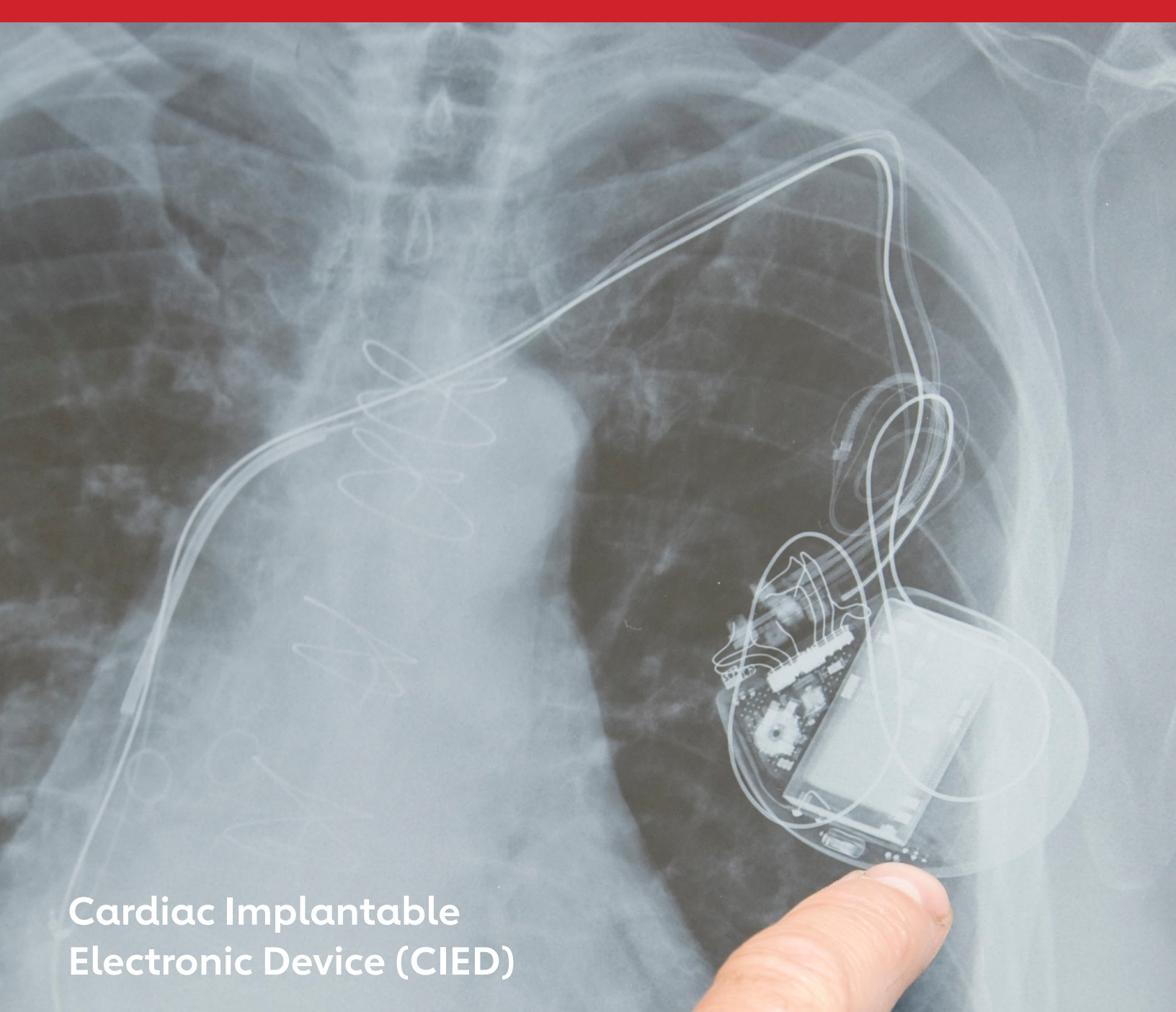




Cardiac Implantable
Electronic Device (CIED)

CIED INFECTION TOOLKIT



American Heart Association.
National CIED
Infection Initiative

Bridging Gaps in Awareness, Detection and
Appropriate Treatment of CIED Infections



Philips Image-Guided Therapy is a proud
supporter of the American Heart Association's
National CIED Infection Initiative.



KEY THINGS TO KNOW ABOUT CIED INFECTION

1 Cardiac implantable electronic devices (CIEDs), such as pacemakers and implantable cardioverter-defibrillators, save and extend lives with minimal problems in most cases. However, for patients who experience infections related to their devices, gaps and delays in guideline-recommended care can lead to preventable illness, disability and death.

2 The presence of abandoned leads is a significant risk factor for infection. These wires, which connect the device to the patient's heart, are sometimes not removed when the patient receives new leads. Infections are more likely when leads are not properly extracted.

3 There are two types of infection: localized (pocket) infection and systemic infection. A localized infection occurs where the device is implanted (pocket) and a systemic infection starts in pocket and spreads to the device leads, the blood stream and can infect the heart.

4 Patients with a CIED infection should be referred to a specialist with expertise in device extraction, and the CIED and all its components should be removed. This recommendation is supported by the American Heart Association, Heart Rhythm Society, British Heart Rhythm Society, European Society of Cardiology, and European Heart Rhythm Association. But despite the recommendations, many patients with CIED infections do not undergo complete system removal.

5 Patients, caregivers, physicians and other clinicians all play a role in CIED infection care, and communication between these stakeholders is critical. Patient education needs to be based on patient needs and concerns rather than limited to information and instructions.



American Heart Association
National CIED
Infection Initiative

CIED INFECTION is a HEALTH CRISIS



SAVE LIVES BY REMOVING DEVICES IN A TIMELY FASHION

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CIED INFECTION OVERVIEW

The use of cardiac implantable electronic devices (CIEDs), such as pacemakers, implantable cardioverter-defibrillators (ICDs), and other implantable devices, is becoming more and more common. While these devices extend and improve people's lives with minimal problems in most cases, for patients who experience infections related to their devices, gaps and delays in guideline-recommended care can lead to preventable illness, disability and death. Data have shown that these kinds of gaps and delays in guideline-recommended care are all too common¹. While so many people have CIEDs, these infections are not rare events; one study found a significant increase in the annual rate of CIED infection from 1.53% in 1993 to 2.41% in 2008². Improved awareness and timely diagnosis of CIED infections are essential to help save lives.

The science is clear about what to do: Patients with a CIED infection should be referred to a specialist with expertise in device extraction, and the CIED and all its components should be removed.

The American Heart Association (AHA) launched an initiative to improve awareness, detection, diagnosis and treatment of CIED infection through a [National CIED Infection Summit and Health Care Professional Education](#). For more information about the initiative, please visit: heart.org/treat2beatciedinfection.

View this webinar to learn more about CIED infection incidence, impact and gaps in care.





TYPES OF CIED INFECTIONS

CIED infections can be categorized as localized to the CIED pocket, such as generator erosion or pocket infection, or as systemic, such as bacteremia or lead-associated endocarditis, an inflammation of the heart lining associated with the leads, or wires, that connect the device to the heart. Local infections can lead to systemic infections if not identified and treated promptly according to established guidelines.

Infection presentation may range from subtle to more obvious:



View this webinar to learn more about delays in identification and removal of the infected device.



POCKET INFECTION

Pocket infection symptoms may include⁵ inflammatory skin changes (e.g. pain, swelling or redness), warmth, skin and soft tissue ulceration and drainage, or erosion of generator or protrusion of leads through the skin at the site of the implant pocket.

SYSTEMIC INFECTION

Systemic infection may develop if a localized CIED infection spreads to the device leads, enters the blood stream (bacteremia) or infects the heart (endocarditis). Symptoms of systemic infection may include fever, chills, anorexia, malaise, disorientation, or respiratory distress⁶:





EVIDENCE-BASED DIAGNOSTIC AND TREATMENT STRATEGIES

Timely detection and diagnosis of a CIED infection is essential for providing best-practice care. Below is a sample CIED infection classification criteria and sample algorithm for suspected CIED Infections.

Pocket Findings*

1. **Physical exam:** device erosion through skin, purulence emanating from pocket, fluctuance, or sinus tract.
2. **Intraoperative findings:** purulence within the generator pocket site.
3. **Cultures:** positive cultures (significant microbial growth, i.e., tissue and swab sample growth when colonies grow on ≥ 2 quadrants of the culture plate and device sonication sample growth when ≥ 20 colonies are isolated from 10 ml of sonicate fluid) from explanted CIED.

* Proposed MAYO CIED infection classification criteria⁷

Clinical Findings*

MAJOR

1. Two or more positive blood cultures for organisms typical of CIED infection, such as *S. aureus*, coagulase-negative staphylococci (CoNS), or enterococci, with no alternative source.
2. TEE findings consistent with vegetation on the device lead and/or heart valve.
3. Positron emission tomography-computed tomography (PET-CT) imaging consistent with device infection.

MINOR

1. Prolonged bacteremia (>72 h) with microorganisms other than listed in major criteria.
2. TEE findings not meeting major criteria.
3. Recent pocket manipulation (<3 months prior to presentation).
4. Fever (38°C or higher).
5. Embolic phenomena (typically septic pulmonary emboli from lead vegetations or right-sided endocarditis).
6. Pocket erythema or tenderness.

CIED Infection Classification Criteria*

1. Definite CIED infection: combination of any 2 major clinical findings or 1 or more pocket findings.
2. Probable CIED infection: 1 major clinical finding and 1 or more minor clinical findings.
3. Possible CIED infection: suspected CIED infection case that does not meet "Definite" or "Probable" criteria.



* Proposed MAYO CIED infection classification criteria⁷

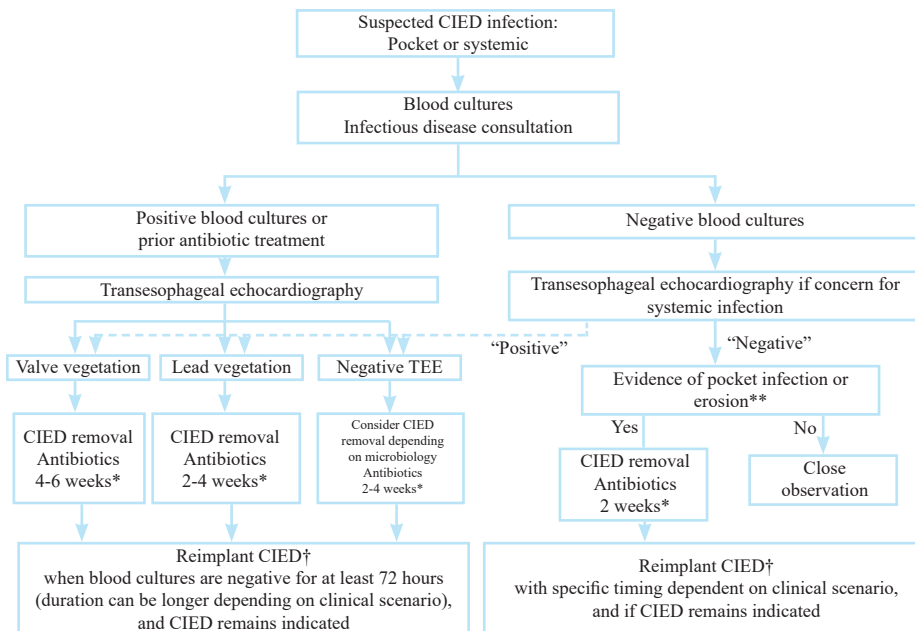


Figure 2 Management of suspected CIED infection *Refer to text for specific recommendations depending on microbiology. Antimicrobial therapy should be at least 4-6 weeks for endocarditis (4 weeks for native valve, 6 weeks for prosthetic valve or staphylococcal valvular endocarditis). If lead vegetation 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).

The Heart Rhythm Society's (HRS) revised 2017 guidelines and 2020 European Heart Rhythm Association's (EHRA) international consensus document are clear about what to do^{8, 9}:

- Patients presenting with a definite CIED infection, endocarditis (regardless of device involvement), or unexplained or persistent bacteremia or fungemia, should be referred to an expert in the treatment of CIED infection.
- The Heart Rhythm Society's guidelines also call for antibiotics to be initiated after two sets of positive blood cultures are obtained. However, antibiotic treatment alone is not enough.
- The device and its components should be removed promptly and completely. Other major professional organizations recommending complete removal in patients with a definite CIED infection include the AHA, British Heart Rhythm Society, and European Society of Cardiology.^{10, 11}

Despite the consensus, many patients with CIED infections do not receive recommended care.

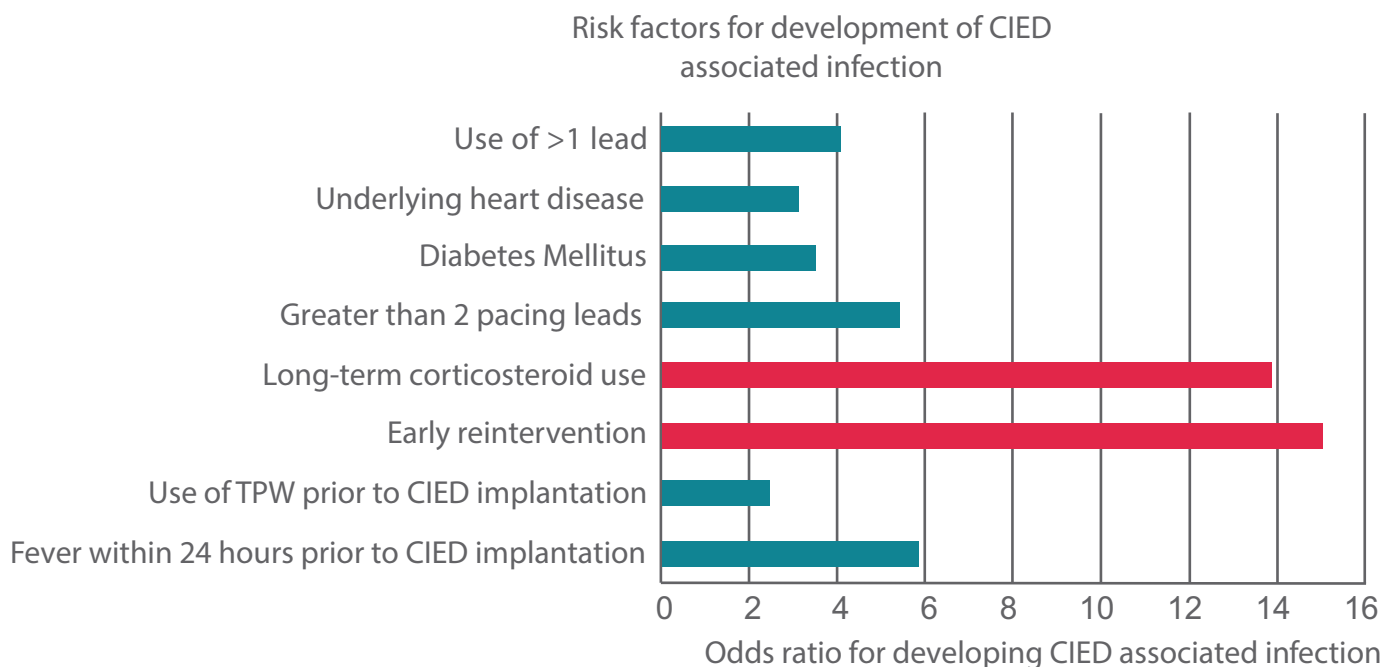
View this webinar to learn about some of the common misconceptions about CIED infection and treatment





RISK FACTORS

Both the volume and complexity of implantations of pacemakers and other implantable devices has increased over time. The number of implantations increased by 96% between 1993-2008¹². Additionally, patients having devices implanted are older than before. The risk of infection increases with age, comorbidities such as diabetes and chronic kidney disease, and complexity of the devices¹³.



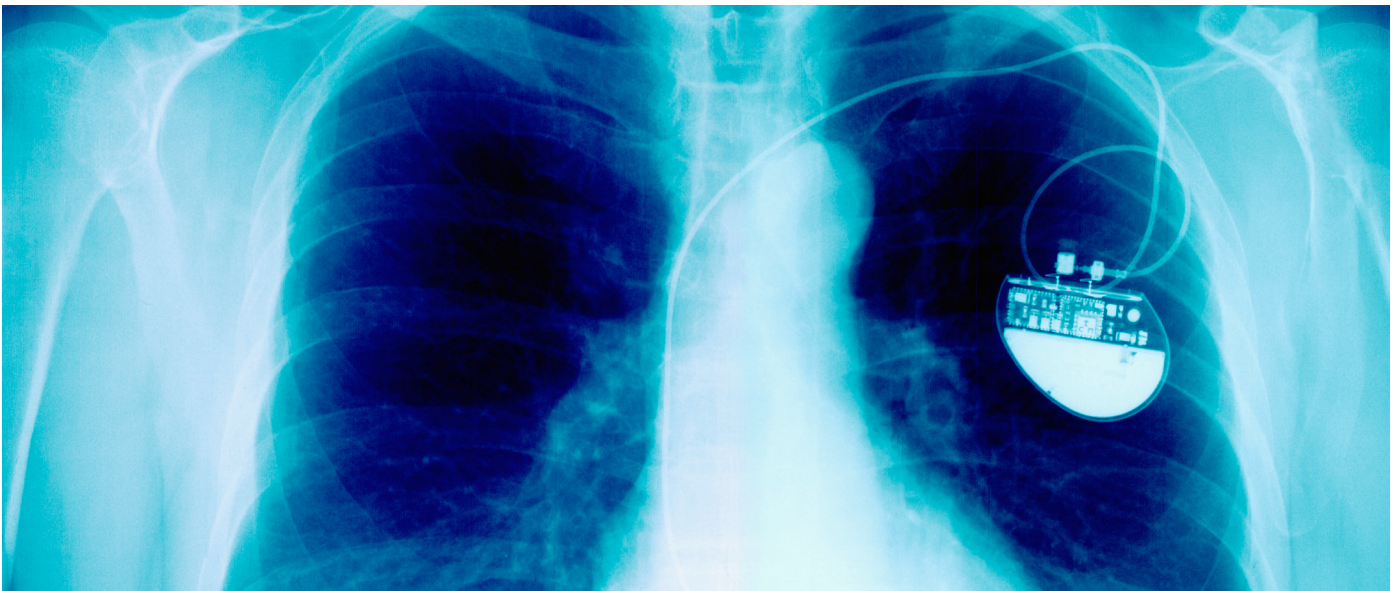
Graph: Risk Factors for Development of CIED Associated Infection¹⁴

The presence of abandoned leads is a significant risk factor for infection¹⁵. These wires, which connect the device to the patient's heart, are sometimes not removed when the patient receives new leads. Infections are more likely when leads are not properly extracted¹⁶. Sometimes, leads are not extracted because physicians and patients think that extraction is riskier than leaving the leads in. However, abandoned leads increase the infection rate, and removing previously abandoned leads from a patient with an infection may carry increased risk. In that situation, patients are more likely to experience a procedural complication when the abandoned leads are extracted¹⁷.

Patient comorbidities can also increase the risk of CIED infection^{17, 18}:

PATIENT COMORBIDITIES

- diabetes mellitus
- end-stage renal disease
- renal insufficiency
- chronic obstructive pulmonary disease
- malignancy
- heart failure
- pre-procedural fever
- anticoagulant drug use
- skin disorders
- post-operative hematoma
- reintervention for lead dislodgement
- lack of antibiotic prophylaxis
- temporary pacing
- central venous thrombosis in the area of the leads





FINANCIAL BURDEN OF CIED INFECTION

Patients and their families bear the greatest cost when CIED infections reduce the quality and length of the patients' lives. Patients with infections also require additional procedures, and if best-practice management guidelines are not followed, they may experience morbidity and/or mortality as a result. Some costs are direct: Average annual medical costs were 2.4 times higher for CIED patients with an infection, compared to those without an infection¹⁹. An analysis of claims through commercial insurers and Medicare supplement insurance estimated that infections increase the per-patient cost of care from \$62,256 to \$110,141 for initial implants and from \$64,810 to \$110,332 for replacement implants²⁰. Indirect costs include lost productivity for the patient and family caregivers, and intangibles such as pain, disruption and lost time due to illness, disability and treatment.

Reasons for higher costs:

- High resource utilization
 - Hospitalizations
 - Cost increased with time to device extraction.
 - Increased length of stay
-

Compared to endocarditis of prosthetic and native valves, patients with CIED infective endocarditis had the longest length of stay (17 days) and highest hospital costs (mean \$56,000).¹⁹



PATIENT COMMUNICATION STRATEGIES

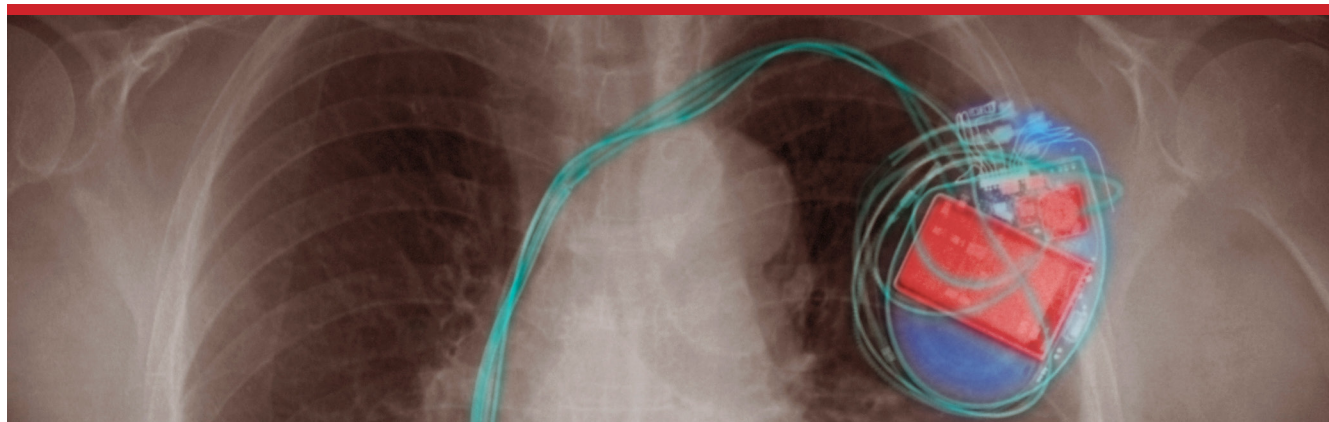
A group of CIED experts met in March 2022 and identified patient and clinician communication as a common barrier that prevents patients from early infection identification. Patients and physicians play a role in CIED infection care, and communication between these stakeholders is critical. Communicating with your patients about CIED infections or device removal can be a difficult conversation, but a necessary one.

Effective and open communication leaves patients and healthcare teams happier and can result in better health outcomes. To be effective, patient education should be tailored to a patient's needs and concerns rather than just information and instructions. Here are a few tips to better communicate with your patients:^{21, 22, 23}

Listen to a conversation about the value of shared decision-making between patient and healthcare professionals when it comes to preventing and managing device infections



- Be attentive and exercise active listening
- Ask open-ended questions to learn more about your patients
- Involve friends and family
- Use proper tone when communicating with patients to show that you are working together as a team
- Take your patient's situation and background into account
- Use a multidisciplinary approach
- Be aware of bias
- Communicate in different ways and utilize multimedia – such as short educational videos
- Use shared decision-making
- Keep records and share your notes with patients
- Incorporate [“Teach Back”](#) during patient visits to increase understanding²⁴.



LOOKING AHEAD

This multi-layered call to action relies on healthcare professionals to evaluate how CIED infection patients are being treated, drive guideline adherence and get the message out that gaps in care exist. Patients are called upon to be advocates for their own health. In March 2022, the AHA led by a nine-member planning committee convened multidisciplinary stakeholders at an [in-person CIED Infection Summit](#) that focused on three categories of action:

Driving Detection and Diagnosis:

Identifying the most critical problems across clinical settings and connecting the dots for clinicians, including the role of informatics.

Improving Treatment and Management of CIED Infection:

Following best practices for enhancing systems of care.

Awareness and Education:

Learning from impactful consumer and healthcare professional initiatives in other diseases.

Use this toolkit, recorded webinars, podcasts and other resources made available from [AHA's CIED Infection Initiative](#) to increase awareness of CIED Infection and evidence-based treatment and management.

Infections are a lifelong risk for patients with CIEDs, but prompt, expert, guideline-directed treatment can reduce the impact of infections on patients' lives. Quality improvement initiatives and care redesign programs can enhance the care that patients with CIEDs receive within health systems. These initiatives should build greater awareness among patients, caregivers and health care professionals of the risk of infection and the best ways to manage it; promote earlier detection and diagnosis of infection; encourage guideline directed treatment and management; and establish measurement of and feedback on care performance.

Review the CIED Infection Initiative proceedings document for key summit takeaways and preliminary actionable solutions





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