

Table 1. ESC 2021 GL on pacing and CRT. Complications of pacemaker and cardiac resynchronization therapy implantation

Incidence of complications after CIED therapy	%
Lead-related reintervention ^{354,639-690,692,695,700,701} (including dislodgement, malposition, subclavian crush syndrome, etc.)	1.0–5.9
CIED-related infections, <12 months ^{354,639,641,645,685,695,702}	0.7–1.7
Superficial infection ³⁵⁴	1.2
Pocket infections ³⁵⁴	0.4
Systemic infections ³⁵⁴	0.5
CIED-related infections, >12 months ^{702–709}	1.1–4.6
Pocket infections ⁷⁰²	1.3
Systemic infections ^{702,705}	0.5–1.2
Pneumothorax ^{354,658,690,692,700,701,707}	0.5–2.2
Haemothorax ⁶⁹⁵	0.1
Brachial plexus injury ⁶⁹⁵	<0.1
Cardiac perforation ^{354,663,690,692,695}	0.3–0.7
Coronary sinus dissection/perforation ^{710,288}	0.7–2.1
Revision due to pain/discomfort ^{354,690}	0.1–0.4
Diaphragmatic stimulation requiring reintervention ^{711,712,665,713}	0.5–5
Haematoma ^{354,639,650,652,654,690,700,714,715}	2.1–5.3
Tricuspid regurgitation ^{716–718}	5–15
Pacemaker syndrome ^{146,701,719}	1–20
Generator/lead problem ^{354,639,690}	0.1–1.5
Deep venous thrombosis (acute or chronic) ^{354,720,721}	0.1–2.6
Any complication ^{354,639,690,692,695,707,722,723}	5–15
Mortality (<30 days) ^{354,694}	0.8–1.4

CIED = cardiovascular implantable electronic device.

Table 2. 2024 Update of the AHA Statement on CIED Infections. American Heart Association Clinical Definitions of Cardiovascular Implantable Electronic Device Infection

	Pocket infection	Lead or valvular infection
Definite	Preextraction Device erosion through skin; purulent drainage from pocket; fluctuance; sinus tract; with or without positive blood cultures OR [¹⁸F]FDG PET/CT* with abnormal activity at pocket/generator site Postextraction Intraoperative findings consistent with infection, including purulence within the generator pocket site or inflammation OR Positive device, tissue, sonicate fluid cultures, positive broad range PCR/sequencing, or metagenomic next-generation sequencing with intraoperative findings consistent with infection	Preextraction Two or more positive blood cultures for <i>Staphylococcus aureus</i> or the same species of coagulase-negative staphylococci with no alternative source AND TEE findings consistent with echodensity on the device lead† or vegetation(s) on the heart valve OR [¹⁸F]FDG PET/CT with abnormal heterogeneous activity along leads, or native or prosthetic heart valves Postextraction Positive device, tissue, sonicate fluid culture, broad range PCR/sequencing or metagenomic next-generation sequencing with the same organism isolated from blood cultures
Possible	Pocket erythema, induration, or tenderness within 3 mo of implantation, with no alternative explanation‡	Persistent (>72 h) bacteremia due to nonstaphylococcal organisms§ despite adequate pathogen-directed therapy, with no alternative source, ±TEE findings consistent with echodensity on the device lead OR embolic phenomena (frequently septic pulmonary emboli) Presence of SIRS criteria,¶ negative blood cultures, no alternative source of infection and [¹⁸F]FDG PET/CT with abnormal activity along leads, or heart valves
Rejected	Firm alternative explanation for local findings that may include superficial cellulitis at the surgical site without device involvement, retained suture, contact dermatitis, or allergy to device components	Firm alternative source of bloodstream infection with resolution of syndrome after pathogen-directed treatment course TEE alone demonstrating a lead echodensity in the absence of SIRS criteria or positive blood cultures with alternative source of infection that responds to targeted antimicrobial therapy and source control.

These definitions are provided to support clinicians in their practice but are not intended as a substitute for clinical judgment. [¹⁸F]FDG PET/CT indicates fluorine-18-fludeoxyglucose positron emission tomography/computerized tomography scanning; PCR, polymerase chain reaction; SIRS, systemic inflammatory response syndrome; and TEE, transesophageal echocardiography.

*Not required to establish a diagnosis.

†A negative TEE for lead echodensities does not rule out cardiovascular implantable electronic device lead infection.

‡Alternative explanations may include superficial cellulitis at the surgical site without device involvement, retained suture, contact dermatitis, or allergy to device components.

§Includes mainly nonstaphylococcal gram-positive organisms, *Pseudomonas aeruginosa*, *Serratia marcescens*, and *Candida* species.

¶SIRS criteria defined ≥ of the following: temperature ≥38.3°C or ≤36°C, pulse rate >90/min, respirations >20/min, and peripheral white blood cell count >12 000/μL or <4000/μL or >10% immature forms.

Table 3. The BLISTER Score

BLISTER component	Criteria	Points
Blood results	eGFR < 30ml/min/1.73m ² at time of procedure CRP ≥ 50mg/l within 24 hours of procedure	2 1
Long procedure time	Pocket open for ≥120 minutes during procedure	2
Immunosuppressed	Current steroid or immunosuppressant medication use, or immunocompromised by co-morbidity (e.g. HIV infection)	2
Sixty years old (or younger)	<60 years old 60-69 years old	2 1
Type of procedure	ICD implant or generator change CRT implant or generator change New lead inserted or existing lead revised without extraction Lead extracted	1 4 4 6
Early re-intervention	Intervention on the same pocket within 2 years of a previous procedure	7
Repeat procedure	1 previous procedure 2 or more previous procedures	2 4

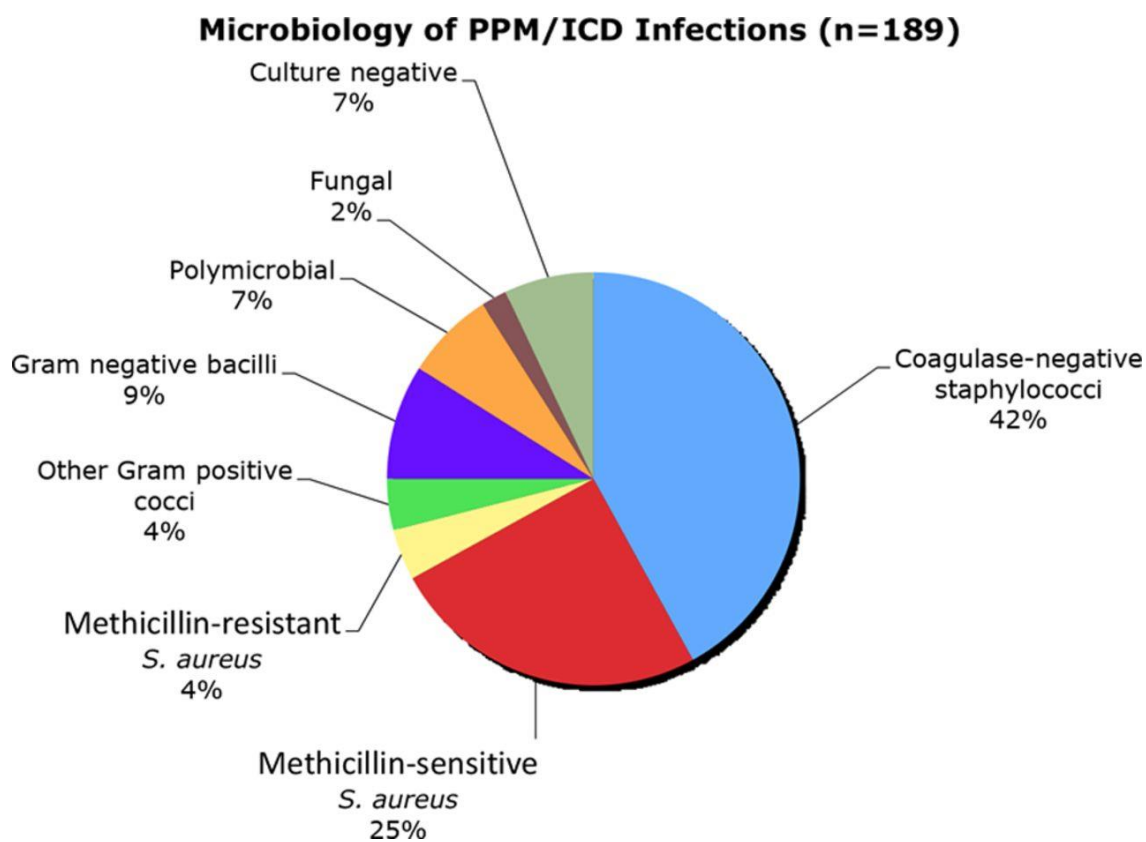


Figure 1. Microbiology of PPM/ICD infections.

ICD indicates implantable cardioverter-defibrillator; and PPM, permanent pacemaker.

Sohail MR, et al. Management and outcome of permanent pacemaker and implantable cardioverter-defibrillator infections. J Am Coll Cardiol. 2007;49:1851–1859.

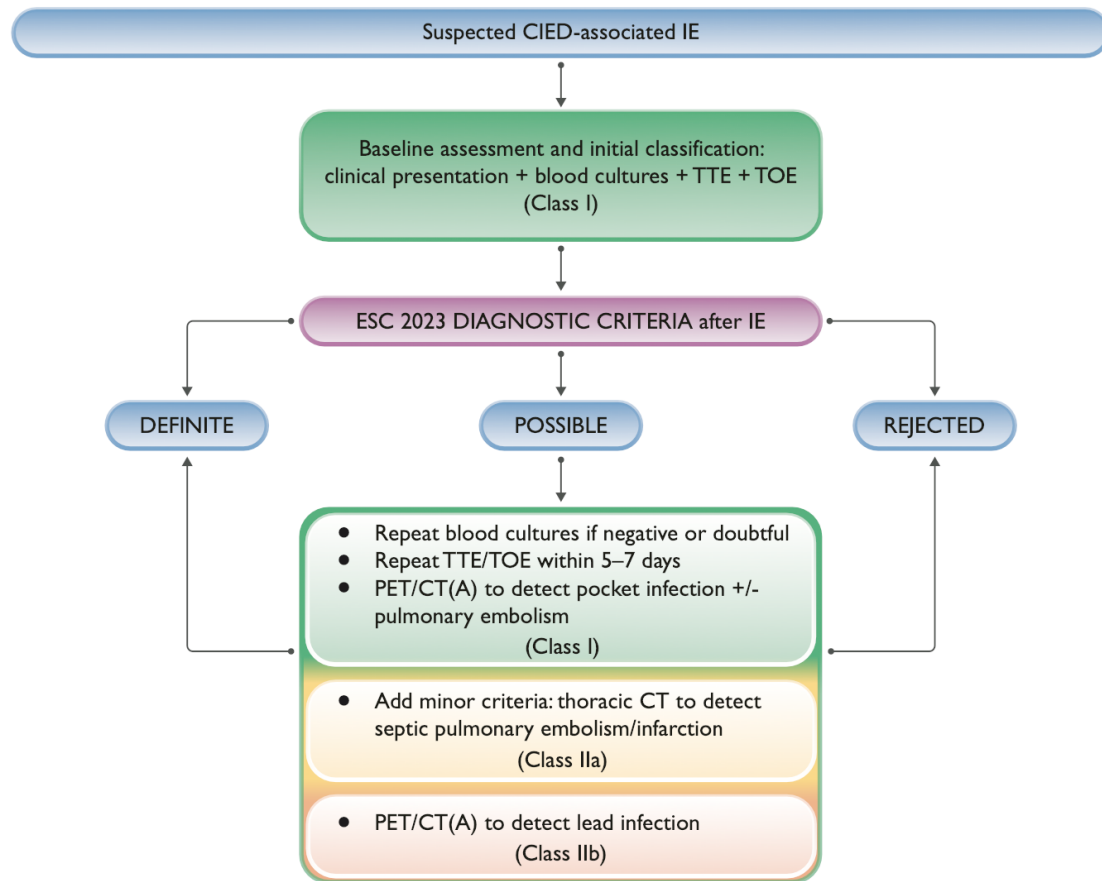
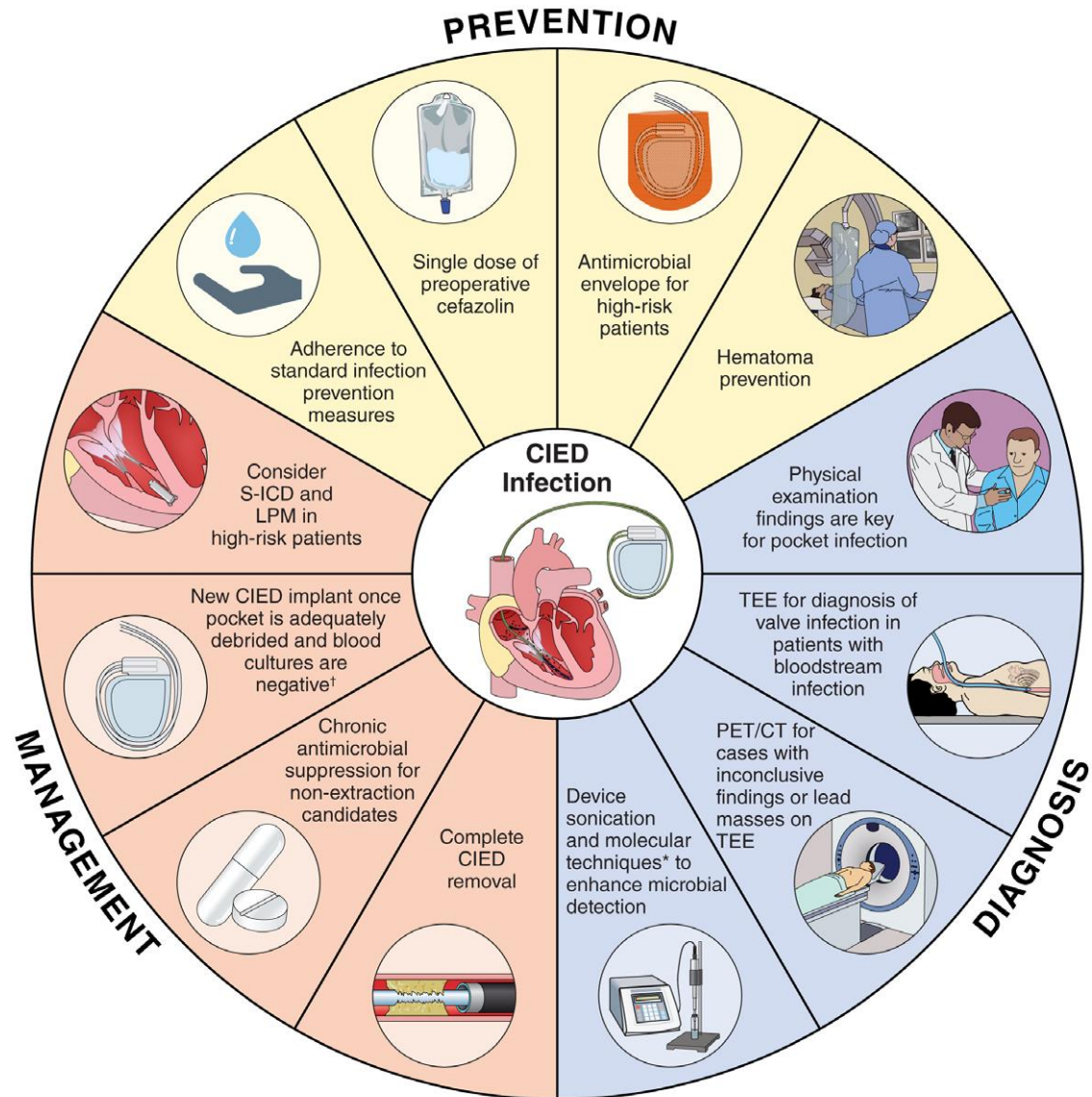


Figure 2. ES 2023 GL on endocarditis European Society of Cardiology 2023 algorithm for diagnosis of cardiac device-related infective endocarditis.

CIED, cardiovascular implanted electronic device; CT, computed tomography; CTA, computed tomography angiography; ESC, European Society of Cardiology; IE, infective endocarditis; PET, positron emission tomography; TOE, transoesophageal echocardiography; TTE, transthoracic echocardiography; WBC SPECT, white blood cell single photon emission tomography.



*16S ribosomal RNA gene (rRNA) polymerase chain reaction (PCR)/sequencing or metagenomic next-generation sequencing (mNGS) of sonicate fluid may be helpful in select cases

†Some favor delaying new device placement for up to 14 days after initiation of antimicrobial therapy in the setting of valvular endocarditis

Figure 3. 2024 Update of the AHA Statement on CIED Infections. Central Illustration

CIED indicates cardiovascular implantable electronic device; LPM, leadless pacemaker; PET/CT, positron emission tomography/computerized tomography scanning; S-ICD, subcutaneous implantable cardioverter defibrillator; and TEE, transesophageal echocardiography.

Table 4. Management of device-related infections.

AHA 2010 scientific statement on cardiovascular implantable electronic device (CIED) infections	
Recommendations for diagnosis of CIED infection and associated complications	
All patients should have at least 2 sets of blood cultures drawn at the initial evaluation before prompt initiation of antimicrobial therapy for CIED infection.	I-C
Generator-pocket tissue Gram stain and culture and lead-tip culture should be obtained when the CIED is explanted.	I-C
Patients with suspected CIED infection who either have positive blood cultures or who have negative blood cultures but have had recent antimicrobial therapy before blood cultures were obtained should undergo TOE for CIED infection or valvular endocarditis.	I-C
All adults suspected of having CIED-related endocarditis should undergo TOE to evaluate the left-sided heart valves, even if transthoracic views have demonstrated lead-adherent masses. In paediatric patients with good views, transthoracic echocardiography may be sufficient.	I-B
Patients should seek evaluation for CIED infection by cardiologists or infectious disease specialists if they develop fever or bloodstream infection for which there is no initial explanation.	Ila-C
Percutaneous aspiration of the generator pocket should not be performed as part of the diagnostic evaluation of CIED infection.	III-C
Recommendations for antimicrobial management of CIED infection	
Choice of antimicrobial therapy should be based on the identification and in vitro susceptibility results of the infecting pathogen.	I-B
Duration of antimicrobial therapy should be 10 to 14 days after CIED removal for pocket-site infection.	I-C
Duration of antimicrobial therapy should be at least 14 days after CIED removal for bloodstream infection.	I-C
Duration of antimicrobial therapy should be at least 4 to 6 weeks for complicated infection (ie, endocarditis, septic thrombophlebitis, or osteomyelitis or if bloodstream infection persists despite device removal and appropriate initial antimicrobial therapy).	I-C
Recommendations for removal of infected CIED	
Complete device and lead removal for all patients with definite CIED infection, as evidenced by valvular and/or lead endocarditis or sepsis.	I-A
Complete device and lead removal is recommended for all patients with CIED pocket infection as evidenced by abscess formation, device erosion, skin adherence, or chronic draining sinus without clinically evident involvement of the transvenous portion of the lead system.	I-B
Complete device and lead removal is recommended for all patients with valvular endocarditis without definite involvement of the lead(s) and/or device.	I-B
Complete device and lead removal is recommended for patients with occult staphylococcal bacteraemia.	I-B
Complete device and lead removal is reasonable in patients with persistent occult Gram-negative bacteraemia despite appropriate antibiotic therapy.	Ila-B
CIED removal is not indicated for a superficial or incisional infection without involvement of the device and/or leads.	III-C
CIED removal is not indicated for relapsing bloodstream infection due to a source other than a CIED and for which long-term suppressive antimicrobials are required.	III-C
Recommendations for new CIED implantation after removal of an infected CIED	
Each patient should be evaluated carefully to determine whether there is a continued need for a new CIED.	I-C
The replacement device implantation should not be ipsilateral to the extraction site. Preferred alternative locations include the contralateral side, the iliac vein, and epicardial implantation.	I-C
When positive before extraction, blood cultures should be drawn after device removal and should be negative for at least 72 hours before new device placement is performed.	Ila-C
New transvenous lead placement should be delayed for at least 14 days after CIED system removal when there is evidence of valvular infection.	Ila-C
Recommendations for use of long-term suppressive antimicrobial therapy	
Long-term suppressive therapy should be considered for patients who have CIED infection and who are not candidates for complete device removal.	IIB-C
Long-term suppressive therapy should not be administered to patients who are candidates for infected CIED removal.	III-C
Recommendations for antimicrobial prophylaxis at the time of CIED placement	
Prophylaxis with an antibiotic that has in vitro activity against staphylococci should be administered. If cefazolin is selected for use, then it should be administered IV within 1 hour before incision; if vancomycin is given, then it should be administered IV within 2 hours before incision.	I-A
Recommendations for antimicrobial prophylaxis for invasive procedures in patients with CIEDs	
Antimicrobial prophylaxis is not recommended for dental or other invasive procedures not directly related to device manipulation to prevent CIED infection.	III-C
Recommendations to avoid microbiological studies in cases of CIED removal for noninfectious reasons	
Routine microbiological studies should not be conducted on CIEDs that have been removed for noninfectious reasons.	III-B

ESC 2023 GL on endocarditis. Recommendations for cardiovascular implanted electronic device-related infective endocarditis

Antibiotic prophylaxis covering <i>S. aureus</i> for CIED implantation.	I A
TTE and TOE in case of suspected CIED-related IE to identify vegetations	I B
Complete system extraction without delay in patients with definite CIED-related IE under initial empirical antibiotic therapy	I B
Obtaining at least three sets of blood cultures before prompt initiation of empirical antibiotic therapy for CIED infection, covering methicillin-resistant staphylococci and Gram-negative bacteria.	I C
If CIED reimplantation is indicated after extraction for CIED-related IE, it should be performed at a site distant from the previous generator, as late as possible, once signs and symptoms of infection have abated and until blood cultures are negative for at least 72 h in the absence of vegetations, and negative for at least 2 weeks if vegetations were visualized	I C
Complete CIED extraction in case of valvular IE, even without definite lead involvement, taking into account the identified pathogen and requirement for valve surgery.	IIa C
In cases of possible CIED-related IE with occult Gram-positive bacteraemia or fungaemia, complete system removal in case bacteraemia/fungaemia persists after a course of antimicrobial therapy.	IIa C
Extension of antibiotic treatment of CIED-related endocarditis to (4–6) weeks following device extraction should be considered in the presence of septic emboli or prosthetic valves.	IIa C
Use of an antibiotic envelope in select high-risk patients undergoing CIED reimplantation to reduce risk of infection	IIb B
In cases of possible CIED-related IE with occult Gram-negative bacteraemia, complete system removal in case of persistent/ relapsing bacteraemia after a course of antimicrobial therapy.	IIb C
In non- <i>S. aureus</i> CIED-related endocarditis without valve involvement or lead vegetations, and if follow-up blood cultures are negative without septic emboli, 2 weeks of antibiotic treatment following device extraction.	IIb C
Removal of CIED after a single positive blood culture, with no other clinical evidence of infection, is not recommended.	III C

CIED, cardiovascular implanted electronic device; IE, infective endocarditis; TOE, transoesophageal echocardiography; TTE, transthoracic echocardiography.

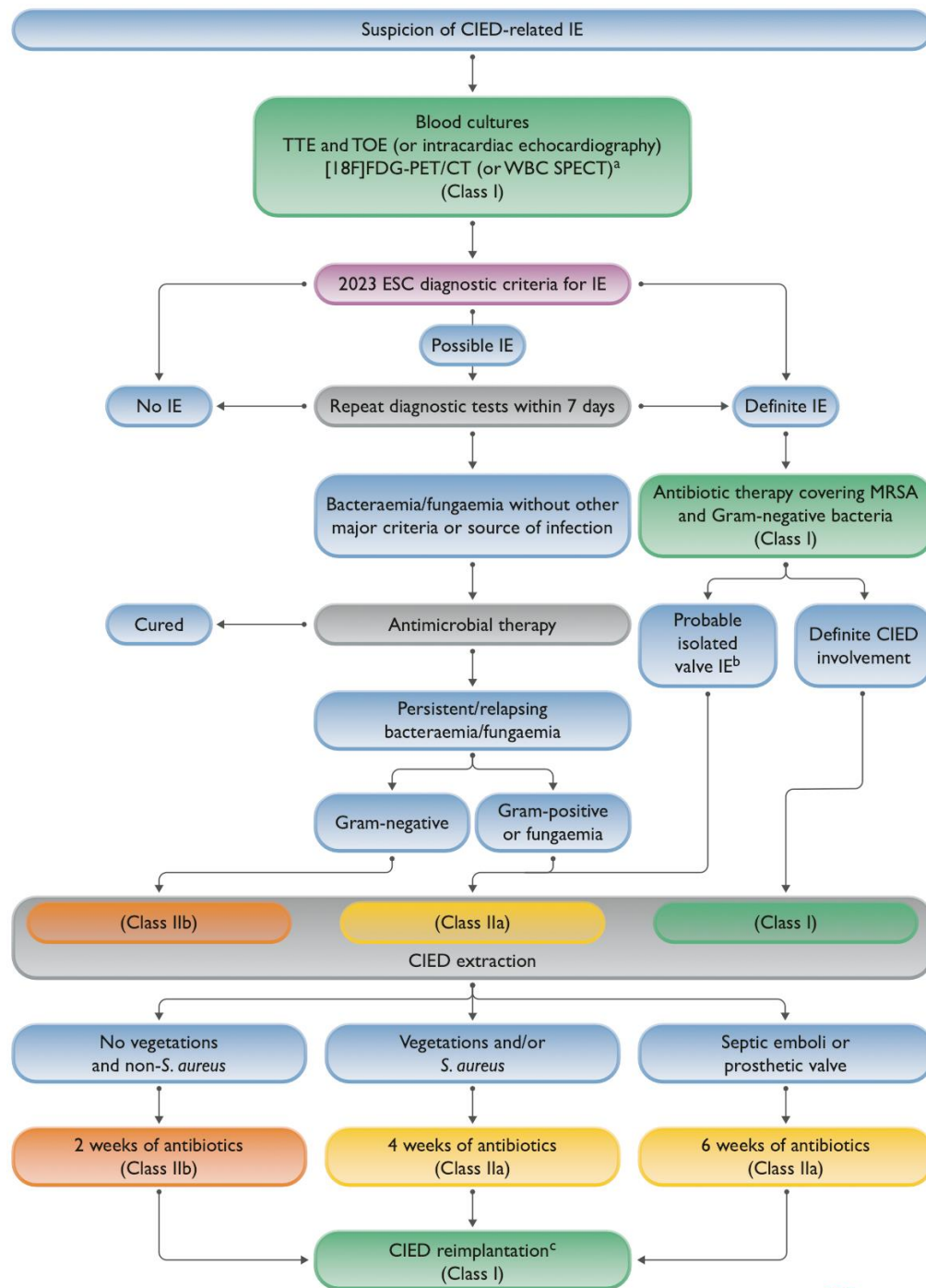


Figure 4. ESC 2023 GL on endocarditis Management of cardiovascular implanted electronic device-related infective endocarditis.

[18F]FDG-PET/CT, ¹⁸F-fluorodeoxyglucose positron emission tomography/computed tomography; CIED, cardiovascular implanted electronic device; ESC, European Society of Cardiology; IE, infective endocarditis; MRSA, methicillin-resistant *S. aureus*; TOE, transoesophageal echocardiography; TTE, transthoracic echocardiography; WBC SPECT/CT, white blood cell single photon emission tomography/computed tomography. ^aIf no signs of pocket infection and negative TOE. ^bTaking into account the identified pathogen, procedural risk, and requirement for valve surgery. ^cAt a distant site and postponed as long as possible (until signs and symptoms of infection have resolved and blood cultures are negative for >72 h in the absence of vegetations and/or 'ghosts', or otherwise after >2 weeks of negative blood cultures).

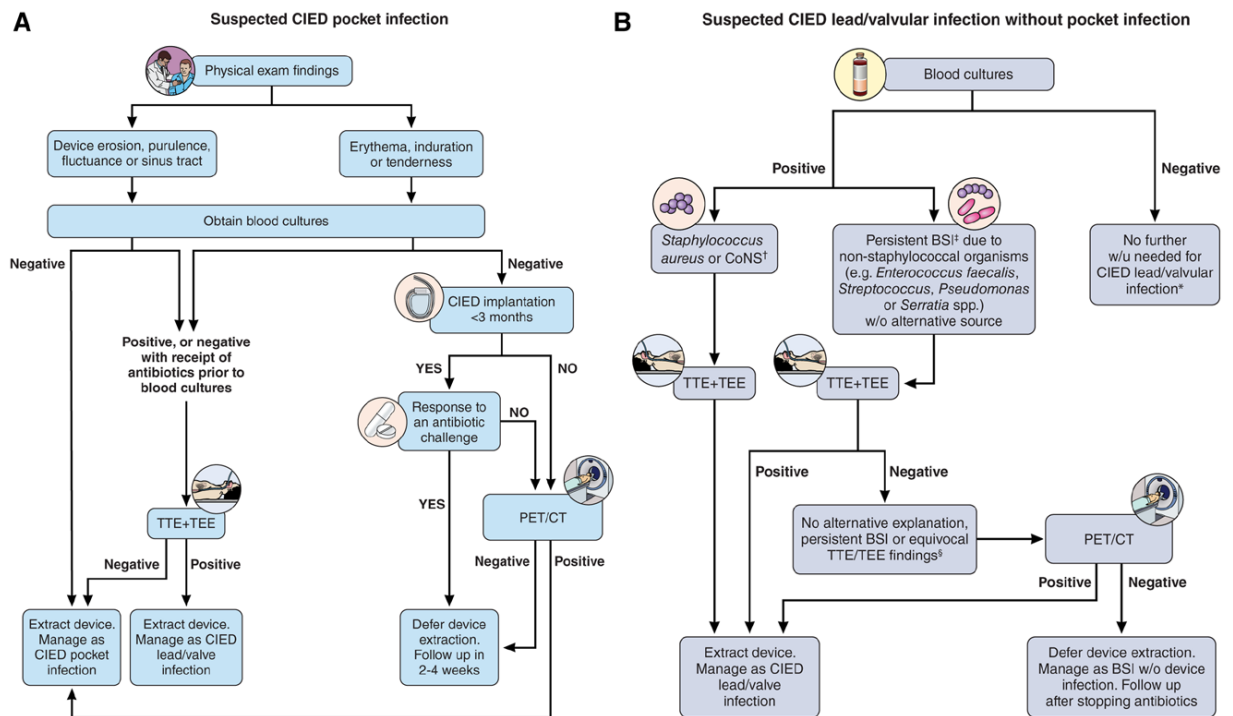


Figure 5. 2024 Update of the AHA Statement on CIED Infections. Diagnosis and management algorithms for suspected CIED pocket infection (A) and suspected CIED lead/valvular infection without pocket infection (B).

BSI indicates bloodstream infection; CIED, cardiovascular implantable electronic device; CoNS, coagulase-negative staphylococci; PET/CT, positron emission tomography/computerized tomography scanning; TEE, transesophageal echocardiography; TTE, transthoracic echocardiography; w/o, without; and w/up, work up.

Table 5. EGM Characteristics of LF and Conditions That Can Be Confused With Lead Failure (LF)

Typical EGM Characteristics		Clues to Diagnosis
Early or late post-implant		
LF—pace-sense component		
Conductor fracture	Typical nonphysiological signals, variable in amplitude and timing; see text for details.	Pacing or shock may increase amplitude or frequency of nonphysiological signals and cause oversensing. Pacing impedance may increase abruptly. Rarely, loss of pacing capture.
Connection problem (DF-1 lead)	Indistinguishable from lead fracture	Radiography may show incomplete pin insertion. Abrupt increases in impedance often followed by periods of return to baseline; most common in first year after surgery. Pocket manipulation may reproduce nonphysiological signals if set screw is loose.
Insulation breach—in pocket	Pectoral myopotentials on dedicated-bipolar EGM	Pectoral muscle exercise or pocket manipulation often reproduces oversensing. Pacing impedance may decrease abruptly.
Insulation breach—intravascular	Spikes	Simultaneous spikes may occur on multiple EGM channels. Pacing impedance may be decreased.
LF—high-voltage component		
High-voltage coil fracture	Real-time shock EGM may have nonphysiological signals. Data are limited.	Abrupt increase in shock impedance, rarely failure to defibrillate. Rarely, loss of pacing capture in integrated bipolar leads.
High-voltage coil insulation breach	Real-time shock EGM may have nonphysiological signals. Distinguish from pectoral myopotentials, which are a normal finding.	Rarely, abrupt decrease in shock impedance, failure to defibrillate.
Conditions that may be confused with LF		

Swerdlow CD, Kalahasty G, Ellenbogen KA. Implantable Cardiac Defibrillator Lead Failure and Management. J Am Coll Cardiol. 2016;67:1358-68.