device or technique is unlikely to be proven safe and effective in all situations. Rather, as with many surgical techniques, the instruments used are chosen in a given situation due to the specific needs as they present during the procedure. Further, devices are often used in combination, such as locking stylets and telescoping sheaths, or in tandem, such as laser sheaths followed by polymer sheaths or rotating cutting sheaths. This makes the design of a clinical trial to test a new device or technique very difficult because the effects of the new device or technique alone may be impossible to separate from the effects of all the devices and techniques used as a group. It would be most unwise to devise a clinical trial that mandated that only the new tool

could be used or that the new tool had to be compared to a single existing tool. The interpretation of results from such trials is further complicated by difficulties in the definitions of success and complications, by the lack of adequate data, by sources of bias (such as unbalanced crossover), and by patient selection criteria. Therefore, it is essential that systematic principles are applied to the technical and clinical evaluation of both new techniques and new tools.

## Recommendation for clinical evaluation of lead extraction devices

New devices typically follow a path from a proof of concept stage (phase 1) to preclinical studies (phase 2) and only then to clinical studies (phase 3). We provide the following recommendations for these trials:

- The clinical trial (phase 3) to examine safety and effectiveness should not be initiated until a stable technique or tool has been established with phase 1 and phase 2 evaluations. The initial evaluation (phase 1) should involve bench and animal testing and the proof of concept clinical testing. The phase 2 evaluation should be done in 3 to 5 centers having prolonged and documented experience with lead extraction. The goal is to document the utility of the tool, provide for minor modifications in the design and technique, and to confirm the lack of predictable harm.
- The phase 3 clinical trial design should be appropriate to assess the marginal effects of a new device on safety and effectiveness, given the combined use with existing devices.
- Given that lead extraction is now a relatively mature science with standard tools available, it is appropriate that new tools for lead extraction be submitted to randomization in prospective controlled trials.
- The phase 3 clinical trial design should have a statistical plan addressing adequate sample size, stratification (e.g., ICD vs pacing lead), crossover bias if applicable, assessment of covariates, and appropriate methods for hypothesis testing.
- All of these studies should use the definitions of indications, successes, and complications that have been delineated in this document.

## Conclusion

The procedure of lead extraction has now become part of the larger concept of lead management. While extraction has matured into a definable, teachable art with its own specific tools and techniques, there remain challenges in our ability to impart these skills to physicians so that safe and effective transvenous lead extraction is available to patients around the world. While the authors strongly endorse the indications as described, we also recognize the unique circumstances surrounding each patient and clinical situation. What cannot be accepted is the application of these techniques by those not adequately trained, or by those practicing at institutions that do not provide the level of support required to assure the safety of the patient during an extraction procedure. This up-

dated document is intended to serve as a resource and set of guidelines to define and support the development of this safe medical environment.

It is also no longer acceptable to treat most CIED infections in a "conservative" manner. Curative therapy nearly always requires removal of the foreign bodies from the infected site, with re-implantation of a new system at an alternate site. The use of suppressive antibiotics should be reserved for special cases as noted in the text of this document, and there is rarely (if ever) a place for pocket revision by reimplanting an eroded or infected device in the same pocket that has been debrided.

Complications will periodically occur, even in the most experienced hands and centers, during transvenous lead extraction and the survival of the patient requires that the operator and extraction support team be prepared. It is the

rapid response of the physician, extraction team, and the surgical backup that will give the patient the greatest chance of surviving.

The fundamental precept in the provision of quality is measurement. We have precisely provided definitions for indications, clinical and procedural success and complications. It is just as clear what personnel and the facility requirements that are required to assemble, train and maintain the extraction team. However, implementation of these recommendations will require significant effort and cooperation from practicing physicians, medical societies, hospital administrations, and industry. The final, missing and required element in order for each extraction program and operator to measure quality is to have a tool for each center to collect, review and compare its individual outcomes to national benchmark data.

## Appendix

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\*Significant

A relationship is considered to be "significant" if (1) the person receives \$10,000 or more during any 12-month period or 5% or more of the person's gross income; or (2) the person owns 5% or more of the voting stock or share of the entity or owns \$10,000 or more of the fair market value of the entity.

A relationship is considered to be "modest" if it is less than "significant" under the preceding definition.

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