Heart Rhythm Society SM

Summary of Expert Consensus Statement for CLINICIANS

2017 HRS Expert Consensus Statement on Cardiovascular Implantable Electronic Device Lead Management and Extraction

This is a summary of the Heart Rhythm Society Expert Consensus Statement titled *2017 HRS Expert Consensus Statement on Cardiovascular Implantable Electronic Device Lead Management and Extraction*, which was released during the APHRS-HRS Joint Session on Lead Management and Extraction at the 10th Asia Pacific Heart Rhythm Society Scientific Session held in conjunction with the Annual Meeting of the Japanese Heart Rhythm Society, in Yokohama, Japan. Please refer to the full statement for more information.

Over the past 60 years, cardiovascular implantable electronic devices (CIEDs) have become established as an important therapeutic modality of cardiovascular care for the treatment of patients with bradycardia, tachycardia, and heart failure. Although recent technological advances have eliminated the need for transvenous or epicardial leads for CIEDs used in selected patient groups, lead management remains critical for a variety of reasons. Recent estimates suggest that 1.2–1.4 million CIEDs are implanted annually worldwide. Questions on lead management arise in several situations, including when changes in a patient's clinical condition make a different functionality more or less important, if a lead becomes nonfunctional, and if the presence of a lead is thought to interfere with the patient's optimal treatment.

Lead Survival

A lead model and clinical scenario-specific strategy of increased surveillance and management can be useful for CIED leads that have been identified with higher-than-expected failure rates. (COR IIa; LOE C-EO)

Existing Cardiovascular Implantable Electronic Device Lead Management

Leaving the lead in a condition that will permit future extraction and prevents retraction into the vessel is recommended for any abandoned lead. (COR I; LOE C-EO)
Careful consideration with the patient on the decision on whether to abandon or remove a lead is recommended before starting the procedure. The risks and benefits of each course of action should be discussed, and any decision should take the patient's preference, comorbidities, future vascular access, and available programming options into account. (COR I; LOE C-EO)

Lead abandonment or removal can be a useful treatment strategy if a lead becomes clinically unnecessary or nonfunctional. (COR IIa; LOE B-NR)

Indications for Lead Extraction (Infectious)

Cardiovascular Implantable Electronic Device Infection
If antibiotics are going to be prescribed, drawing at least 2 sets of blood cultures before starting antibiotic therapy is recommended for all patients with suspected CIED infection to improve the precision and minimize the duration of antibiotic therapy. (COR I; LOE C-LD)
Gram stain and culture of generator pocket tissue and the explanted lead(s) are recommended at the time of CIED removal to improve the precision and minimize the duration of antibiotic therapy. (COR I; LOE C-LD)
Preprocedural transesophageal echocardiography (TEE) is recommended for patients with suspected systemic CIED infection to evaluate the absence or size, character, and potential embolic risk of identified vegetations. (COR I; LOE B-NR)
Evaluation by physicians with specific expertise in CIED infection and lead extraction is recommended for patients with documented CIED infection. (COR I; LOE C-EO)
TEE can be useful for patients with CIED pocket infection with and without positive blood cultures to evaluate the absence or size, character, and potential embolic risk of identified vegetations. (COR IIa; LOE B-NR)
Evaluation by physicians with specific expertise in CIED infection and lead extraction can be useful for patients with suspected CIED infection. (COR IIa; LOE C-EO)
Additional imaging may be considered to facilitate the diagnosis of CIED pocket or lead infection when it cannot be confirmed by other methods. (COR IIb; LOE C-LD)
Management
A complete course of antibiotics based on identification and in vitro susceptibility testing results after CIED removal is recommended for all patients with definite CIED system infection. (COR I; LOE B-NR)
Complete device and lead removal is recommended for all patients with definite CIED system infection. (COR I; LOE B-NR)
Complete removal of epicardial leads and patches is recommended for all patients with confirmed infected fluid (purulence) surrounding the intrathoracic portion of the lead. (COR I; LOE C-EO)
Complete device and lead removal is recommended for all patients with valvular endocarditis without definite involvement of the lead(s) and/or device. (COR I; LOE B-NR)
Complete device and lead removal is recommended for patients with persistent or recurrent bacteremia or fungemia, despite appropriate antibiotic therapy and no other identifiable source for relapse or continued infection. (COR I; LOE B-NR)
Careful consideration of the implications of other implanted devices and hardware is recommended when deciding on the appropriateness of CIED removal and for planning treatment strategy and goals. (COR I; LOE C-EO)

Indications for Lead Extraction (Noninfectious)

Chronic Pain
Device and/or lead removal can be useful for patients with severe chronic pain at the device or lead insertion site or believed to be secondary to the device, which causes significant patient discomfort, is not manageable by medical or surgical techniques, and for which there is no acceptable alternative. (COR IIa; LOE C-EO)
Thrombosis/Vascular Issues
Lead removal is recommended for patients with clinically significant thromboembolic events attributable to thrombus on a lead or a lead fragment that cannot be treated by other means. (COR I; LOE C-EO)
Lead removal is recommended for patients with SVC stenosis or occlusion that prevents implantation of a necessary lead. (COR I; LOE C-EO)
Lead removal is recommended for patients with planned stent deployment in a vein already containing a transvenous lead, to avoid entrapment of the lead. (COR I; LOE C-EO)
Lead removal as part of a comprehensive plan for maintaining patency is recommended for patients with SVC stenosis or occlusion with limiting symptoms. (COR I; LOE C-EO)
Lead removal can be useful for patients with ipsilateral venous occlusion preventing access to the venous circulation for required placement of an additional lead. (COR IIa; LOE C-LD)
Other
Lead removal is recommended for patients with life-threatening arrhythmias secondary to retained leads. (COR I; LOE C-EO)
Lead removal can be useful for patients with a CIED location that interferes with the treatment of a malignancy. (COR IIa; LOE C-EO)
Lead removal can be useful for patients if a CIED implantation would require more than 4 leads on one side or more than 5 leads through the SVC. (COR IIa; LOE C-LD)
Lead removal can be useful for patients with an abandoned lead that interferes with the operation of a CIED system. (COR IIa; LOE C-EO)
Lead removal may be considered for patients with leads that due to their design or their failure pose a potential future threat to the patient if left in place. (COR IIb; LOE C-LD)
Lead removal may be considered for patients to facilitate access to MRI.* (COR IIb; LOE C-EO) **Removal of leads to prevent their abandonment, removal of broken or abandoned leads, or removal of leads to allow implantation of an MRI conditional system*
Lead removal may be considered in the setting of normally functioning nonrecalled pacing or defibrillation leads for selected patients after a shared decision-making process. (COR IIb; LOE C-EO)

Outcomes and Follow-up

Extraction programs and operator-specific information on volume, clinical success rates, and complication rates for lead removal and extraction should be available and discussed with the patient prior to any lead removal procedure. (COR I; LOE C-EO)

Lead Abandonment Clinical Scenarios

Patient scenario	Management strategies	Key points
An 86-year-old man with complete heart block who underwent dual-chamber pacemaker implantation 14 years ago, with most recent generator replacement 3 years ago. Two leads are in place. His medical history is significant for chronic lymphocytic lymphoma and recently diagnosed prostate cancer. He presents with noise on the right ventricular lead and inhibition of ventricular pacing consistent with lead malfunction.	• Assess possibility of reprogramming to unipolar. • Consider likelihood of ipsilateral venous occlusion, which would require contralateral lead placement for addition. • Management options discussed included extraction of 14-year-old pacemaker lead with new lead implantation vs abandonment of old lead and placement of new right ventricular lead. • Values elicited in discussion included patient's desire to avoid hospitalization and not wanting to be dependent on his children. • Although the risks of lead addition and lead extraction are comparable in the literature, the risk of major complications and a more prolonged hospital stay appear higher for an extraction procedure, particularly given the patient's advanced age, comorbidities, and older leads. The decision was made to add a new pace-sense lead and abandon the previously placed lead.	• Age and medical comorbidities contribute to the lead management decision making. • Lead type and dwell time contribute to the risk and benefit analysis in lead management decision making. • Abandoned leads are a contraindication for MRI, which is often used in the follow-up of cancer.
A 46-year-old woman with a history of mechanical mitral valve replacement complicated by complete heart block, who underwent placement of a dual-chamber pacemaker 3 years ago. She presents with dislodgement of the atrial lead associated with symptoms of loss of AV synchrony.	• Management options discussed included extraction and replacement of atrial lead, attempt to reposition, and addition of a new atrial lead. • Values elicited in discussion included the desire to have the best possible functional CIED system and not have abandoned leads, even if this resulted in a longer hospital stay due to anticoagulation management. • Despite the mechanical mitral valve, the ease of extraction of a 3-year-old pacemaker lead is reasonable. The decision was made to extract and replace the lead.	• Young age and long-term need for functional CIED therapy and the desire to avoid an abandoned lead contributed to the decision-making process.

A 25-year-old man who underwent a secondary prevention ICD placement with a dual-coil lead 14 years ago for a ventricular fibrillation cardiac arrest. His ICD lead fractured 6 years ago, and he underwent addition of a new ICD lead and abandonment of his first ICD lead. During the follow-up, the new ICD lead was found to be fractured, with inappropriate detections due to noise.	• Management options discussed included adding a third lead; abandoning both transvenous ICD leads and implanting a subcutaneous ICD; extracting both leads and adding a new ICD lead; extracting both leads and implanting a subcutaneous ICD. • Primary concerns elicited were the potential for long-term complications from the ICD leads and the possibility of needing an MRI in his lifetime. The decision was made to extract both leads and implant a subcutaneous ICD lead, after discussing the risks and benefits of a subcutaneous ICD system vs a transvenous ICD system.	• The lead extraction procedure was higher risk due to the previous decision to abandon a malfunctioning lead in a young patient.
A 40-year-old woman with familial LQT2 who underwent primary prevention ICD placement with a dual-coil lead 8 years ago due to pregnancy, concerns about increased risk of arrhythmias during the postpartum setting, and strong family history of peripartum sudden death. She has two children, will not have future pregnancies, and has never had ICD therapies. ICD generator is ERI, and she no longer wants ICD therapy.	• Management options discussed included abandoning lead and generator; removing generator and abandoning lead; and extracting lead and generator. • Values elicited included a desire to not have a prolonged hospitalization or recovery and not wanting a generator in the pocket. • The patient did not want to undergo extraction. At her request, the decision was made to remove the generator and abandon the lead.	• The option of removing only the generator would leave the patient with a contraindication for MRI. • The patient remains at ongoing risk for lead infection, which would require a higher risk extraction in the future. • Opening the pocket to remove the generator exposed the patient to a risk of infection.

A 52-year-old man with a history of complete heart block, leading to a diagnosis of cardiac sarcoidosis, underwent dual-chamber ICD with a single-coil ICD lead 4 years ago. He has had ATP therapy for VT. Remote interrogation shows impedance of 150 and episodes of noise on RV lead. Noise is reproducible on exam with pocket manipulation.	• Management options discussed included addition of new RV pace-sense lead; and ICD lead extraction and replacement. • Values elicited during discussion included his desire for a reliable system, concerns about the effect of more leads in his vasculature, and his desire to be able to easily undergo MRI in the future. • The decision was made to extract and reimplant a new ICD lead.	• Should the strategy of an additional lead be applied, vein patency would need to be considered. In case of extraction and reimplantation, the lead's original insertion point would need to be evaluated in case this represents damage from the costoclavicular ligaments. • Adding a pace-sense lead is sometimes a suboptimal choice, because the ICD shock coil can also be at high risk of failure in the setting of a pace-sense component fracture.

ATP = antitachycardia pacing; AV = atrioventricular; CIED = cardiovascular implantable electronic device; ERI = elective replacement indicator; ICD = implantable cardioverter defibrillator; MRI = magnetic resonance imaging; VT = ventricular tachycardia.

Risk Factors for Cardiovascular Implantable Electronic Device Infection

Patient-related factors	Procedure-related factors	Microbe-related factors
Age	Pocket reintervention (generator change, upgrade, lead or pocket revision)	Highly virulent microbes (eg, staphylococci)
Chronic kidney disease		
Hemodialysis		
Diabetes mellitus	Pocket hematoma	
Heart failure	Longer procedure duration	
Chronic obstructive pulmonary disease	Inexperienced operator	
	ICD (compared with PM)	
Preprocedure fever	Lack of use of prophylactic antibiotics	
Malignancy		
Skin disorder		
Immunosuppressive drug		
Prior CIED infection		
Anticoagulation		

CIED = cardiovascular implantable electronic device; ICD = implantable cardioverter defibrillator; PM = pacemaker.

Factors Associated with Extraction Procedure Complications and Longer-Term Mortality

Factor	Associated risk
Age	1.05-fold ↑ mortality
Female sex	4.5-fold ↑ risk of major complications
Low body mass index (<25 kg/m^2)	1.8-fold ↑ risk of 30-day mortality ↑ no. of procedure-related complications
History of cerebrovascular accident	2-fold ↑ risk of major complications
Severe LV dysfunction	2-fold ↑ risk of major complications
Advanced HF	1.3- to 8.5-fold ↑ risk of 30-day mortality 3-fold ↑ 1-year mortality
Renal dysfunction	ESRD: 4.8-fold ↑ risk of 30-day mortality Cr ≥2.0: ↑ in-hospital mortality and 2-fold ↑ risk of 1-year mortality
Diabetes mellitus	↑ in-hospital mortality 1.71-fold ↑ mortality
Platelet	Low platelet count: 1.7-fold ↑ risk of major complications
Coagulopathy	Elevated INR: 2.7-fold ↑ risk of major complications and 1.3-fold ↑ risk of 30-day mortality Anticoagulant use: 1.8-fold ↑ 1-year mortality
Anemia	3.3-fold ↑ risk of 30-day mortality
Number of leads extracted	3.5-fold ↑ risk of any complication 1.6-fold ↑ long-term mortality
Presence of dual-coil ICD	2.7-fold ↑ risk of 30-day mortality
Extraction for infection	2.7- to 30-fold ↑ risk of 30-day mortality 5- to 9.7-fold ↑ 1-year mortality CRP >72 mg/L associated with ↑ 30-day mortality 3.52-fold ↑ mortality
Operator experience	2.6-fold ↑ no. of procedure-related complications
Prior open heart surgery	↓ risk of major complications

Cr = creatinine; CRP = C-reactive protein; ESRD = end-stage renal disease; HF = heart failure; ICD = implantable cardioverter defibrillator; INR = international normalized ratio; LV = left ventricular.

Extraction Procedure-Related Complications

	Incidence, %
Major	0.19%–1.80%
Death[64]	0.19%–1.20%
Cardiac avulsion	0.19%–0.96%
Vascular laceration	0.16%–0.41%
Respiratory arrest	0.20%
Cerebrovascular accident	0.07%–0.08%
Pericardial effusion requiring intervention	0.23%–0.59%
Hemothorax requiring intervention	0.07%–0.20%
Cardiac arrest	0.07%
Thromboembolism requiring intervention	0.07%
Flail tricuspid valve leaflet requiring intervention	0.03%
Massive pulmonary embolism	0.08%
Minor[64,216,246,247,287,307]	0.60%–6.20%
Pericardial effusion without intervention	0.07%–0.16%
Hematoma requiring evacuation[64,216,287]	0.90%–1.60%
Venous thrombosis requiring medical intervention[64,216]	0.10%–0.21%
Vascular repair at venous entry site[64,216,246]	0.07%–0.13%
Migrated lead fragment without sequelae[64]	0.20%
Bleeding requiring blood transfusion[64,246,287]	0.08%–1.00%
AV fistula requiring intervention[64]	0.16%
Coronary sinus dissection[64]	0.13%
Pneumothorax requiring chest tube[287]	1.10%
Worsening tricuspid valve function[287]	0.32%–0.59%
Pulmonary embolism[246]	0.24%–0.59%

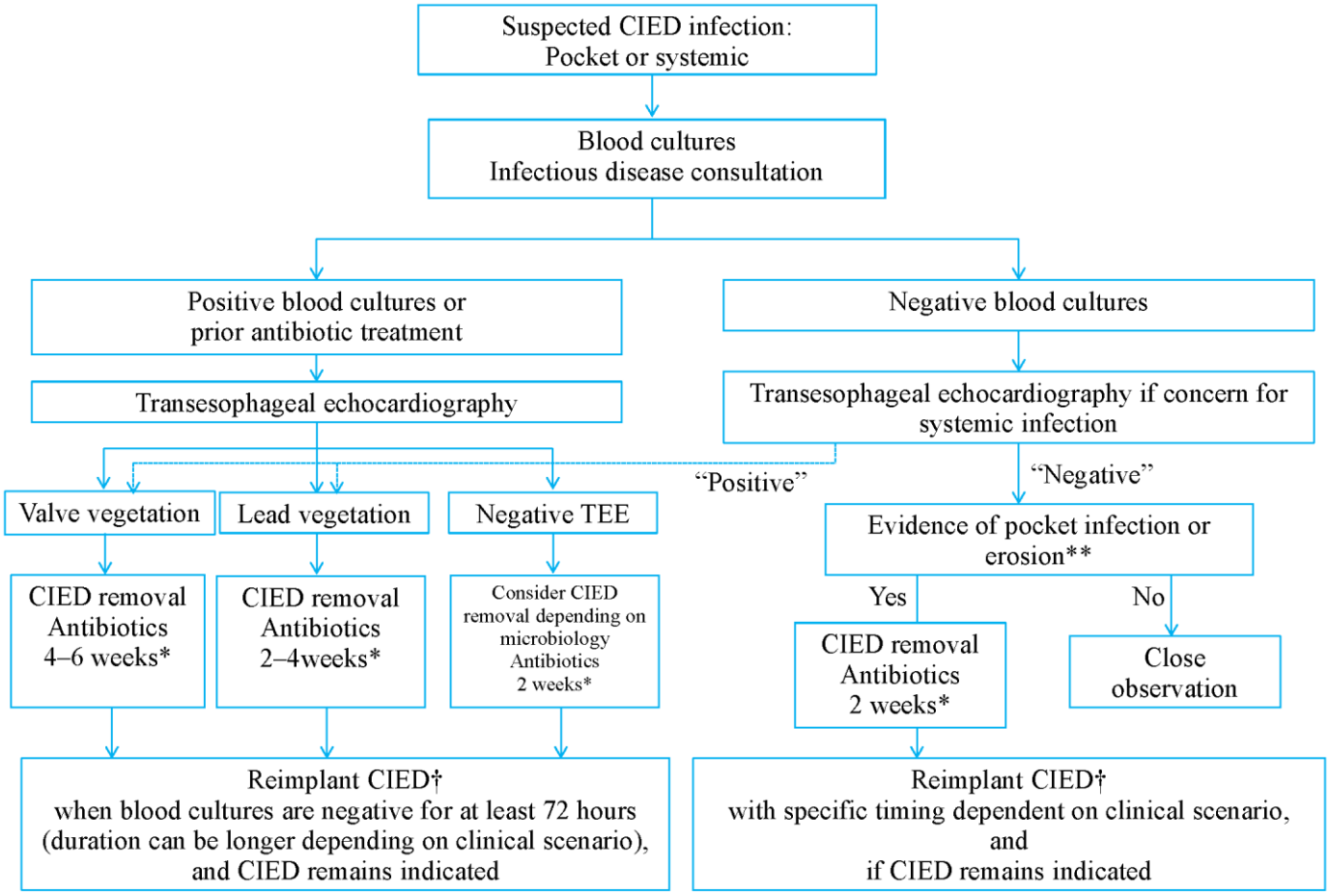

Figure 1 Management of suspected CIED infection.
*Refer to text and table for specific recommendations depending on microbiology. Antimicrobial therapy should be at least 4–6 weeks for endocarditis (4 weeks for native valve, 6 weeks for prosthetic valve or staphylococcal valvular endocarditis). If lead vegetation is present in the absence of a valve vegetation, 4 weeks of antibiotics for Staphylococcus aureus and 2 weeks for other pathogens is recommended. †Usually the contralateral side; a subcutaneous ICD may also be considered. **2010 AHA CIED Infection Update distinguishes between pocket infection and erosion (Baddour et al. Circulation 2010;121:458–477).

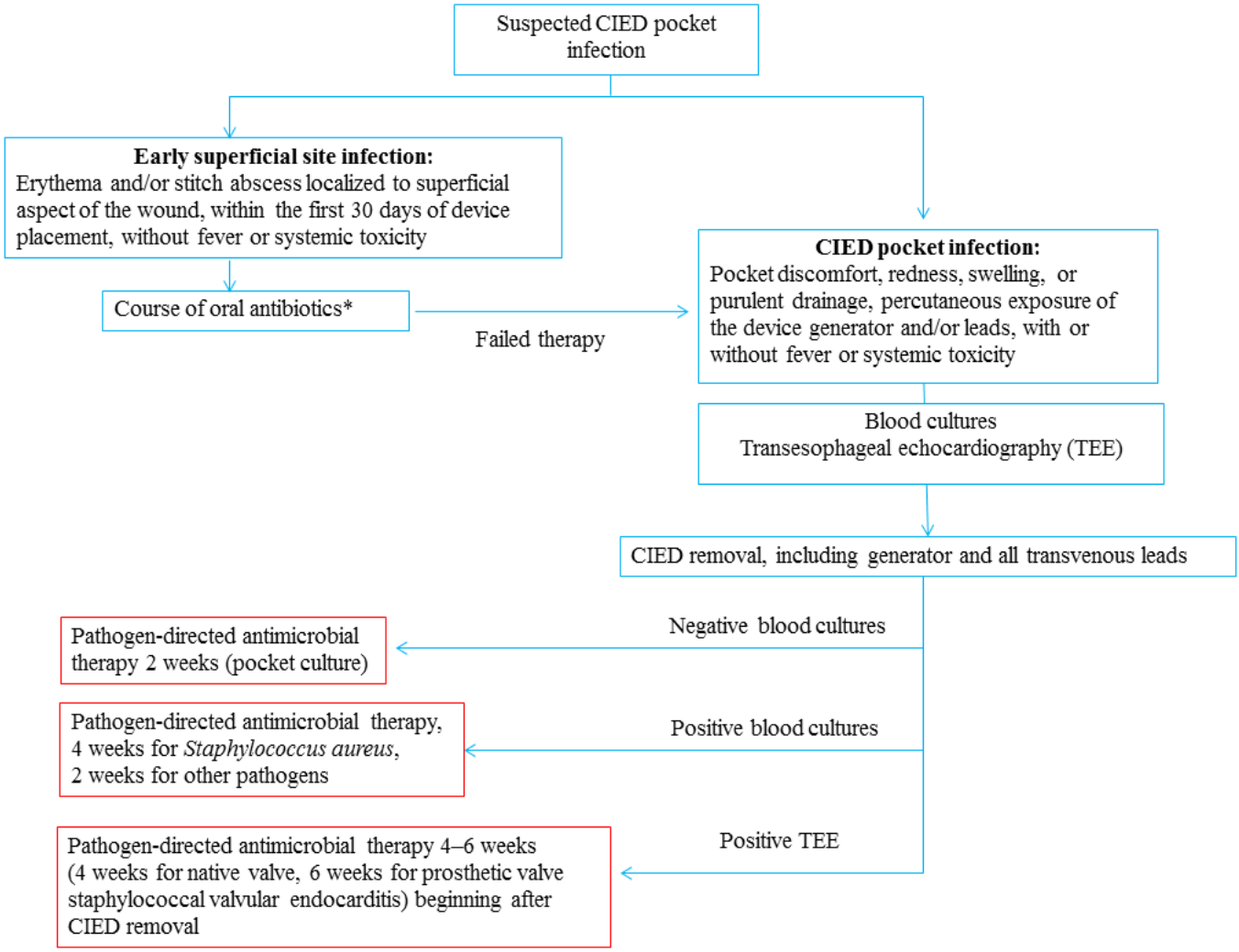

Figure 2 Management of suspected pocket infection.
*See text for examples.

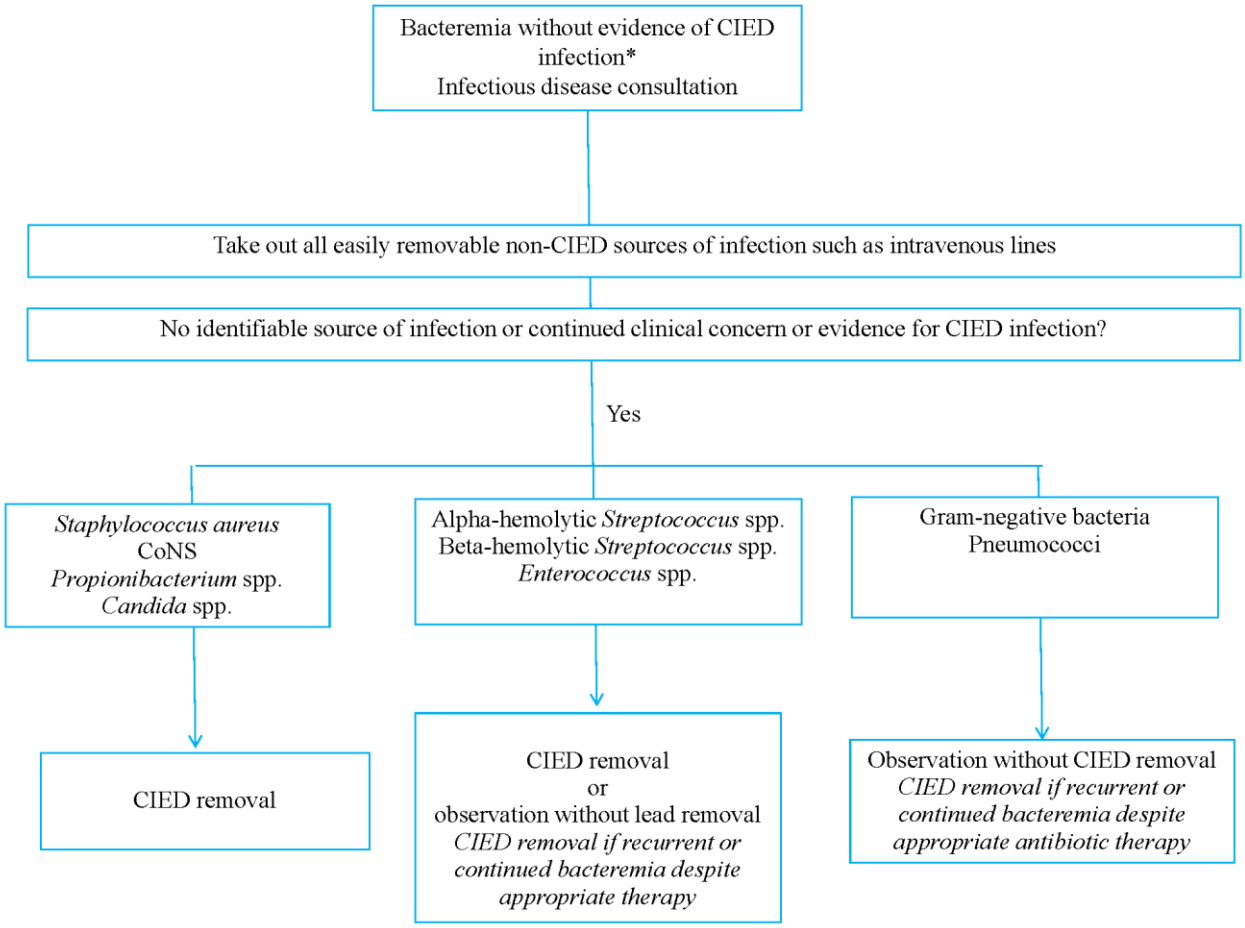

Figure 3 Management of bacteremia without evidence of CIED infection.
*Important to distinguish between blood stream infection and contamination in bacteremia involving skin flora.

This consensus statement was developed in collaboration with the American College of Cardiology (ACC), American Heart Association (AHA), Asia Pacific Heart Rhythm Society (APHRS), American Society of Anesthesiologists (ASA), European Heart Rhythm Association (EHRA), Infectious Diseases Society of America (IDSA), Latin American Heart Rhythm Society (LAHRS), Pediatric and Congenital Electrophysiology Society (PACES), and Society of Thoracic Surgeons (STS).