# AHA's National Cardiac Implantable Electronic Device (CIED) Infection Initiative Podcast Series

## Episode 2 - Treating Pacemakers and Other Implantable Devices: Case Study Review and Implications

00:00:10:25 - 00:00:35:24
**Intro:** This podcast is part of the American Heart Association's National Cardiac Implantable Electronic Device or CIED Infection Initiative. The goal of this initiative is to address the gaps in awareness, detection, and appropriate treatment of pacemakers and other implantable device infections. For the latest information about upcoming events and other resources on this topic, please visit heart.org/treat2beatciedinfection.

00:00:45:27 - 00:01:01:17
The opinions expressed in this podcast are solely those of the presenters and not necessarily of the American Heart Association/American Stroke Association (AHA/ASA). The American Heart Association/American Stroke Association does not endorse any specific products or devices.

00:01:02:08 - 00:01:54:09
**Renee Sednew:** Welcome to this episode of "Treating Pacemakers and Other Implantable Devices: Case Study Review and Implications." The use of pacemakers and CIEDs 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 common. Improved awareness and timely diagnosis are essential to help save lives. Today we welcome two speakers Dr. Jim Cheung and Ms. Ann M. Spalding, to review a case and have a conversation on the importance of timely CIED infection identification, and management.

00:01:54:19 - 00:02:48:03
**Renee Sednew:** Before we begin our discussion today, I'd like to introduce our speakers. Dr. Jim Cheung is a professor of medicine, the director of the Cornell Cardiac Electrophysiology Fellowship Program, and the Director of Clinical Electrophysiology Research at Weill Cornell Medicine. He is the co-founder of the Weill Cornell Cardiovascular Outcomes Research Group (CORG), whose mission is to assess the effectiveness and outcomes of cardiovascular interventions with a focus on the treatment of heart rhythm disorders and structural heart disease and the improvement of health care delivery. Dr. Cheung is the chair of the ACC Electrophysiology Section Leadership Council, Vice-Chair of the HRS Electrophysiology Fellowship Program Directors Subcommittee, and HRS Delegate to the American Medical Association House of Delegates.

00:02:49:08 - 00:03:06:02
**Renee Sednew:** Ms. Ann Spalding is a nurse practitioner. She began her career caring for cardiac patients at Massachusetts General Hospital in Boston and is now a nurse practitioner for the Cardiac Electrophysiology (EP) Service at New York Presbyterian Weill Cornell in New York. She has experience in several areas within Cardiac EP at this institution. In recent years, Ms. Spalding has been focused on caring for patients in the setting of the Cardiac EP Device Clinic, including providing post procedure care, in-clinic interrogation of CIEDs, and managing remote monitoring of these devices.

00:03:26:23 - 00:03:31:08
**Renee Sednew:** Dr. Cheung, Anne, we're thrilled to have you here today. Welcome.

00:03:31:27 - 00:03:34:25
**Dr. Cheung:** It's an absolute pleasure to be here. Thank you so much for having us.

00:03:35:23 - 00:03:37:02
**Ann Spalding:** Thank you so much, Renee.

00:03:39:05 - 00:03:49:05
**Renee Sednew:** Before we review today's case, I'd like to begin by hearing about your roles caring for patients with cardiac implantable electronic devices. Dr. Cheung, let's start with you.

00:03:50:05 - 00:04:30:17
**Dr. Cheung:** Sure. As an electrophysiologist at a busy academic center in New York City, I implant all forms of cardiac electronic devices, which include transvenous and venous pacemakers, implantable defibrillators, cardiac resynchronization therapy devices, and other implantable monitoring devices. Our cardiac device clinic at Cornell manages over 5,500 patients with these devices through a combination of in-office visits and remote monitoring. I will oversee the care of a significant proportion of these patients for a long time—from the day they come into my office for consultation talking about undoing a device procedure, to the day they actually have the procedure done, and to the many years that they will return to our offices for follow up.

00:04:30:28 - 00:04:33:09
**Renee Sednew:** Thank you, Dr. Cheung. Ann, what about you?

00:04:33:11 - 00:05:04:06
**Ann Spalding:** Thanks, Renee. I'm part of our EP device clinic team, which is an outpatient role, but our clinic is right in the hospital. Our EP labs, the procedure labs, are literally directly outside the doors. So we work very closely with the cardiac electrophysiologist on a daily basis. We're a multidisciplinary team, actually. We have technicians, nurse practitioners, and RNs, and it's a really actually a nice mix because we all come from different backgrounds and have different strengths, and we work very collaboratively.

00:05:04:15 - 00:05:47:07
**Ann Spalding:** In this role I see routine CIED follow-up appointments, post ops. During those appointments, I do interrogations of the devices with the programmer, and for the post-op visits, also, I check the wounds to make sure that they're healing properly. Another piece to this role is fielding telephone calls. We get many, many telephone calls from patients with either symptoms that could be related to an arrhythmia. And in that case, we follow up looking at the remote monitors to see if they in fact, did have an arrhythmia. Also, any wound issues would come through those phone calls as well.

00:05:47:12 - 00:05:56:18
**Renee Sednew:** It's wonderful to have both of you here. Thank you. So, let's dive into this case. Dr. Cheung, please walk us through an overview of the patient and the case.

00:05:57:02 - 00:06:35:01
**Dr. Cheung:** Thank you, Renee. So the case that we will be presenting today is not a particularly unusual case, but rather a case that I felt had a lot of important teaching points. In fact, it's a case I had just encountered this past month. So it's pretty fresh in my memory. So our case today starts with a 72-year

old man with a history of paroxysmal atrial fibrillation, coronary artery disease, hypertension and chronic kidney disease who presented in 2021 with complete heart block. At that point, he underwent a dual chamber transvenous pacemaker implant, which was uncomplicated, and he did very well.

00:06:35:06 - 00:07:08:08
**Dr. Cheung:** He really didn't have any issues until about a year and a half later, which was in August of last year, when he was admitted to a local hospital after developing a week of fever and malaise. At that point, he had blood cultures drawn, which were notable for staph aureus bacteremia. This led to quite an extensive workup, which included a normal transthoracic echocardiogram, a normal transesophageal echocardiogram, as well as a normal indium scan which showed no clear evidence of a source of infection.

00:07:08:14 - 00:07:36:18
**Dr. Cheung:** So about after three days of intravenous antibiotic therapy, he turned around quickly, and his blood cultures were cleared. And unfortunately, his course was further complicated by kidney failure, for which he required placement of an indwelling catheter for hemodialysis. He did quite well after initiation of antibiotics and hemodialysis and was discharged a couple of weeks later. And at that point he did okay, but then was admitted soon thereafter.

00:07:36:20 - 00:08:15:27
**Dr. Cheung:** This was in September of 2022 with worsening lower back pain. At that point, he was diagnosed with spondylodiscitus as well as osteomyelitis. He did not have any positive blood cultures at that time. Given the osteomyelitis, the infectious disease service was consulted, at which point pacemaker removal and lead extraction were considered. The general cardiology service at the hospital was consulted, but due the patient's pacemaker-dependent status, as well as negative blood cultures, the decision was made to defer pacemaker removal and to place the patient on chronic suppressive antibiotics.

00:08:16:03 - 00:08:34:27
**Dr. Cheung:** Unfortunately, the patient then, after going home, presented five months later with pocket swelling, which was noted by his nephrologist during a dialysis treatment session. At this point he was referred to our device clinic, and here I will turn it over to Ann, who will tell us what she saw.

00:08:35:15 - 00:09:30:11
**Ann Spalding:** Thanks, Dr. Cheung. So this gentleman came into the office, and I knew he was coming in to have the pocket check. But also, of course, I was doing my normal pacemaker interrogation, heard his history as I was, and of course, my antenna kind of went up hearing his story. And when I did examine him, you could see the pocket swelling. But also, when I actually palpated the area, you could feel it was fluid filled. So he had a seroma there. The only other abnormality on the exam was some erythema. It was very small, less than a half a centimeter in rounds, no open skin lesions or anything like that. But as soon as you see any sort of fluid in a pacemaker pocket, especially in addition to that having the erythema, it was immediately brought to our attendings to be expedited because that is never a normal finding with a pacemaker or defibrillator pocket.

00:09:30:24 - 00:10:10:24
**Dr. Cheung:** So at that point Ann called us over to the device clinic. And when we saw that, given the patient's history, as well as an abnormal pocket exam, we scheduled the patient for pocket exploration with the expectation that we would find evidence of infection. And indeed, we saw gross evidence of gross purulent infection, which required complete system removal, including lead extraction. The removal

of the system actually went fine. That was actually relatively...it was quite straightforward. But due to how infected the pacemaker pocket was, there was a lot of trouble getting the bleeding to stop.

00:10:10:26 - 00:10:53:00
**Dr. Cheung:** So we actually had to cauterize area extensively. The wound had to be packed open, and so that made it a more challenging procedure. In addition, given that the patient was pacemaker dependent, a temporary transvenous pacing lead was placed, and the patient was monitored over the course of several days. Fortunately for the patient, the bleeding did subside, and eventually, a few days later, the patient had leadless pacemaker implantation and wound closure. And since then, the patient has been doing well at home but was in the hospital for quite a number of weeks for management of his infection, but more importantly for management of the wound and all the issues that followed the procedure.

00:10:53:12 - 00:11:06:21
**Renee Sednew:** Ann and Dr. Cheung, thank you for illustrating that case and walking us through it from start to finish. I'd like to go back to the hospitalization in August of 2022. Dr. Cheung, what stood out to you about that admission?

00:11:06:24 - 00:12:15:07
**Dr. Cheung:** Well, I think the thing that was notable about the August admission was, first of all, that the patient had a systemic infection. But the thing that was a particular red flag was the particular microbe that was involved. And in this case, a bacterium that was involved was staph aureus, which is a particularly virulent microbe that can cause significant symptoms of fever and rigor. Especially, special about this particular pathogen, though, is that it has the hallmark feature of forming a protective biofilm that is a protective mechanism for the microbe itself. What it does is it renders it resistant to host defenses and antibiotic therapy. And this is particularly important when considering this in the context of device infection. So what happens is that when patients have a systemic staph aureus infection, this biofilm which is formed by the bacteria, then coats the device and the leads, and it basically prevents the antibiotic therapy and host's white blood cells of completely eradicating the bug. And so in these cases, unless you eliminate and remove the devices and the leads, you cannot completely eliminate the infection.

00:12:15:09 - 00:12:43:08
**Dr. Cheung:** So going back to that August presentation, I would say that even though our patient had a normal device pocket exam, extensive normal imaging tests, including normal echocardiograms, it was very likely that his pacemaker was already seeded with bacteria at that time. So even at that time, without clear evidence of device infection itself, device removal should have probably been considered given the presence of high-grade staph aureus bacteremia.

00:12:43:29 - 00:12:51:22
**Renee Sednew:** Thanks, Dr. Cheung. So therefore, it wasn't surprising that the patient showed up back in the hospital with continued symptoms. Is that correct?

00:12:51:26 - 00:13:14:16
**Dr. Cheung:** Yes. And in fact, it was quite a dramatic finding that within just a month, the patient comes back with signs of infection. And the fact that the patient now presents with back pain due to spinal osteomyelitis further underscores that this was a systemic infection. So given that the bacteria had also seeded the spine, it's really hard to imagine that the pacemaker would be spared.

00:13:15:03 - 00:13:20:16
**Renee Sednew:** Ann, what do you think are some of the barriers or challenges preventing timely detection?

00:13:21:00 - 00:13:55:22
**Ann Spalding:** I think that's a great question, and I honestly think it's mostly awareness that pacemaker and ICD infections can actually look pretty mild. I think when we think of infections, we think of exactly as this patient presented…fevers and things like that. Most patients, when this infection is even pretty advanced, can just have some mild swelling, maybe a little bit of erythema. There might not be any open skin areas and when the pocket's opened, it can look a lot worse than you would ever anticipate.

00:13:55:24 - 00:14:12:29
**Ann Spalding:** So generally speaking, if there's any fluid in a pacemaker or defibrillator pocket, it should just be taken seriously and referred out to EP to have them evaluate it and see if it is a time to actually explore the pocket and see what's going on.

00:14:13:25 - 00:14:19:07
**Renee Sednew:** Dr. Cheung, are there any additional barriers or challenges that you can think of preventing timely detection?

00:14:19:20 - 00:14:55:28
**Dr. Cheung:** Yes, I think that, again, I completely echo Ann's comments, and think that what makes it also challenging is that even for the patient, that generally patients are very attuned to the wound soon after a procedure. So during the first few weeks after the procedure, naturally the patient is going to be very attuned to whether it's swollen, if there's increased pain and redness, and things like that. But what I think we could do a better job of informing our patients is the fact that months, years later, the device can still be infected if it becomes seeded by a systemic infection.

00:14:56:08 - 00:15:46:09
**Dr. Cheung:** So that awareness and radar for looking for issues related to device pocket our antenna are definitely up in the first few weeks after the procedure. But they start to go down. And I think that the fact that we need to again, it's important to not scare the patient into thinking that at any point the device can get infected. But the reality is, that actually can be the case if there are other systemic infections going on. So being aware that you have to be vigilant at all times, and this is not just the patient, of course. This also applies to physicians who are taking care of the patient. And a lot of times the patients may not even be seeing their cardiologist, or you know, electrophysiologist years after the pacemaker goes in. This is their primary care doctor. This could be their nephrologists. So I think, you know, all of us need to be aware of these issues from all sides.

00:15:46:24 - 00:16:03:09
**Renee Sednew:** Thank you for emphasizing the importance of that awareness, really from all angles. I'd like to go back and talk about that infectious disease consult that happened during the September admission. Dr. Cheung, can you walk us through that decision making process following the consult?

00:16:03:20 - 00:16:36:18
**Dr. Cheung:** Yes. I think in this particular case of the infectious disease consult service appropriately recognized the virulence of the pathogen involved and recommended pacemaker removal. But unfortunately, the general cardiology service that was involved in this case had opted not to remove the system because there were concerns about the risks of device removal. Both probably… again, we do not have the notes to detail the decision making, but I would imagine that there probably were concerns about the risks of lead extraction itself, as well as the fact that the patient was pacemaker dependent.

00:16:36:20 - 00:17:07:04
**Dr. Cheung:** So there were probably concerns that the patient would require a transvenous pacing wire for an extended period of time. So that may have factored into the decision not to remove the device, and I think that the other thing that probably lulled some into thinking that the patient was fine without device removal was the fact that he was afebrile. He still had negative blood cultures and had, you know, just a month prior, had negative transesophageal echo and indium scans, which may have led to the impression that the infection had cleared.

00:17:07:06 - 00:17:47:24
**Dr. Cheung:** And I think that, if anything, that sort of underscores maybe the misconception that the device infection is always associated with imaging findings. So, you know, there is a sense that we typically rely on a transesophageal echocardiogram showing, say, a vegetation on the lead to be evidence that the device is infected. And when in fact you don't have to have a vegetation, all it takes is, like I said, a biofilm of bacteria on the device that is imperceptible by our current imaging technology, which would already mean that the patient has an active, ongoing device infection which needs to be managed with appropriate device removal.

00:17:48:08 - 00:18:03:18
**Renee Sednew:** Thank you. I want to switch gears a little bit and talk about the pocket swelling noted by this patient's nephrologist. Ann, for someone who's not as familiar with pocket swelling, can you describe how it might present to both a patient and to a clinician?

00:18:03:27 - 00:19:09:09
**Ann Spalding:** Yes, absolutely. So first of all, kudos to the nephrologist, because it is not that...I saw this patient. And it is not as if this patient walked in and I thought, “Oh, my gosh, this looks terrible!” It's pretty mild, some of the presentations that these patients have. So I think it's pretty impressive that the nephrologist did send him to us so rapidly. Patients typically, I would say, think their device feels bigger. That's the biggest complaint I've had from patients. This patient did feel like it was more swollen, and it did present as being, you know, it was a seroma on top of the pacemaker. You could clearly see it and feel it. But it's not always something that they would say. Typically, they say their device feels larger. And so, if a patient calls and complains of that, it's something we just always see a patient in the office with that complaint. For a healthcare provider, like I said, if you just look at the device, you might not really think it looks too bad. And then when you go to actually feel it, you might notice that there is fluid in that pocket.

00:19:09:11 - 00:20:04:10
**Ann Spalding:** If you're not sure, then definitely it's a reason to have EP evaluate the patient. Often there is not any erythema. There are no fevers. And like I said, there are no open areas. So just pocket swelling alone, with or without this history, this patient obviously had a history that immediately made us concerned. But even without that, it is a reason to have them refer it out. And earlier, Dr. Cheung had mentioned we don't want to stress patients out either. We want to make people aware of this. But the other time I've had patients call me and say their device is bigger or swollen—sometimes when people have rapid weight loss, it can appear that way. So again, this is why it's so important to see somebody in the office and evaluate them and see if the pocket does have fluid in it, and if it's something that should be either explored further or referred out to an electrophysiologist, depending on what your specialty is.

00:20:04:20 - 00:20:28:11
**Renee Sednew:** I want to thank both of you for this really excellent conversation and for bringing up several key points, including that sense of urgency and the importance of timely detection and referral and

also awareness from both the patient and provider perspective and all clinicians involved in the case. What are any additional learnings from this case that you'd like to share?

00:20:29:03 - 00:21:00:01
**Dr. Cheung:** Thanks, Renee. I think the one thing we should mention here was there was some delay I think, in this case of the patient getting the appropriate definitive therapy, which would have been the device and lead extraction. But the patient ultimately did okay. Although, I think that earlier intervention might have made a difference. I think in this particular case, because the pocket had been so infected, there was a significant amount of bleeding during the case. I think that had this been removed several months earlier, I think that that could have been avoided.

00:21:00:03 - 00:21:56:09
**Dr. Cheung:** And I think we were fortunate that the patient ultimately did well enough. But, you know, we've certainly had cases where infection goes on way too long. And, unfortunately, these can become chronic conditions. And a lot of times the patients are in a hospital for long periods of time. There's a lot of time that they can't go to work, which can exert a lot of financial stress for these patients. And of course, for some cases, their lives may be at risk. So timing is really quite critical here. And there has been a wealth of data now showing that early intervention, early device removal, can really lead to significantly better outcomes, avoiding some of those prolonged hospitalizations that I just had mentioned.

00:21:56:14 - 00:21:57:24
**Renee Sednew:** Ann, what about you?

00:21:57:26 - 00:22:29:20
**Ann Spalding:** So, I think, and Dr. Cheung has spoken about some of this earlier. It's interesting because I've worked in EP for 16 years and lead extraction used to be like, oh my gosh, we do not want to do a lead extraction. It has come such a long way. Of course, we take every precaution, but the risk of keeping a potentially infected device in, is obviously much greater than a patient undergoing a procedure like lead extraction at this point. So that has been a big...even in my own thinking, being in this field for so long.

00:22:29:22 - 00:23:03:17
**Ann Spalding:** Things have changed, and we are much more expert at certain things that maybe we weren't before. And now, like Dr. Cheung said, the data has just shown how important it is to expedite these situations. And even though this patient was pacemaker dependent, they will still do much better with early intervention and maybe needing a temp wire for a period of time. And as you heard, this patient got a leadless device in the end. But I think that's one of the biggest learning points here for me at least, is just how things have changed.

00:23:03:19 - 00:23:16:11
**Ann Spalding:** And it's so important to rapidly address these issues and to recognize that lead extraction is something that has changed dramatically from many years ago.

00:23:17:04 - 00:23:33:27
**Renee Sednew:** Thank you, Anne. And we have a diverse group of healthcare professionals who are interested in this content. Dr. Cheung, do you have any final thoughts to share with our audience about CIED infection, timely identification, and management?

00:23:34:06 - 00:24:05:03
**Dr. Cheung:** Thank you, Renee. I think that the message that we can gather from this case is that, you know, cardiac devices are lifesaving treatments for our patients. And all those studies show that as our patient population ages, as they live longer, more and more patients are getting these devices. And for each patient who is getting a device they are living longer and longer with them, which is a good thing. And, you know, device infections are still quite infrequent, but it's important to recognize that they can really have devastating consequences for our patients.

00:24:05:05 - 00:24:37:02
**Dr. Cheung:** And I think this is an area where we certainly can and I'm confident that we will do better because we owe it to our patients. And what's unique about this is that this is truly an area that we can really engage everyone on, you know. Starting with the patient at the center and then with everyone who cares for the patient during their lifetime. And so this means each and every physician and nurse across every specialty going from the primary care provider, the nephrologists, who as Ann pointed out, a normal exam to the cardiologists and electrophysiologist.

00:24:37:04 - 00:25:08:10
**Dr. Cheung:** And I think that through efforts to inform our patients, to look after their wounds and their devices, to our physicians, recognizing that what the proper treatment is and how we need to enact these treatments of device removal in a timely fashion. And that, as Ann underscored that our success rates are very high, and the complications rates are very low in experienced centers. And I think that through a multi-pronged approach with everyone kind of in this together, I think this will lead to significantly better outcomes.

00:25:08:26 - 00:25:15:17
**Renee Sednew:** Thank you, Dr. Cheung, for that excellent summary. Ann, do you have anything else to add that you'd like to share with our audience?

00:25:16:08 - 00:26:04:13
**Ann Spalding:** Very similar to what Dr. Cheung just said. So, we're obviously a large urban teaching institution. We have patients who travel from quite far away to have procedures with us and even follow up in our device clinic because we actually only see people every six months to once a year, depending on what kind of device they have, because remote monitoring is now the gold standard. So I think it just really does underline this mission to increase awareness for CIED infections because most likely the patients that are three hours away from us are going to be discussing any concerns with their pacemaker or defibrillator pocket, with their primary care doctor or endocrinologist or nephrologist or whatever physicians they tend to see most often.

00:26:04:15 - 00:26:48:09
**Ann Spalding:** So that's why this is such an important thing to spread the word throughout all of health care. And like Dr. Cheung mentioned, also, for patients to be aware if they have concerns about their device site changing or looking concerning. So, we're actually training a new staff member right now. And it was really perfect because I was thinking about this the other day. If you're someone that does not normally see pacemakers and defibrillators, it can be a little hard to know what's normal. So one good practice is just to always inspect and palpate your patient's pacemaker or defibrillator pocket to get kind of an idea of what's normal because there is a wide range of normal based on body type and exactly where the pocket's located.

00:26:48:11 - 00:27:25:22
**Ann Spalding:** And of course, and I think I've said this several times at this point, any fluid around an implantable device, pacemaker or defibrillator, needs to be taken seriously. Any time you see any sort of a skin lesion like an open area on top of a pacemaker site, even though you think it might be something, you know, a dermatology issue, you still need to take that seriously because it could be related to infection. The final thing, which I didn't really talk about this, but another presentation sometimes with patients with infections can be pain because if there is fluid and swelling, they might feel pain.

00:27:25:24 - 00:27:40:00
**Ann Spalding:** So all of these issues are just something that should be evaluated in the office. And if it's something unclear to that health care provider, whether it's something that is potentially an infection, it should be referred out to EP.

00:27:40:02 - 00:27:47:06
**Renee Sednew:** Dr. Cheung, Ann, thank you for joining us today and for sharing your insights. We've learned a great deal from this conversation.

00:27:48:15 - 00:28:12:09
**Outro:** This podcast is part of the AHA's National CIED Infection Initiative. This project is supported by Philips Guided Image Therapy. For the latest information about upcoming events and other resources related to CIED infections, please visit heart.org/treat2beatciedinfection. Thank you for listening.