Process Mapping Strategies to Prevent Subcutaneous Implantable Cardioverter-Defibrillator Infection

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ABSTRACT

Background: Infection remains a major complication of cardiac implantable electronic devices (CIEDs) and can lead to significant morbidity and mortality. Extrathoracic devices that avoid epicardial or transvenous leads, such as the subcutaneous implantable cardioverter-defibrillator (S-ICD), can reduce the risk of serious infection-related complications, such as bloodstream infection and infective endocarditis. While the 2017 AHA/ACC/HRS guidelines include recommendations for S-ICD use for patients at high risk of infection, currently, there are no clinical trial data that address best practices for the prevention of S-ICD infections. Therefore, an expert panel was convened to develop consensus on these topics.

Methods: An expert process mapping methodology was used to achieve consensus on the appropriate steps to minimize or prevent S-ICD infections. Two face-to-face meetings of high-volume S-ICD implanters and an infectious diseases specialist, with expertise on cardiovascular implantable electronic device infections, were conducted to develop consensus on useful strategies pre-, peri-, and post-implant to reduce S-ICD infection risk.

Results: Expert panel consensus of recommended steps for patient preparation, S-ICD implantation, and post-operative management were developed to provide guidance in individual patient management.

Conclusion: Achieving expert panel consensus by process mapping methodology for S-ICD infection prevention was attainable, and the results should be helpful to clinicians in adopting interventions to minimize risks of S-ICD infection.

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Abbreviations: CIED: cardiovascular implantable electronic device; EP: electrophysiologist; S-ICD: subcutaneous implantable cardioverter-defibrillator; TV: transvenous; ICD: implantable cardioverter-defibrillator

INTRODUCTION

The subcutaneous implantable cardioverter defibrillator (S-ICD) offers a beneficial choice for ICD-indicated patients, providing safety and efficacy comparable to transvenous (TV)-ICDs without many of the risks inherent to vascular leads[1-4]. AHA/ACC/HRS guidelines published in 2017 include a Class I recommendation for S-ICD use in patients who are at high risk for infection, and in whom pacing for bradycardia or VT termination or as part of CRT is neither needed nor anticipated.[5] While the use of the S-ICD reduces the risk of life-threatening complications, such as bloodstream infection and infective endocarditis due to the lack of vascular exposure, infections still occur. The size, location and additional incisions and surgical tunneling required for implantation of the S-ICD harbor an increased risk for infection, which, while generally non-systemic and safer to extract compared to TV lead infections, still require additional medical care with an increased financial burden.

Current practice for treatment of S-ICD infections tend to follow recommendations for intrathoracic ICD infections, which stipulate complete device and lead extraction once infection is confirmed[6], yet there has been no clinical data published to guide best practices specifically for the prevention and management of S-ICD infection. The unique S-ICD implantation technique and its non-vascular location present a different risk potential for both the development and treatment of infection. As the number of S-ICD implantations increase to involve more patients with close to 100,000 S-ICDs implanted already, it is important to establish best practices for both S-ICD implantation as well as post-implant patient management to minimize the risk of device infection to assure optimal device efficacy and patient safety. As no prospective clinical trials have been conducted to date to evaluate different potential infection prevention measures pre-, peri-, and post-S-ICD implantation, a modified process mapping methodology with high-volume S-ICD implanters and an infectious disease specialist was convened to establish recommended practices for the prevention and management of S-ICD

infections. The panel's consensus on the diagnosis and management of S-ICD infections was recently published[7]. This report describes the consensus developed through this panel's mapping process in the development of practice guidelines for the prevention of S-ICD infection.

METHODS

A modified process mapping methodology was employed during one initial and one follow-up face-to-face meeting of experienced electrophysiologists (EPs) and an infectious diseases specialist who has expertise in the field of cardiovascular device infections. Details of the modified process mapping approach have been outlined in a prior publication that examined anesthesia for S-ICD implantation.[8] In brief, a focused review of a stepwise approach of the unique steps of S-ICD implantation and specific approaches to minimize infection permitted input from all participants on both behavioral workflow and cognitive decision-making steps in individual patient prevention of S-ICD infections. Figure 1 is provided an overview of the phases of infection prevention, while the full map is shown as Supplemental Figure 1.

SHARED DECISION MAKING

Several studies have evaluated patient-, device-, and procedure-related factors that predict CIED infection[9,10]. Because current guidelines indicate the S-ICD for patients at high risk of infection, it is critical to fully evaluate the patients' co-morbidities to identify potential infection risk factors to choose the best device for that patient. While the shared decision-making between TV-ICD and S-ICD involves many factors, including the need (or possible future need) for pacing or ATP, it is equally important to evaluate a patient's current and future potential risk of device infection, such as renal disease that may progress to the need for chronic hemodialysis, which has been identified as a major risk factor associated with TV CIED infection[11]. Also, an important

consideration at implant is acknowledging the higher risk of serious complications of a TV-ICD system in relation to S-ICD. Assessing these risks at initial consultation should help guide the decision for the optimal device in each patient. The current or future risk of a need for vascular access, other implanted devices including mechanical valves, as well as the need for brady pacing or ATP should be considered to define the optimal ICD for patients.

EP LAB ENVIRONMENT AND STAFF SKILLS

A major step in preventing infection occurs long before the patient arrives for the scheduled procedure. All EP laboratory staff involved, including anesthesia personnel, should be fully aware of the need for infection prevention and control (Figure 1). With increased incisions and tunneling required for S-ICD implantation, the procedure necessitates meticulous aseptic practice as applied to all surgical procedures. Moreover, procedures should be established for training and continuous improvement of EP lab staff aseptic techniques, including implementation of new, improved techniques where needed, and thorough training for new employees. Limiting the number of people in the room, reducing the number of times a lab door is opened, and discouraging staff changes during the procedure can all contribute to a reduction in infection risk. Creation and consistent use of pre-, peri-, and post-operative checklists incorporating infection prevention measures can enhance consistency. Indeed, implementation of an infection-control protocol for implantation of cardiac devices has been shown to reduce infection by 54%[12].

PRE-OPERATIVE TECHNIQUES

Once the choice of an S-ICD is established, there are several pre-operative steps that can help reduce the risk of implant-related infections; see Figure 2a.

ANTIBIOTIC PROPHYLAXIS

The choice of pre-, peri- and post-operative antibiotics is one that should be considered well in advance of the implantation date. One dose of intravenous cefazolin given within 30 minutes to one hour prior to procedure is recommended. For patients with a past history of penicillin or beta-lactam allergy, further evaluation is required as a large number (~90%) of these patients will be eligible for cefazolin prophylaxis. Therefore, consultation with a specialist in allergic diseases should be obtained prior to device placement. If a patient is deemed a non-candidate for cefazolin prophylaxis, then vancomycin is often selected. Due to the current interest in limiting vancomycin use to diminish the likelihood of selection of antibiotic resistance, its lack of gram-negative coverage, and questions about its prophylaxis efficacy, allergy consultation should be obtained early to avoid vancomycin use. Clindamycin is another alternative, but because of its risk of *Clostridioides difficile* infection and its complications, avoidance of clindamycin is recommended.

Antimicrobial prophylaxis in the peri- and post-operative periods has been further addressed below in the "Implant Techniques" section.

ANTICOAGULANT USE

For patients on oral anticoagulant (OAC) medications, an important step to reduce the risk of infection is to establish the peri-operative plan for OAC use. The use of OACs increases the risk of surgical bleeding and hematoma formation[13,14], which is strongly associated with increased risk of TV device-related infections[15]. Because peri-operative interruption of OACs may lead to an unacceptable risk of clotting sequelae, heparin bridging has been used as an alternative to OAC continuation during surgery, but this too is associated with an increased risk of hematoma formation[16,17]. Alternatively, OAC interruption pre-operatively for 24-48 hours without heparin bridging may be a viable option to reduce infection risk for those patients able to tolerate this approach without undue clotting risk. Otherwise, uninterrupted anticoagulation should be considered[18]. Careful

consideration of the opposing risks of hematoma formation and subsequent infection risk with that of clotting or thromboembolic event need to be weighed for each patient prior to implantation.

OPTIMAL IMPLANT TECHNIQUE CONSIDERATION

Since the introduction of the S-ICD, implant techniques have been refined, including the two-incision technique with the electrode delivery system in which the supra-sternal incision is avoided, leaving just the pocket and xiphoid incisions [19-21]. Reducing the number of incisions may reduce the risk of superficial incisional infections, and it can also reduce the overall procedure time[22,23] without adversely impacting the rate of complications[24]. The inter-muscular technique, in which the defibrillator device is placed in between the latissimus dorsi and serratus anterior muscle layers, has been developed to provide the optimal placement for the generator in the axillary pocket[20,21,25]. This placement can assure optimal location for appropriate rhythm detection, and potentially provide better cosmesis due to the deeper location. Optimal placement of the device, along with objective assessment of device placement using the Praetorian score[26], may also improve sensing and reduce IAS while providing high conversion success[27], thus also reducing the potential need to reposition the device either during the implant after conversion testing, or a subsequent revision surgery, both of which will greatly increase infection risk. Use of blunt dissection to separate the muscle layers will help avoid nicking the muscle layers, which could result in excessive and unnecessary bleeding with increased infection risk.

PATIENT OPTIMIZATION

Pre-op bloodwork 3-30 days prior to implant procedure is often obtained. The most common pre-operative blood testing includes, complete blood count (CBC), chemistry and blood glucose levels. These will facilitate evaluation of anemia or an occult infection and serum creatinine concentration will guide the dosing of antibiotics and anesthetic. An elevated glucose concentration may alert the implanter of possible postponement of the implant if it is above 250 mg/dL.

In addition, patients should be instructed on the use of an antibacterial cleanser to reduce bacterial skin colonization for the few days preceding and the morning of the implantation.

PRE-OPERATIVE PREPARATION AND ANTIBIOTIC ADMINISTRATION

Upon arrival on the day of the procedure, the patient is brought to the pre-operative area, where an updated history and physical is obtained, bloodwork is performed to evaluate CBC, INR, blood chemistry panel, urine pregnancy test as applicable, and blood glucose level, and an IV access is secured. A temperature over 100.0 F is considered a fever and should lead to procedure postponement for further evaluation of a possible infection source. Otherwise, skin in the incision area is carefully examined for rash, eruptions, or evidence of infection. The hair should be removed with an electric clipper with care taken to avoid abrasions, followed by the use of tape to removed clipped hair.

PREPPING AND DRAPING

Once the patient is moved into the EP lab, attention to detail in the aseptic skin preparation and draping is key to reducing infection risk (Figure 2b). Because the S-ICD implant requires two or three incision sites over a much larger area than TV-ICDs, it is critical that the full area be appropriately, aseptically prepped beyond the incision sites with the recommended aseptic treatment, such as chlorhexidine. In many centers the device is positioned on the skin with fluoroscopy guidance, then the skin is marked prior to the aseptic preparation of the skin. Furthermore, care must be taken in placing the defibrillator patches prior to prepping and draping the patient. That step is usually completed by the scrub nurse, technician or the physician performing the procedure.

Draping the patient requires similar meticulous attention to detail. Use of surgical drapes and adhesive dressings such as Ioban™ antimicrobial incision drapes are important as they have been proven to reduce infection risk[28]. Placement of the drape well beyond the incision area is important. However, with the additional incisions required for the S-ICD, the larger surgical prep and drape area may require additional time and/or more than one adhesive dressing. The use of pacemaker drapes to create two windows for the 2-incision

technique has been proposed to assure sufficient aseptic prep with lower overall preparation time[29]. If radiographs are necessary, then use a sterile cover on the radiographic device to maintain sterility of the surgical site. Ideally this step is performed initially when the patient is draped and not as an aftermath. Once the draping is complete, it is critical to determine if the final drape placement is optimal, and if not, redo until this is achieved. Everyone in the room plays a crucial role observing others and verbalizing any concern.

IMPLANT TECHNIQUES (Figure 3)

Once the patient is ready for the first incision, it is highly advised to take a surgical time-out and review the antibiotic delivery time to assure the optimal interval has passed but not been exceeded between the start of the IV delivery and first incision. If necessary, administer a follow-up dose. This is also a good time to recheck the last dose of anticoagulation, if applicable.

When making the incisions, utmost care should be taken to create clean incisions with minimal tissue damage or lacerations to improve wound healing. Avoid aggressive retractions, and avoid dissecting into the muscle layers, which could lead to excessive bleeding. Take the time to achieve thorough hemostasis. Use of cautery tools such as the lighted PhotonBlade™ can help illuminate the deep pocket to detect and stop any bleeding. In addition, use of the 2- versus 3-incision technique has been shown to reduce implant time[22], which may reduce the infection risk.

The procedure used to place the electrode between the device pocket and the xihpoid incision, and between the xihpoid and supra-sternal incisions in the three-incision technique, require subcutaneous tunneling, a technique not required for other CIED implants. Research into techniques used for dermal filler injections demonstrate that infection incidence varies with injection technique, with the fanning technique, in which the needle is pulled back, then advanced in a new direction immediately before the needle is withdrawn, produced the

highest infection incidence[30]. These results suggest that a consistent forward motion, without pulling back and advancing again, may provide the lowest infection risk during S-ICD electrode tunneling.

Many EPs utilize a variety of antibacterial pocket washes once an implant pocket is created. While there is no known adverse effect of this practice, there are no prospective, clinical trial data to support its use; this includes the PADIT that is addressed below. Such practices may involve flushing the implant pocket with an antibiotic solution, both before and after device insertion into the pocket, and/or placing antibiotic-soaked lap sponges in the pocket during the implant procedure, although specific details about the antibiotic, dose, and volume vary. The PADIT trial compared conventional antibiotic prophylaxis (cefazolin or vancomycin single-dose IV pre-implant infusion) to a more extensive, incremental antibiotic prophylaxis regimen (cefazolin + vancomycin, and an intra-operative pocket wash with bacitracin, and a post-operative oral antibiotic for two days) in a prospective, randomized cross-over design study of over 19,000 patients across 28 centers undergoing CIED implant. While the numbers of infections and infection-related hospitalizations were lower in the incremental treatment group, the differences did not achieve statistical significance[31], possibly due, in part, to the lower-than-expected overall infection rate that reduced statistical power.

The use of an antimicrobial pouch for generator placement to prevent CIED infection has also been evaluated. The efficacy of a second-generation absorbable pouch was evaluated in the WRAP-IT study, which demonstrated effectiveness at reducing infection in TV CIED implants, reducing infections from 1.2% in the control group to 0.7% in the TyRx group[32]. It should be noted that certain high-risk patients, such as those with a previous device infection or those with renal disease on dialysis, were excluded from the study. In addition, the antibacterial drug is released from the mesh over the first seven days, designed to provide prevention of surgical infection, but it is not designed to address potential subsequent infections from a distant seeding site, such as indwelling catheters. In addition, when considering the number needed to treat analysis[33] and the cost of the pouch, this is not likely a feasible option for most patients, but it should be strongly considered for patients at higher risk of

surgical site infection. It is noteworthy that the use of the antibiotic envelope decreased CIED infection by 82% in patients who developed hematoma in the WRAP-IT trial[15,17]l, so it could be considered in patients at high bleeding risk such as those treated with dual antiplatelet therapy or antiplatelet and anticoagulant therapy.

WOUND DRESSING AND POST-OP CARE (Figure 4)

Wound closure is a critical step in infection prevention. With multiple incisions to close, including a larger incision for the device pocket than required for TV-ICDs, the S-ICD closure technique must be optimized to prevent wound dehiscence and resulting pocket infection. While no published data exist indicating the superiority of specific techniques, and techniques vary between EPs, general recommended best practices are presented. Due to the deeper location of the device pocket, particularly with the adoption of the inter-muscular technique, a three-layer closure is recommended for the pocket incision, with two layers used for the internal layers, along with the superficial skin closure. The use of interrupted stitches with 2-0 vycril for deep layers may be preferred. Superficial layer closure must be both strong and cosmetically acceptable, with the use of surgical glue, ZipLine closure devices, or 4-0 sutures with steri-strips being well-accepted options (Figure 4a). For the subcuticular plane a good alternative is barbed sutures such as 4-0 V-Loc™ to provide great cosmetic results and avoid skin dehiscence. Note that if conversion testing is to be performed, many EPs choose to perform conversion testing after closure of the inner device pocket layers to assure a secure placement of the device, but prior to the outer layer closure in case repositioning needs to occur. A two-layer closure is typically acceptable for the xihpoid and supra-sternal incisions. Once all incisions are closed, it is recommended to obtain a digital photograph of each incision to use as a baseline against which to evaluate subsequent photos for wound checks.

Choice of wound dressing is another area lacking specific data to support certain techniques or products for S-ICD implants. Occlusive dressings left on at least overnight to 48 hours should be considered. Use of antibiotic-impregnated dressings may be of value but have not been tested in S-ICD cases. Pressure dressings may be

considered post-operatively for procedures at higher risk of hematoma formation. If pre- and intra-operative antibiotic regimens and aseptic techniques are rigorously maintained throughout the procedure, then post-operative antibiotic administration as prophylaxis should be unnecessary.

The patient should be discharged with very specific instructions on dressing removal and changes, along with any instructions for restarting any anti-coagulation or other medication that may have been held for the procedure. A post-operative wound check should be scheduled for 1-2 weeks post-implant, with very specific instructions for obtaining cell phone photographs of each incision site if the appointment will be remote. Specific early infection signs to assess at the post-implant wound check are: hot or tender to the touch, edema, erythema, fever, hematoma, or wound dehiscence. Signs that may appear later include most of these early signs along with erosion and pocket pain. As discussed in Baddour, et al.[7], if an S-ICD infection is suspected, then there is typically less urgency to immediately extract the device and electrodes as there is with a TV-ICD, which involves a risk of bloodstream infection that has been rarely described among patients with S-ICD infection. Individualize approach is warranted; nevertheless, complete device extraction should be done promptly.

CONCLUSION

Preventing S-ICD infections is multifaceted and should be meticulously planned. Prevention starts with patient selection and involves multiple steps during the pre-, intra-, and post-operative periods by collaboration of a panoply of specialists with EP clinicians. The mapping process described in this publication details these steps and serves as a contemporary educational tool.

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AUTHOR CONTRIBUTIONS

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FIGURE LEGENDS

Figure 1: Overview of the steps for preventing S-ICD infections

Figure 2: A. Preoperative techniques checklists B: Illustrative example of prepping and draping

Figure 3: Implant techniques

Figure 4: A. Examples of wound closures. B. Wound dressing and post-operative care checklist

Supplemental Figure 1: Infection Prevention Map.

Methods - Figure 1

Shared Decision Making

EP Lab Environment and Staff Skills

Pre-Operative Techniques

Implant Techniques

Wound Dressing and Post-Op Care

Figure 2a: Pre-Operative Techniques

Antibiotic Prophylaxis

- ☐ Recommend one dose of intravenous cefazolin alone 30 minutes to 1 hour before procedure
- ☐ Early allergy consultation should be obtained in patients with a history of penicillin or beta-lactam allergy
- ☐ Select either vancomycin or clindamycin as alternative options, but both can include risks

Hint

The choice of using pre- and peri- operative antibiotics is one that should be consulted with an infection disease specialist prior to device placement.

Anticoagulant Use

- ☐ Establish the peri-operative plan for oral anticoagulant (OAC) medications to reduce the risk of infection
- ☐ Remember the use of OACs increases the risk of surgical bleeding and hematoma formation

Patient Optimization

- ☐ Guide the dosing of antibiotics by pre-op bloodwork 3-30 days prior to implant procedure
- ☐ Postpone implant procedure if patient's glucose level is elevated above 250 or if the patient has a fever

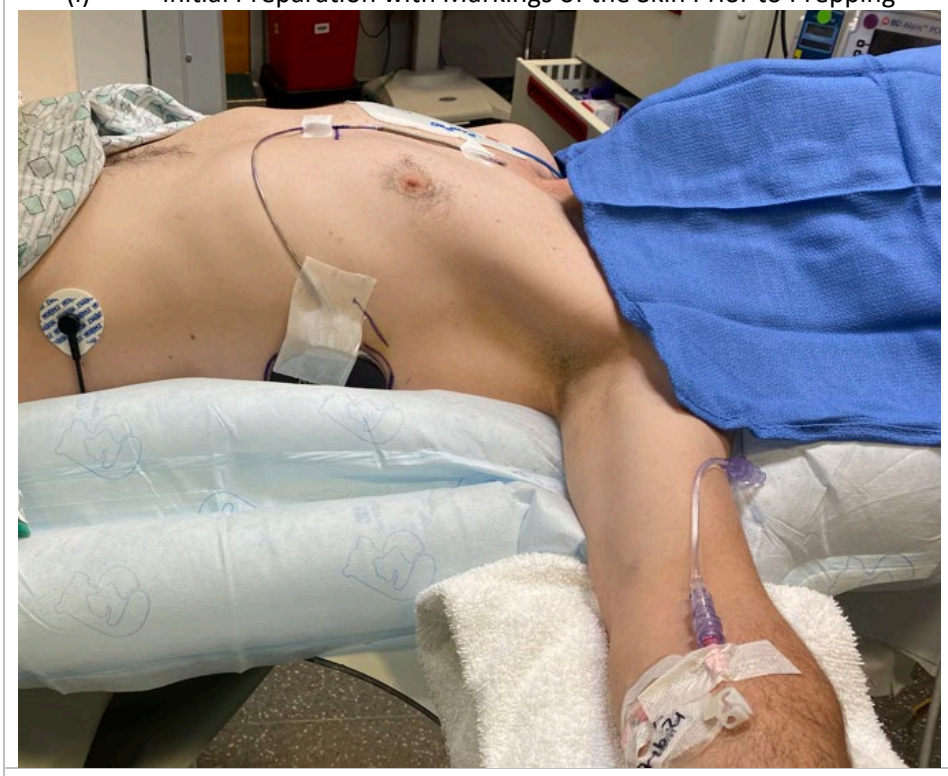
Hint

Patients should be instructed on the use of an antibacterial cleanser to reduce bacterial skin colonization for the few days preceding and morning of the implant.

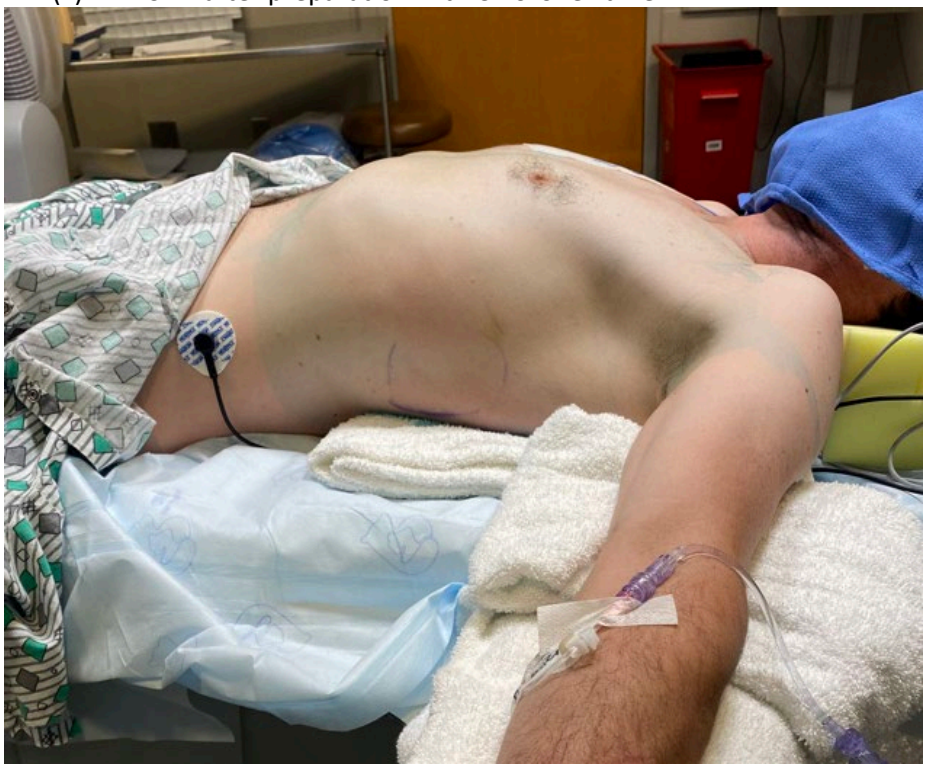
Pre-Operative Preparation and Antibiotic Administration

- ☐ Bring patient to pre-operative area
  - ☐ Obtain updated history and physical patient information
  - ☐ Perform bloodwork to evaluate CBC, INR, blood chemistry panel, and blood glucose level
  - ☐ Complete urine pregnancy test and secure IV access
  - ☐ Make sure patient's temperature is below 100.0º F or postpone procedure
  - ☐ Examine incision skin area for rash, eruptions or evidence of infection
  - ☐ Remove hair with electric clipper and use tape to remove clipped hair

(i) Initial Preparation with Markings of the Skin Prior to Prepping



(ii) Skin after preparation with Chlorohexidine



(iii) Large area of surgical exposure

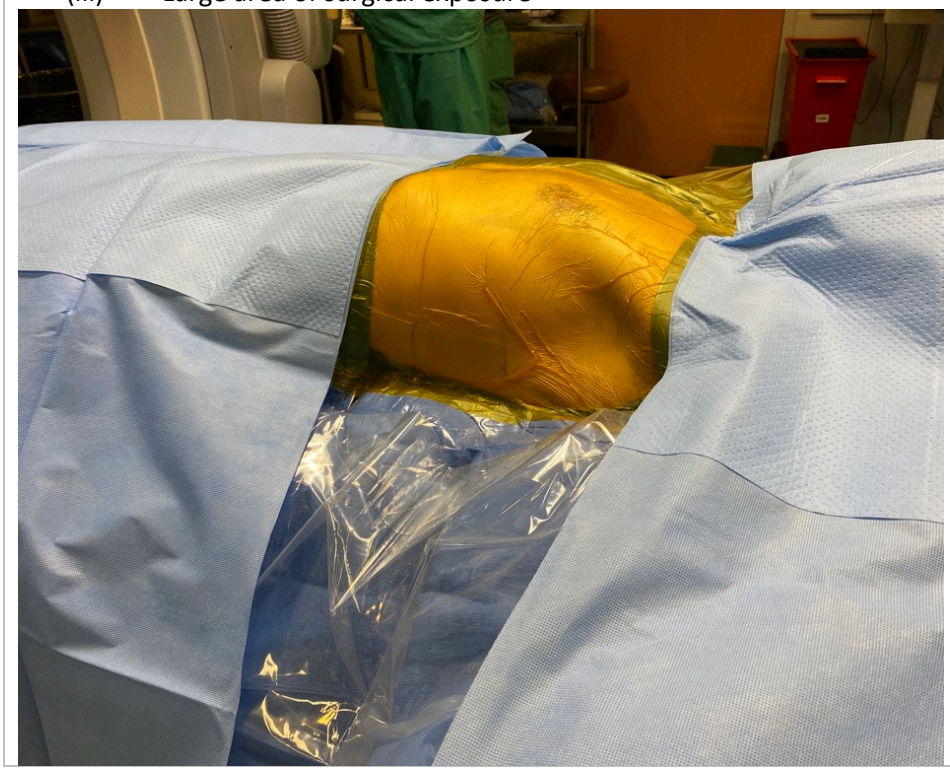


Figure 3:

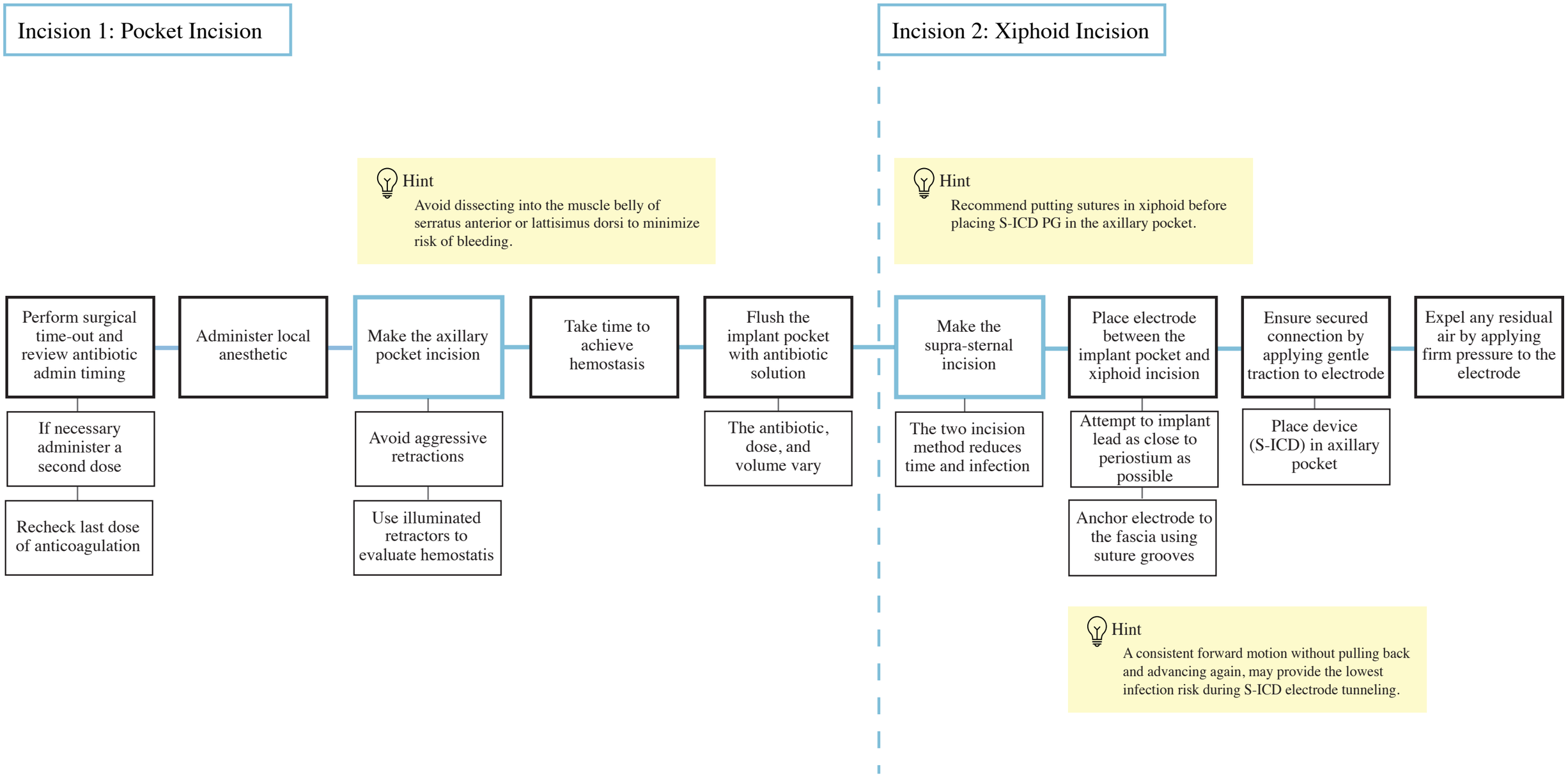
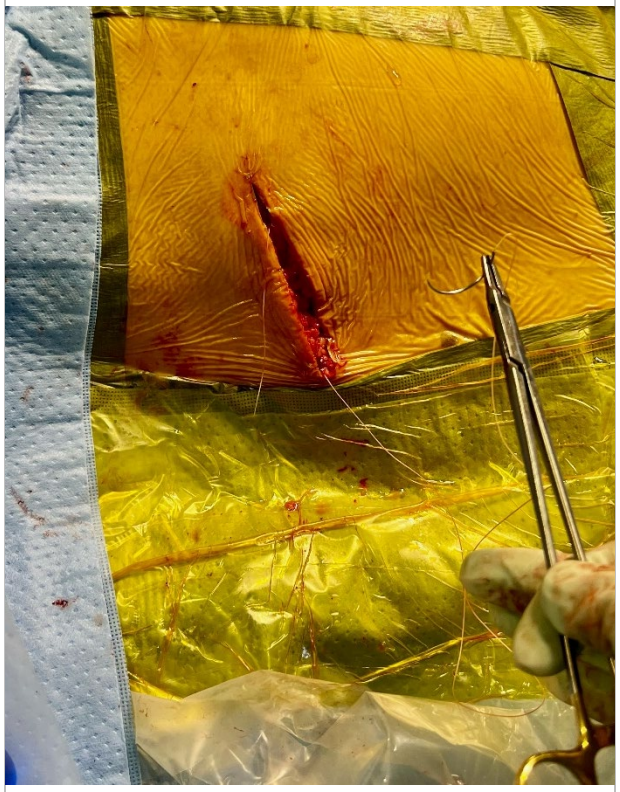
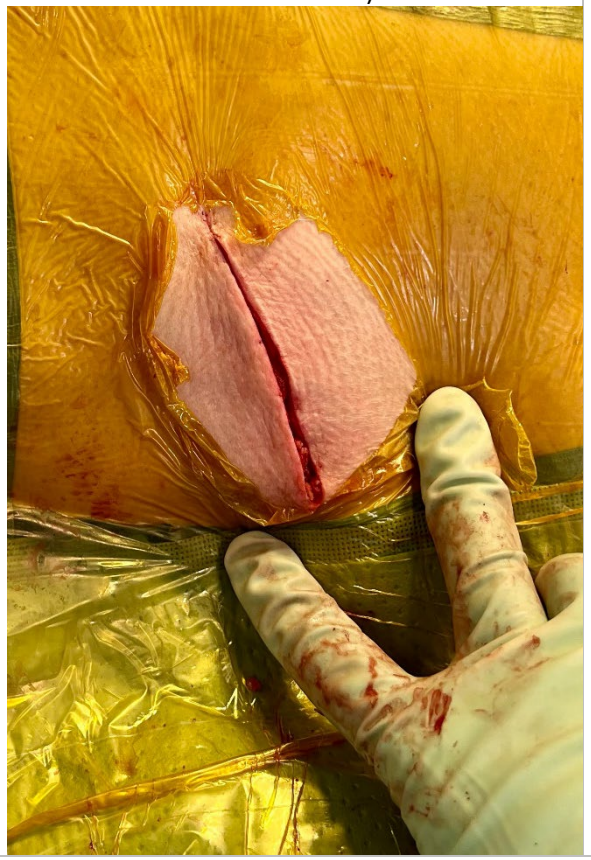

Incision 1: Pocket Incision
Incision 2: Xiphoid Incision
Hint
Avoid dissecting into the muscle belly of serratus anterior or lattisimus dorsi to minimize risk of bleeding.
Hint
Recommend putting sutures in xiphoid before placing S-ICD PG in the axillary pocket.
Perform surgical time-out and review antibiotic admin timing
Administer local anesthetic
Make the axillary pocket incision
Take time to achieve hemostasis
Flush the implant pocket with antibiotic solution
Make the supra-sternal incision
Place electrode between the implant pocket and xiphoid incision
Ensure secured connection by applying gentle traction to electrode
Expel any residual air by applying firm pressure to the electrode
If necessary administer a second dose
Recheck last dose of anticoagulation
Avoid aggressive retractions
Use illuminated retractors to evaluate hemostatis
The antibiotic, dose, and volume vary
The two incision method reduces time and infection
Attempt to implant lead as close to periostium as possible
Anchor electrode to the fascia using suture grooves
Place device (S-ICD) in axillary pocket
Hint
A consistent forward motion without pulling back and advancing again, may provide the lowest infection risk during S-ICD electrode tunneling.

Figure 4a example of wound closure

(i) Subcutaneous layer closure using *2-0 vycril. Note the perfect hemostasis*



(ii) Subcutaneous layer completed (note the borders are well aproximated and no tension on the skin)



(iii) Subcuticular layer closure *using 4-0 sutures*

Figure 4b

Wound Dressing and Post-Operative Care

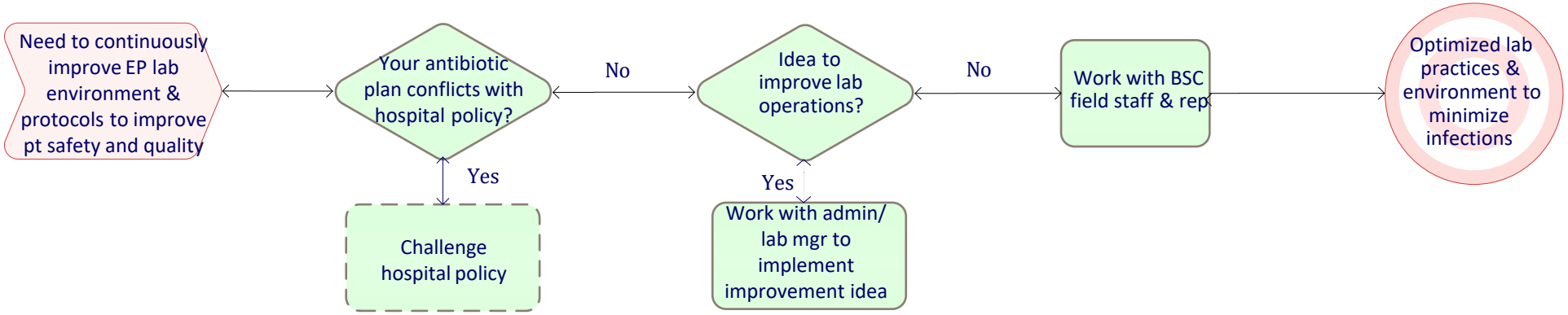
- ☐ Obtain a digital photograph of each closed incision to use as a baseline
- ☐ Discharge patient with very specific instructions on dressing removal and changes
- ☐ Tell patient they can shower postoperatively as soon as 3 days if glue was used or as long as seven days if steri-strips were used
- ☐ Instruct the patient not to remove steri-strips if used
- ☐ Concerning signs for a patient to look for near/on their wound
  - ☐ Redness
  - ☐ Swelling
  - ☐ Heat or Warmth
  - ☐ Fever
  - ☐ Tender to Touch
  - ☐ Pus
  - ☐ Hematoma
  - ☐ Incisions Break Down
- ☐ Give patient instructions for restarting any anti-coagulation or other medication
- ☐ Schedule a post-operative wound check 1-2 weeks post-implant
- ☐ If appointment will be remote provide specific instructions to patient for obtaining cell phone photographs of each incision site.

Hint

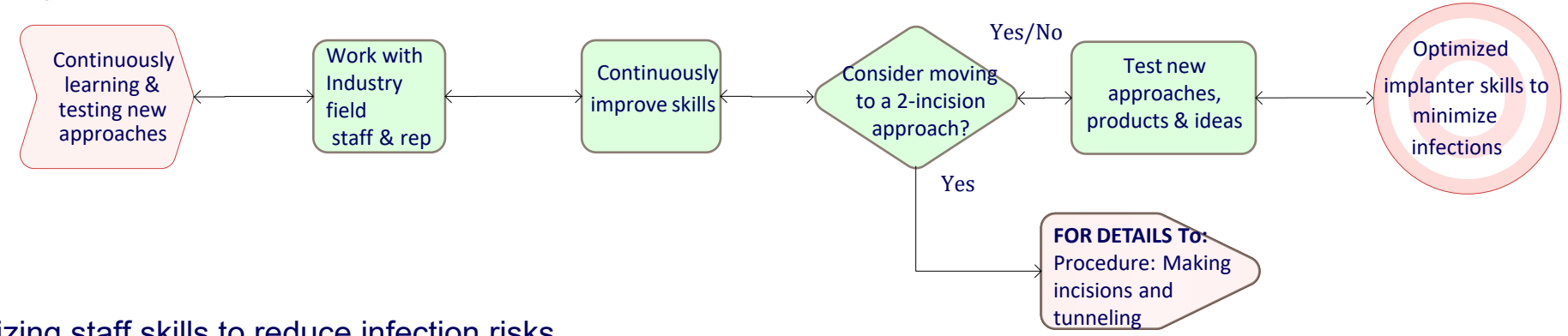
If pre- and intra-operative antibiotic regimens and aseptic techniques are rigorously maintained throughout the procedure, then post-operative antibiotic administration as prophylaxis should be unnecessary.

FIGURE 1: EARLY PREPARATION TO REDUCE INFECTIONS

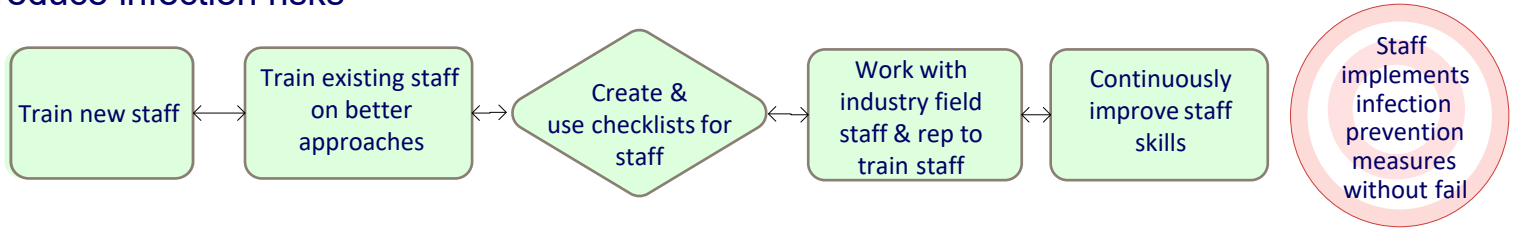
Optimizing the EP lab environment to reduce infection risks



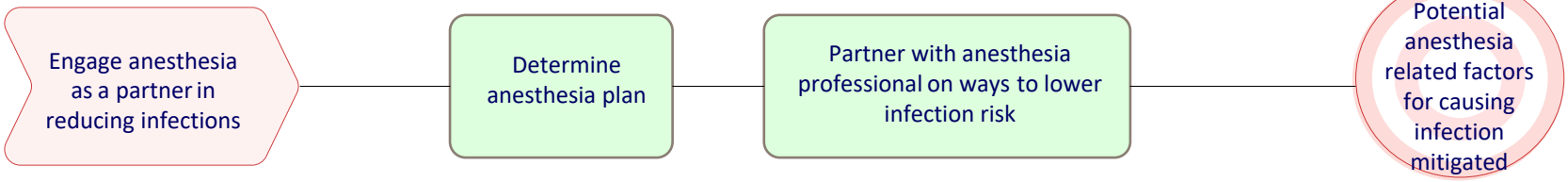
Optimizing implanter skills to reduce infection risks



Optimizing staff skills to reduce infection risks

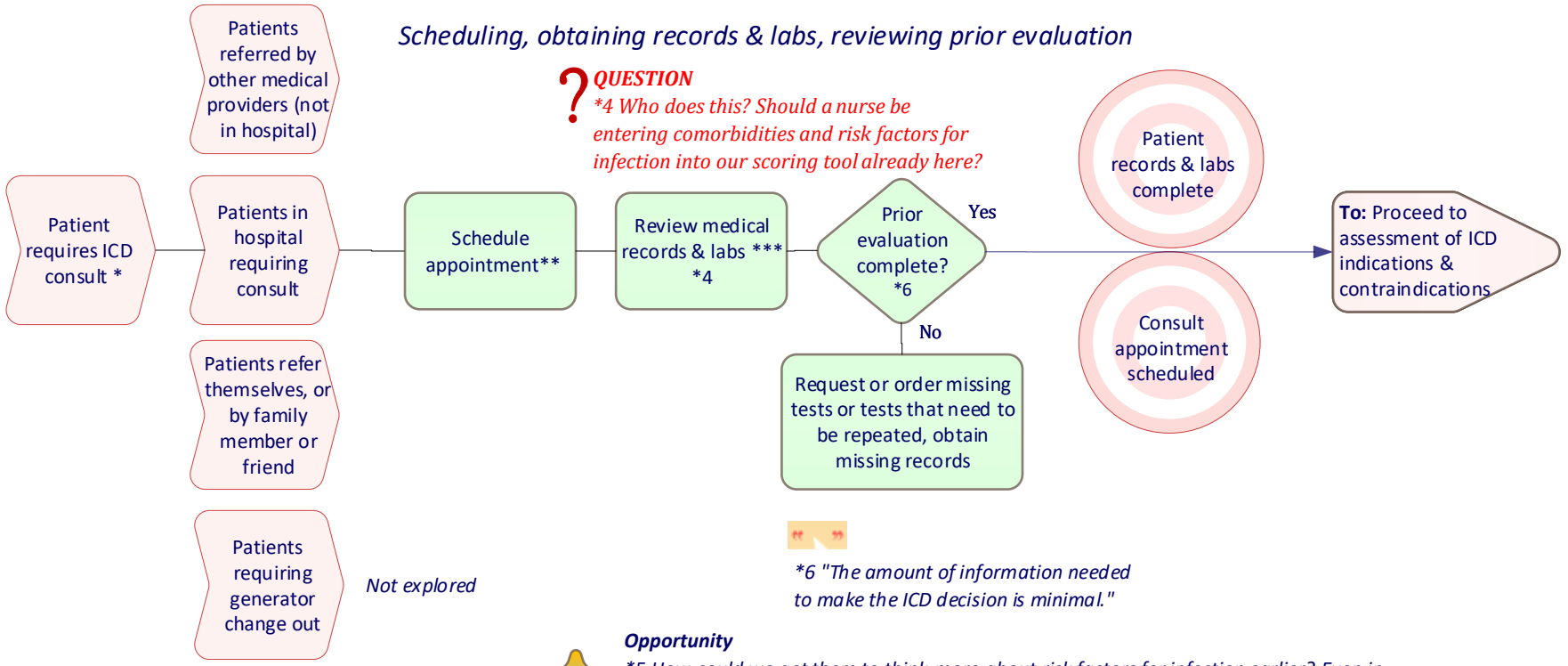


Partnering with anesthesia to reduce infection risks



Consult 1. Scheduling pt and obtaining pt records for consult

Electrophysiologist



Notes, etc.

* Patients may be referred by a general cardiologist, electrophysiologist, heart failure specialist, internist, family practice physician, mid-level provider (nurse practitioner/physician assistant), infectious disease specialist, nephrologist, geneticist or a family member/friend.

** Scheduling this procedure varies by center. As an elective procedure, it can vary more than non-elective procedures.

*** Most pt records are complete. Complete includes:
- EKG
- etc.

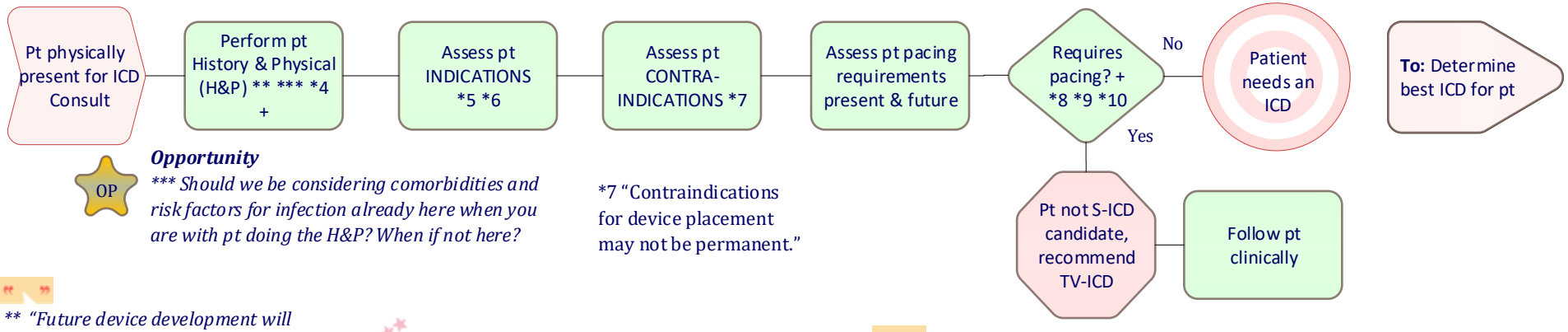
Consult 2. Assessing ICD indications & contraindications *

Electrophysiologist

* " We are assessing pt related factors that are objective indications or contraindications with large expert consensus."

Insight
EPs are using a framework of thinking set before the S-ICD option existed. What needs to change given the new options?

Question
Interestingly, this conversation was difficult. In practice, the decision making goes very fast but there are many factors to consider. Should an EP be thinking about risk factors for infection already at this point? When?



OP

Opportunity
*** Should we be considering comorbidities and risk factors for infection already here when you are with pt doing the H&P? When if not here?*

*7 "Contraindications for device placement may not be permanent."

** "Future device development will influence this decision (when leadless pacemaker is an option)."

What do they think about DeviceMatch.com?
Do they have a checklist?
Who looks at the data to see if there is an indication? Who puts the indication in the medical record?

Insight
There was no reference to the DeviceMatch.com app that has been created for assessing these criteria. An indication is required in the medical chart for the insurance company to approve payment. Perhaps the nurse or scribe is making sure this occurs?

*8 "We are assessing a pt that does not require pacing to narrow down to two device options: TV-ICD or S-ICD."

*9 "We also consider future pacing needs and there is variable opinion on how frequently this occurs."

Russo, AM, Stainback, RF, Bailey, SR, et al., ACCF/HRS/AHA/ASE/HFSA/SCAI/SCCT/SCMR 2013 appropriate use criteria for implantable cardioverter-defibrillators and cardiac resynchronization therapy: a report of the American College of Cardiology Foundation appropriate use criteria task force, Heart Rhythm Society, American Heart Association, American Society of Echocardiography, Heart Failure Society of America, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, and Society for Cardiovascular Magnetic Resonance. Heart Rhythm, 2013. 10(4): p. e11-58.

Notes, etc.

*4 Update as necessary and on day of procedure.

*5 Certain INDICATIONS and CONTRAINDICATIONS are more important to assessing infection risk than others

*6 Mappers listed:
INDICATIONS age, ejection fraction < 35%, genetic abnormality predisposing pt to cardiac arrest (VF/VT), heart failure, prior cardiac arrest, inducible ventricular tachycardia, life expectancy < 1 yr., other forms of cardiomyopathy (HCM/ARVC), prior lethal dysrhythmias, etc.

CONTRAINDICATIONS: cancer, psychiatric illness, active infection, etc.

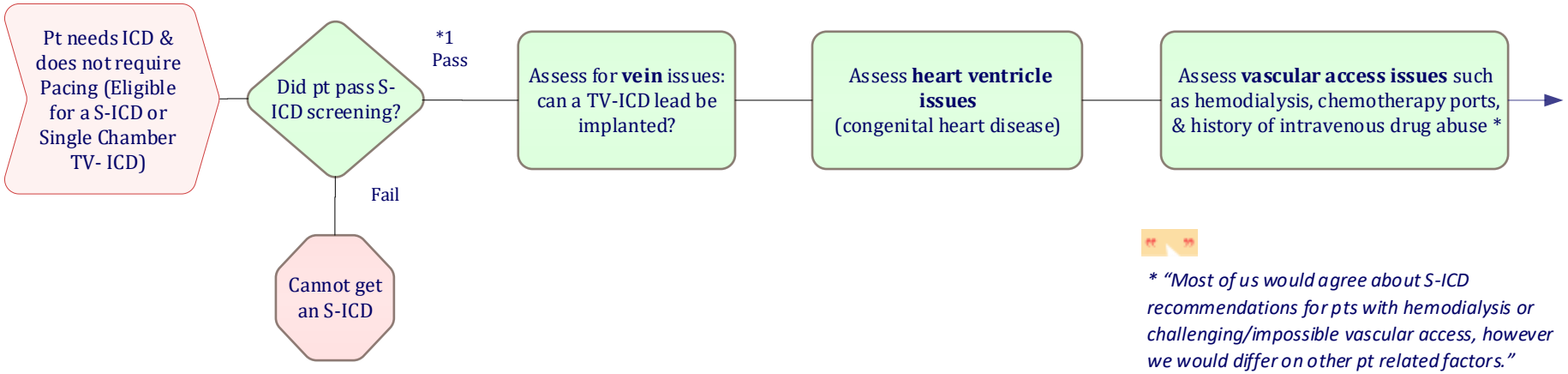
*10 This includes but is not limited to pts presenting with a need for bradycardia pacing, CRT/BiV, and anti-tachycardia pacing

- TV-ICDs are more appropriate & should be recommended for pts requiring pacing
- S- ICD is not eligible if pt needs pacing immediately
- Older pts are the more likely to develop a need for pacing

Consult 3. Assessing a patient for exclusions to a Single Chamber TV-ICD or S-ICD (page 1 of 2)

Electrophysiologist

These tasks are being done simultaneously (to some degree).



** "Most of us would agree about S-ICD recommendations for pts with hemodialysis or challenging/impossible vascular access, however we would differ on other pt related factors."*

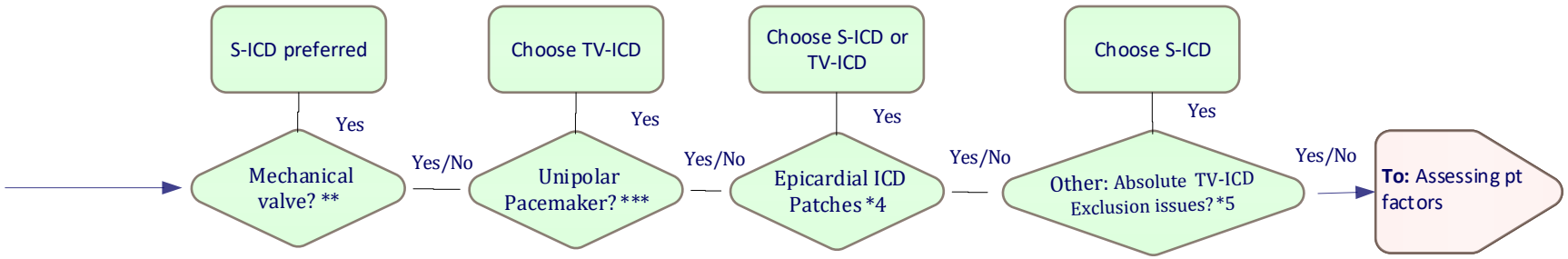
Question
When is screening done? If there are no other options than S-ICD, is this followed 100%?

Notes, etc.

*1 Lead extractors have a bias towards implanting S-ICD

Consult 3. Assessing a patient for exclusions to a Single Chamber TV-ICD or S-ICD (page 2 of 2)

Electrophysiologist



** "Having a mechanical valve has higher implications for an infection, but a mechanical valve is also a risk factor for infection."*

Notes, etc.

** Mechanical heart valves (prosthetic valves) in general & tricuspid valves in particular absolutely preclude TV-ICD.
Mechanical heart valves have significantly higher implications for creating lethal infections, so one would not use a TV-ICD in these cases.

*** Although rare, pts with unipolar pacemakers are ineligible for an S- ICD

*4 Although rare, the pt with epicardial ICD patches is probably ineligible for an S-ICD, although this is debatable as an exclusionary factor

*5 Pt has an LVAD or at high risk for needing an LVAD are excluded.

SEE more info on Consult 4 page under "Assess pt HEALTH implications

Consult 4. Assessing patient risk factors * ** *** *4 (page 1 of 2)

Electrophysiologist

** "Pt related factors help make the decision between TV & S-ICD."*

*** " Most of us agree with procedural, device and situational risk factors, but on the pt-related factors we might have different beliefs."*

**4 "The mortality of S-ICD infections is considerably lower making it the preferred recommendation as infection risk increases."*

**5 "The rate of infection for S-ICD and TV-ICD is about the same but the type of infection is different."*

"See Pt Infection Risk SCORING TOOL"

Pt is candidate for S-ICD, determining best ICD option

S-ICD or TV-ICD

Assess pt HEALTH implications *6

Insight
*** Not thinking very much about infection risk factors consciously, here.*

S-ICD or TV-ICD

Assess pt AGE implications *8 *9 *10

S-ICD or TV-ICD

Assess pt SIZE implications *11 *12 *13

Insight
**13 There is a reluctance to put an S-ICD in a morbidly obese patients, especially females.*

**7 "Every time you tack on an organ that's failed, your infection risk increases."*

**8 " It is important to consider whether or not pt could outlive their leads."*

**9 "It would be hard to get us to agree on the longevity of modernized leads."*

****11 Hint***
If proceeding to deliver an S-ICD to an obese pt, take large bites and use large retractors with lights (Richardson retractors are particularly helpful).

Notes, etc.

*6 Pt HEALTH Risk Factors:
- Diabetes/blood sugar > 250 "Diabetes is a risk factor even if controlled."
- Prior breast implants
- Hemodialysis
- Risk of Hematoma
- History of bloodstream infection
- Prior mastectomy
- Organ failure *6
- Prior ICD infection
- Prior Local Device Removal
- Local skin issues (current & prior)
  e.g., eczema, psoriasis or candidiasis
- Morbid obesity
- Bleeding disorders
- COPD
- IV drug abuse
- Steroid use

*10 Pt AGE risk factors:
- Age is a subjective measure & can influence the decision either way
- Older pts are more likely to develop a need for pacing
- LONG life expectance (decades) suggests S-ICD is more appropriate
- 3 of 4 panelists agreed that "young" means < 50 years old
- A younger pt forms more scar tissue. They're more difficult to extract and have the lead in longer making them much more difficult to extract.
- Risk of TV lead perforation is greater in older population
- The younger the pt the stronger one feels about implanting an S-ICD
- One expert stated he was "biased towards S-ICD in the old because S-ICD has a better atrial fibrillation discrimination (avoiding inappropriate shock)"
- One expert stated he would not let a 26 year old pt leave the clinic without agreeing to an S-ICD instead of a TV-ICD
- It is difficult for experts to agree on the definitive longevity of S-ICD leads
- Some people will argue that TV-ICD better in younger pts as they have better battery longevity than S-ICD
- Transvenous perforation is more common in older pts

*12 Pt SIZE risk factors:
- Is obesity a PROVEN risk factor for infection? IDE study did not find a correlation between BMI and infection risk (Frankel et al.Impact of Body Mass Index on Safety and Efficacy of the Subcutaneous Implantable Cardioverter-Defibrillator. JACC EP 2018; 4(5): 652-659.)
- hard to close because it's just a bunch of fat & a pt doesn't have enough integrity to close with a suture there
- Small pts have higher risk of erosion, discomfort.
- Small pt may be concerned about cosmetic appearance as device may be noticeable.
- S-ICD procedures in obese pts with larger breasts are technically more challenging increasing risk of infection
- Obese pts require larger incisions which are more difficult to close.
- Obesity impairs wound healing as area remains moist
- High BMI pts are technically more difficult to achieve optimal device positioning in due to depth of soft tissue.
- High BMI pts pose an increased risk of leaving fat between the device and chest wall, which reduces effect of shock as energy is lost due to resistance.
- Subcutaneous vs intermuscular in smaller pts?

Consult 4. Assessing patient risk factors (page 2 of 2)

Electrophysiologist

S-ICD or TV-ICD

S-ICD or TV-ICD

Assess pt's ability to TOLERATE DFT (testing) * ** *** *4 *5

Assess GENDER SPECIFIC issues *6

Assess pt ACTIVITY LEVEL *7 *8

Assess OTHER pt factors *9

Assess pt INSURANCE coverage *10

Pt factors accurately assessed & weighted

To: Assessing procedural, device & situational risk factors

** " Factors influencing whether or not a pt can be DFT tested are subjective."*

*** "If you can't test, normally we would put in TV-ICD but consider S-ICD without testing."*

**** " I think people are comfortable with the idea of transvenous devices not being tested."*

**7 "I had a golfer who complained about the site of S-ICD placement."*

Notes, etc.

*4 In practice, ~ 75% of S-ICD pts are DFT tested.

Risk factors precluding DFT testing:

Patients who have or exhibit:
- hemodynamic instability
- hypertrophic cardiomyopathy
- systolic blood pressure < 80
- left ventricular thrombus
- low ejection fractions LVEF (< 15-20%)
- heart failure status

Risk factors arguing against DFT testing:

Patients who have or exhibit:
- likely inability to tolerate deep sedation
- obesity
- AF (atrial fibrillation) without anticoagulation

If someone has Atrial fibrillation and is not anti-coagulated you probably won't test their device which means you may be more inclined to give them a TV-ICD device.

*5 DFT Testing in this document refers to Conversion Testing (cardioversion testing, but not threshold testing)

*6 Female pts have more pain than men due to bra strap overlay. Also, obese female patients require special considerations.

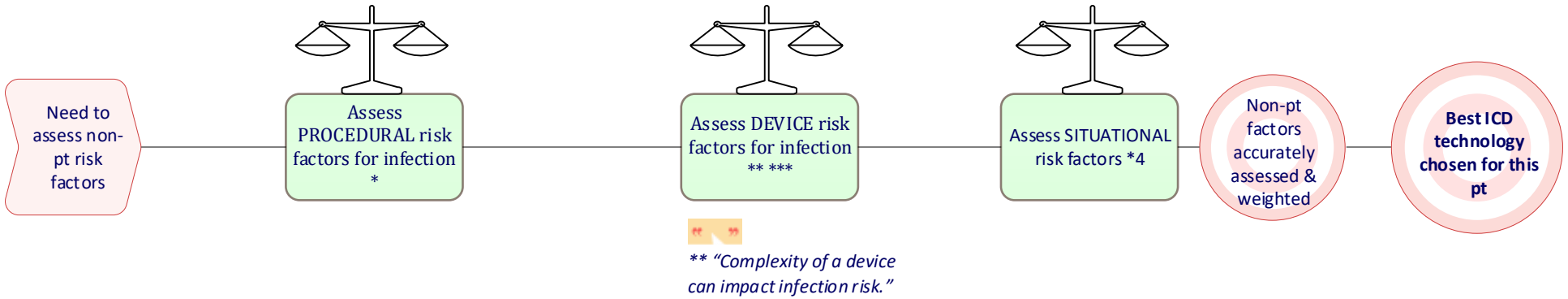
*8 Activity level with pt's profession, hobbies or lifestyle: pts who use their left shoulder more than usual may not be S-ICD candidates (weight lifters, golfers, swimmers, etc.)

*9 For example:
- Need for MRI?
- Material allergies such as titanium, nickel, silicone, stainless, etc.?
- Do previous orthopedic shoulder procedures matter?
- Geographic location of pt-is S-ICD support available? (such as much of South America)

*10 Some insurance plans do not cover S-ICD. May require extra work to get approval, making a TV-ICD an easier option.

Consult 5. Assessing procedural, device & situational risk factors

Electrophysiologist



*** "Complexity of a device can impact infection risk."*

QUESTION: Is there evidence that location of the device shifts the risk of infection?

* PROCEDURAL risk factors:
- Number & size of incisions
- Differences in procedural **duration** between TV-ICD and S-ICD implantation may exclude one or the other device
- Consider the risk of "**repetitive pocket manipulation**" as being immediate vs. later lead revision. This risk may rule out S-ICD.
- Incision location, e.g., not on inframammary crease (not in a place where it would cause pressure on the device)

*** DEVICE risk factors:
- Device sizes? S-ICDs are 2X size of TV-ICDs.
- Risk of infection of a larger device is weighted by it's location:
  - TV-ICD > Pectoral
  - S-ICD > Sub-Axillary
- While the /S-ICD is larger than the TV-ICD, the implant location may minimize the risk of pocket erosion & poor wound healing.

*4 SITUATIONAL risk factors:
- Urgency of device implant & lack of resources immediately available (e.g., anesthesiology may be difficult to schedule quickly so an TV-ICD is implanted as no anesthesia professional need)
- Physicians experience with S-ICD
- Implanter not trained or confident on S-ICD procedure
- Bias towards one or the other technologies

Notes, etc.

Consult 6. Optimizing patient pre-operatively (page 1 of 2) * **

Electrophysiologist

* "None of us are doing these things the same way and so this is an important area of inquiry."

* "Clearly there is an opportunity for decreasing infection."

Pt & Implanter choose best ICD option

Is this a guideline, protocol or something?

Patient has agreed to and is indicated for an S-ICD

Consider what drug to use should an infection occur *** *4 *5 *6

Pt claims penicillin allergy? *7 *8

Yes/ No

Yes

Test for penicillin allergy

Pt on anti-coagulants?

Yes/ No

Yes

Determine perioperative anticoagulation plan *9 *10

Pt history of infection or colonization?

Yes/ No

Yes

Prescribe nasal mupirocin 24 hrs. or more before (though this is not necessarily standard)? *11

Gain pt consent + *13

*** "Should an infection occur, cefazolin will be a superior antibiotic choice over vancomycin or clindamycin if pt is not penicillin allergic."
Infectious Disease Specialist

*4 "Some centers give vancomycin in addition to cefazolin because you can cover more of the methicillin-resistant strains of both Staph aureus & coag negative staph. The downside of giving even 1 dose of vancomycin is it may precipitate acute renal failure."

*9 "We're comfortable putting in TV-ICD devices on uninterrupted blood thinners. But because the S-ICD procedure requires more extensive dissection, we're not as comfortable doing it."

*8 "90% of patients who say they are allergic to penicillin, test negative for penicillin allergy. So if an infection occurs, and we know they are not allergic to penicillin, we can give Cefazolin the best antibiotic choice for device infection or cellulitis."

*11 "The problem is we don't have data to definitively say these methods are working."

*13 "While consent is often done the day of the procedure, it can be signed during consult." Panelists felt it should be day of procedure.

Notes, etc.

*6 Cefazolin is the superior choice for an antibiotic should an infection occur

*7 If pt claims a penicillin allergy, seriously consider confirming with a skin test. Otherwise, should an infection occur, you can use cefazolin to treat an infection, should one occur. Skin tests for penicillin are getting easier to have done these days. The benefits of using cefazolin if an infection occurs are worth the extra work of performing this skin test.

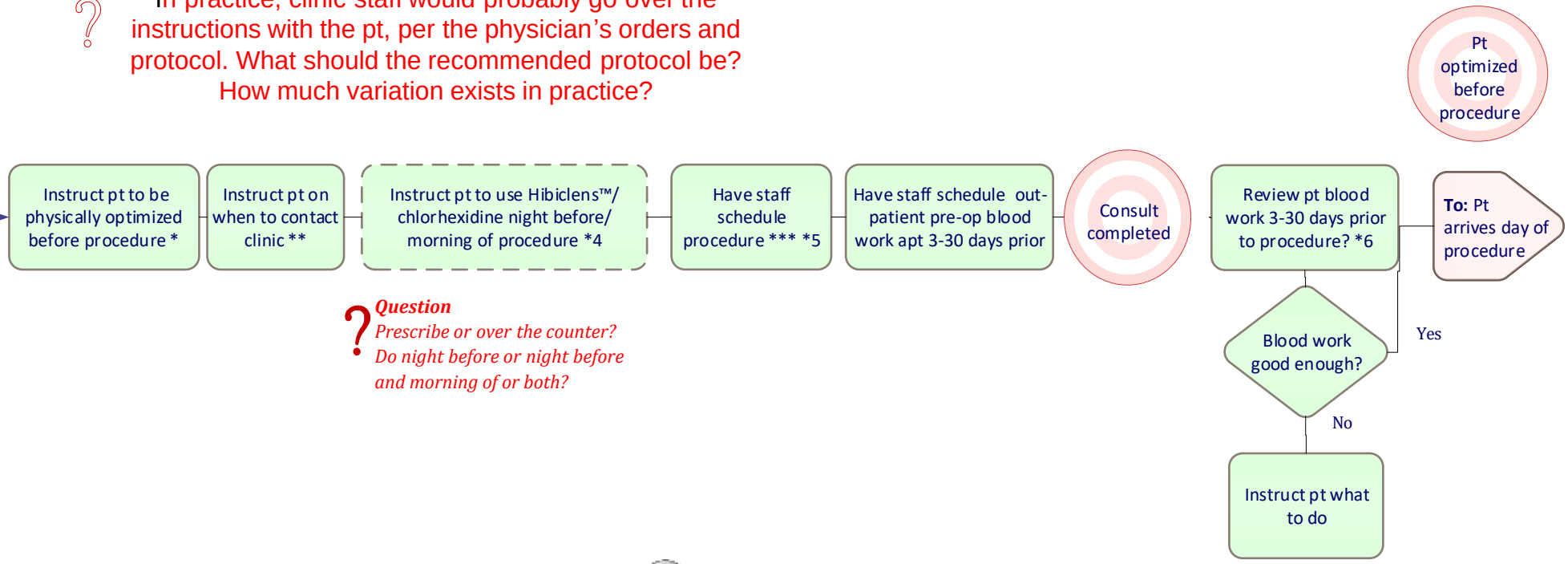
Currently most EPs do not perform skin tests to confirm or deny a pt's stated penicillin allergy. The Infectious Disease expert strongly suggested this be reconsidered and performed routinely.

*10 *** Heparin bridging increases risk of hematoma.
Anticoagulant options:
-Hold anticoagulants preoperatively 24-48 hours
- Bridge anticoagulants
- 2 of 4 experts do not stop coumadin

*11 The PADIT Late Breaking Clinical Trial at HRS 2018 demonstrated that high intensity antibiotics offer no improvement when compared with one dose of preoperative antibiotics with regard to infection risk.

Electrophysiologist

In practice, clinic staff would probably go over the instructions with the pt, per the physician's orders and protocol. What should the recommended protocol be? How much variation exists in practice?



Question
Prescribe or over the counter? Do night before or night before and morning of or both?

Time
**** Can be several weeks (~4-10) between first office visit & device placement (for out-patients)*

QUESTIONS: *See Below

Notes, etc.

* - If diabetic, control blood sugar
- Are there other things to do to get them physically optimized?
- What medications do they take the morning of the procedure?
- If on dialysis, do they have dialysis the day before the procedure?
-

**Pt instructed to notify clinic if: any illness, fever, diarrhea, rash, viral illness, worsening heart failure, hospitalization

*4 Write a prescription for this topical antibiotic? If a pt can't afford it, give it to them?

*5 Elective procedure so scheduling is more variable (similar to consult visit scheduling)

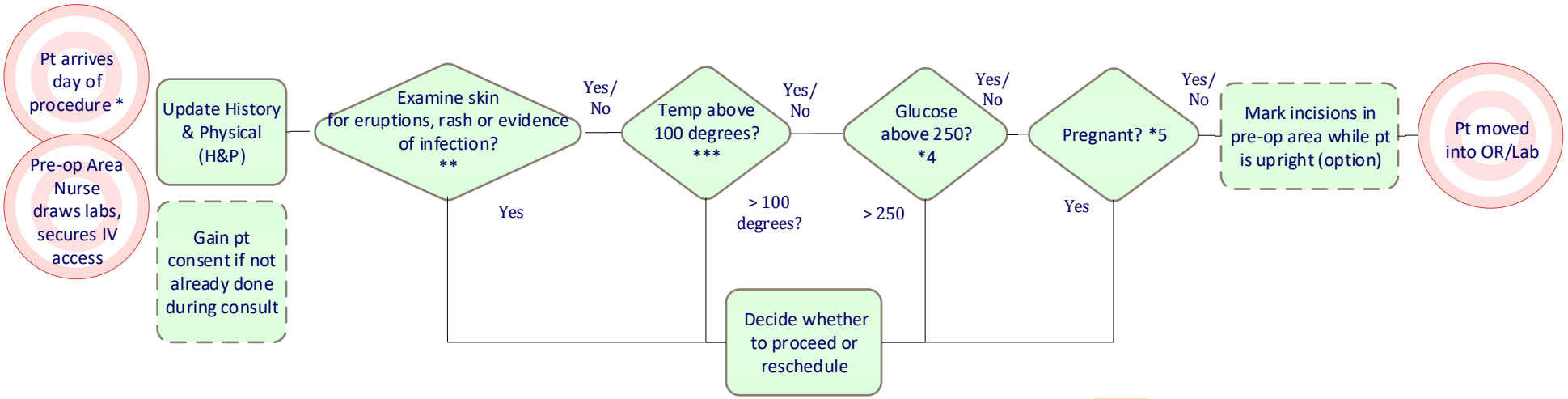
*6 Be concerned if WBC > 10k. Elevated white blood count is the most pertinent indicator to look out for when considering infection prevention. It is important to identify the cause and observe if fever or cough develops.

Procedure 1. Preparing patient in holding area

Electrophysiologist

NOTE

** The S-ICD procedure is well documented. We did not replicate that workflow necessarily. Our focus was to note points in the procedure where additional focus can be taken to prevent infections.*



*4 "If a pt's blood sugar is above 250, I do not perform the procedure."

*5 "We check pregnancy test even if pt states she is not pregnant."

Notes, etc.

* Pre-op Area Nurse secures IV access and draws labs. Repeat blood work should consist of CBC, INR, chemistry panel, urine pregnancy test (optional) & blood glucose.

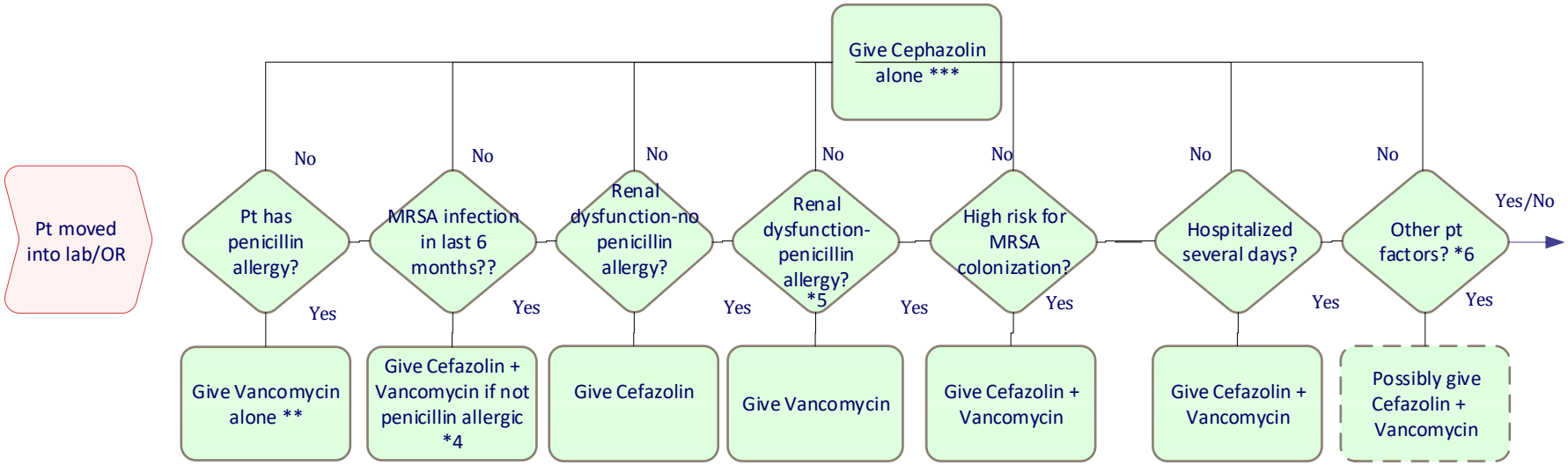
** Nurse does hair removal with electric clipper (no shaving). Skin abrasions must be avoided during shaving.
- Check for Rash

*** 3 of 4 implanters agree 100.5 degrees constitutes a fever. 1 of 4 says 100.4 degrees.
Infectious disease expert states any temperature above 100 degrees constitutes a fever.

Procedure 2. Administering surgical site antibiotic prophylaxis * (page 1 of 2)

Electrophysiologist

Considering factors for choosing antibiotic drug(s) & dose



Idea
** Consult with an infection disease specialist to review your approach*

*** "Give Cefazolin if at all possible. You don't want to give Vancomycin alone as there are at least 2 studies demonstrating that surgical site infections due to Staph aureus methicillin-susceptible goes up if you only give vanc alone."*

**4 "Giving more than one antibiotic is logarithmically more difficult than administering one antibiotic as the surgical site prophylaxis."*
- Infectious Disease Specialist

Notes, etc.

*** Clindamycin is not as good. Plus even one dose of clindamycin predisposes a C-difficile infection.

*** Cefazolin's brand name is Ancef

Cefazolin dosing: 15 mg/kg

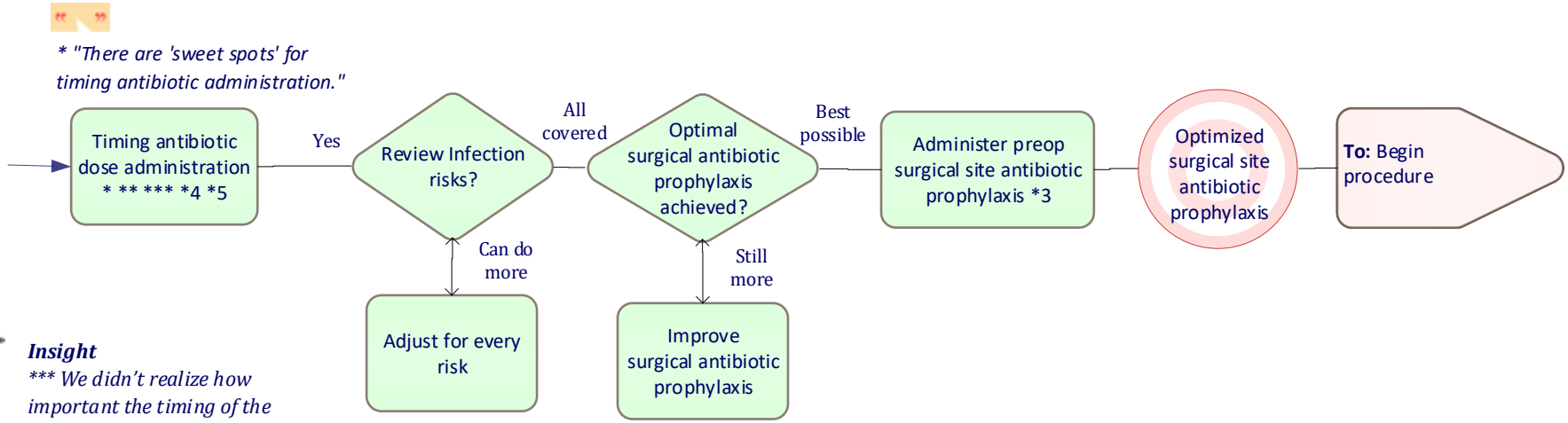
Cefazolin 2g if weight < 120kg
Cefazolin 3g if weight > 120kg
Vancomycin 15mg/kg

*5 If renal dysfunction is present, there are some concerns about worsening renal function in patients with renal disease.

*6 IV drug use, diabetes

Procedure 2. Administering surgical site antibiotic prophylaxis (page 2 of 2)

Electrophysiologist



Insight
**** We didn't realize how important the timing of the antibiotic is.*

"Redosing of antibiotic only necessary if procedure goes >4 hours"

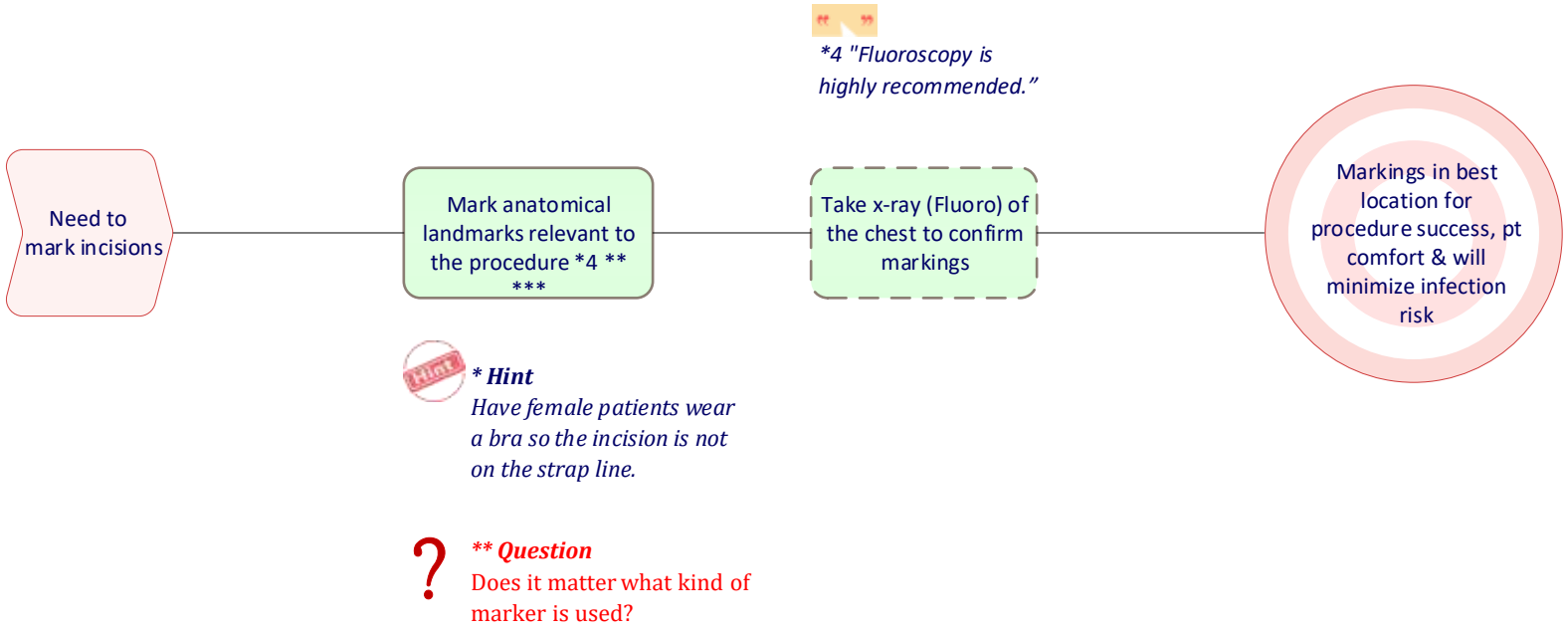
Notes, etc.

** Cefazolin should be administered 30-60 minutes prior to the procedure. Vancomycin should be administered 90-120 minutes prior to the procedure.

*3 It can be very difficult to determine the timing of the surgery. Because of this, most EPs give antibiotics in the EP lab not pre-op holding area. 3 of 4 experts administer preoperative antibiotics in the OR/lab. Antibiotic storage varies by site. If stored in OR/lab, then it is easier to administer there.
Holding room nurses rarely administer preop antibiotics, nor would they want to.
Charge Nurse organizes times for each procedure.

Procedure 3. Locating anatomical landmarks & marking incisions

Electrophysiologist



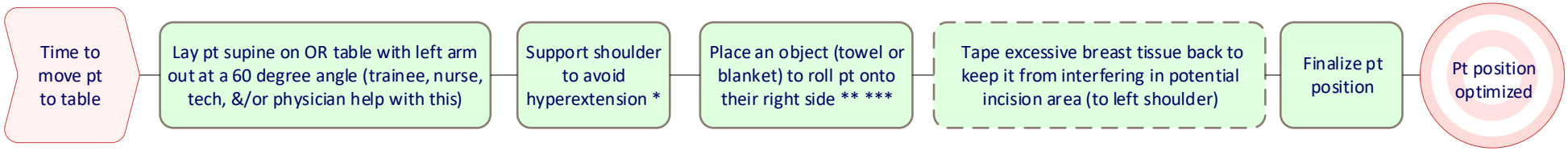
Notes, etc.

*** If not done in the pre-op area with pt standing.
- For large breasts, place incision lateral to inframammary crease. If tape is needed, exclude from sterile field.
- Obese patients pose greater risks to potentially miss anatomic landmarks.

*4 Use fluoroscopy to identify anatomic landmarks (especially important for new implanters, but not always required with experienced implanters).
- Historically, no Fluoro was used because Cameron Health was seeking approval for implants without x-ray.

Procedure 4. Positioning patient on Lab/OR table

Electrophysiologist



Question

**** Is there a contraindication to using a towel? Dr. Burke is adamant about not doing this. Why?*

Notes, etc.

* Beware shoulder hyperextension as it may lead to dislocation during DFT testing
- 2 of experts reported having had shoulder dislocations with hypextension of the shoulder

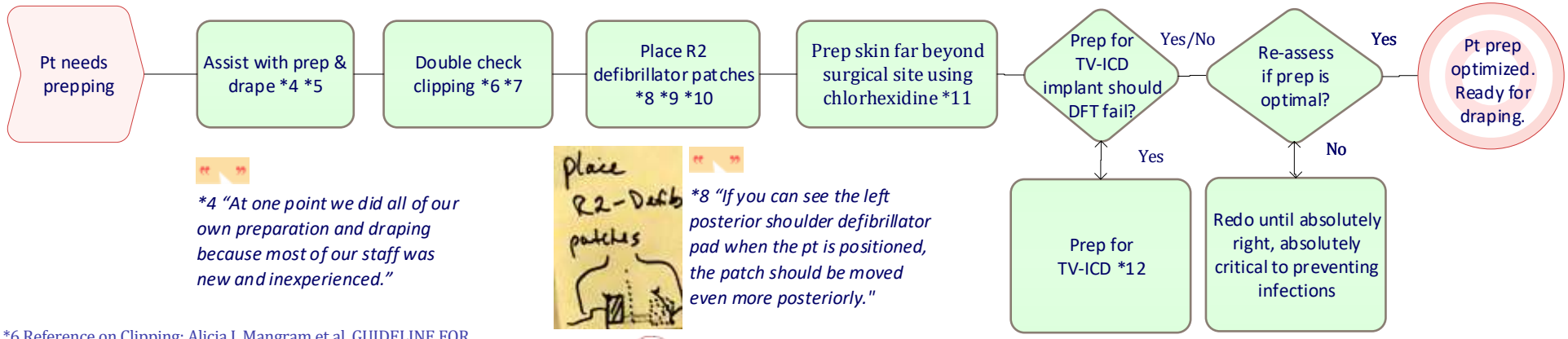
** 3 of 4 experts place an object (towel or blanket) to roll pt onto their right side
- Rotating the table might help turn pt, but using an object to roll the pt exposes more of the axilla so preparation can be extended more posteriorly

Procedure 5. Prepping patient * ** ***

Electrophysiologist

** "The same practices that go on in the surgical lab to prevent infection should also go on in the EP lab for S-ICD implants."*

*** "Excellent prep and drape is the key point in reducing the risk of infection." "Attention to detail with regard to preparation and draping is essential."*



**4 "At one point we did all of our own preparation and draping because most of our staff was new and inexperienced."*

**8 "If you can see the left posterior shoulder defibrillator pad when the pt is positioned, the patch should be moved even more posteriorly."*

**9 "I move the R2 patches to the conventional position when I DFT test." [e.g., into the sterile field, as incisions have already been closed]*

*6 Reference on Clipping; Alicia J. Mangram et al. GUIDELINE FOR PREVENTION OF SURGICAL SITE INFECTION, 1999. Hospital Infections Program National Center for Infectious Diseases Centers for Disease Control and Prevention Public Health Service US Department of Health and Human Services.

Reference *11 Rabih O. Darouiche et al. Chlorhexidine–Alcohol versus Povidone–Iodine for Surgical-Site Antisepsis. NEJM 2010; 362:18-26

OP

Idea

**** Create a poster in the Lab illustrating patch locations, landmarks and pt positioning*

Question

**6 Is tape removal of cutoff hair done by nurses? Is this consistent with best surgical practices? Is there a certain type of tape used so as not to damage the skin?*

Question

****10 Are the R2 patches really in the sterile field for TV-ICD implants or is the sterile field smaller?***

*12 Only 1 of 4 EPs mentioned this

Notes, etc.

*5 EPs are used to entering the room once nurses, fellows or trainees have done prep & drape. For S-ICD procedures, EP involvement is much more important. Some implanters oversee or assist with prep/drape especially when staff is learning the procedure

*7 Sometimes clipping needs to be redone in ER lab
- There is a higher risk of infection with a poorly shaven area
- This should be done the day of the procedure, not the day before.

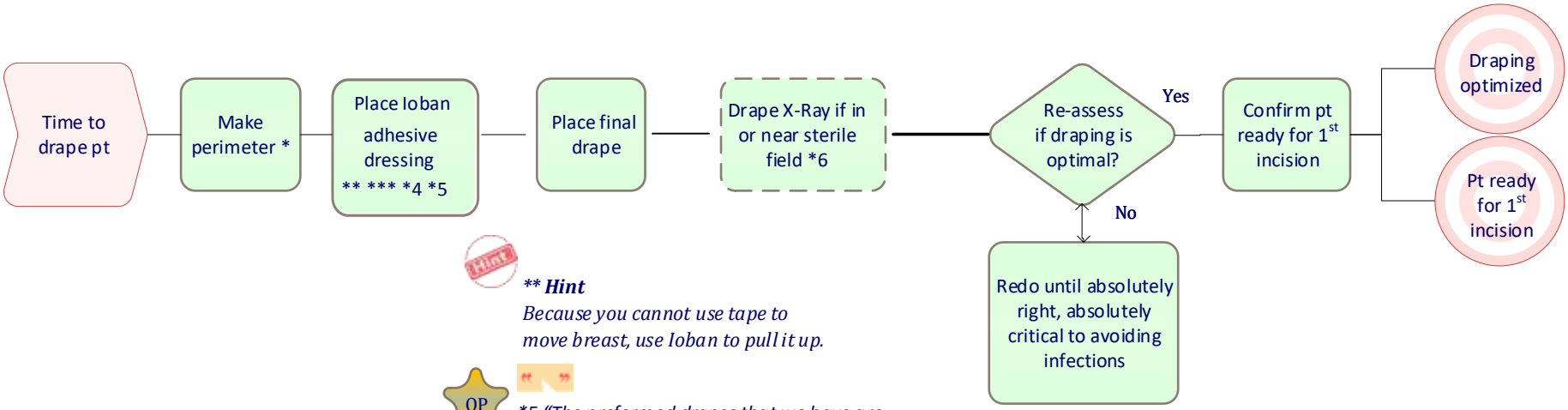
*6 See research on clipping vs shaving.
Clipping Steps:
1) Remove hair with electric clipper,
2) Use Tape removal for cut off hair,
3. Avoid breaking skin, skin abrasions, etc.

*10 R2 patches define the boundaries of the sterile field, Traditionally R2 defibrillator patches are in the sterile field, but with S-ICD they are placed in an nonconventional location. This makes some people nervous.

*11 There is data showing Chlorhexidine is better than betadine, so use chlorhexidine not betadine for pt preparation.
- The surgical field is 5x larger in an S-ICD procedure than traditional EP procedures. Surgical staff may be competent at surgical technique, but unfamiliar with the area or perimeter required for S-ICD procedures.
- The area prepped is where the drape(s) are expected to be placed.
- Typically done by nurse, tech, or fellow. In theory, it shouldn't matter who does it. The implanter needs to check that it was done right.

Procedure 6. Draping patient

Electrophysiologist



**** Hint**
Because you cannot use tape to move breast, use Ioban to pull it up.

OP

**5 "The preformed drapes that we have are not really designed for this procedure."*

Question
The hint about using Ioban to pull up breast contradicts note below saying use tape to move the breast. Please clarify??

Question
Is there any data that Ioban or products for prep & drape are better than one or other?

Question
What do you think about recent prep/drape protocol published by Dr. Amin Streamlined Surgical Draping Reduces Subcutaneous Implantable Cardioverterdefibrillator Implant Procedure Preparation Time. Journal of Innovations in CRM, 2018. 9: p. 3244-3246.

Notes, etc.

* Staff may be competent at surgical technique but not familiar with the area or perimeter required. They need to be trained.

*** S-ICDs are the only EP procedures requiring two Ioban (or one very large one). HINT: Use tape to move the breast so the Ioban pulls it up.

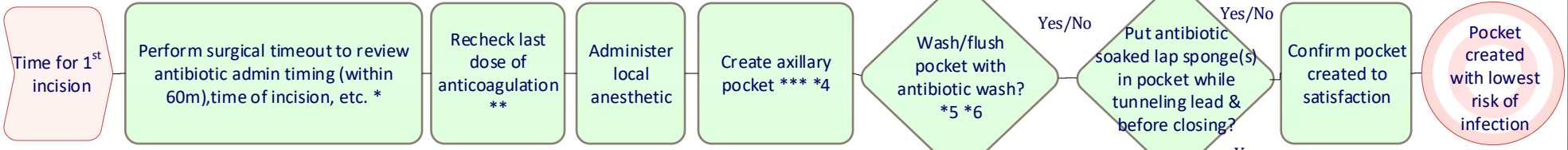
*4 May involve single piece with a large opening, or come in four separate pieces that allow more variability for different body shapes

*6 If X-ray cannot be moved, cover large Intensifier with sterile cover

Procedure 7. Creating the pocket

Electrophysiologist

Insight
We weren't aware of this time out.



***Hints**
- *Avoid tissue injury/maceration/aggressive retraction.*
- *Avoid dissecting into muscle belly of serratus anterior or latissimus dorsi due to their many small bleeders which may be hard to control.*
- *Be gentle with tissue to improve wound healing.*
- *Keep the incisions small to reduce infection risk.*
- *Avoid hematoma by taking time to achieve hemostasis.*

*4 "Plasma blade may be safe on leads but bad at coagulation."

*5 "I do the wash after I put the device in the pocket. It's a mechanical wash that requires three syringes. Sometimes I give 1 more squirt before I close."
SEE "Procedure 10: Prepping the pocket for closure"

Notes, etc.

* Nurse documents in pt chart

** SEE "Consult 6. Optimizing patient pre-operatively" page for more discussion on anticoagulation

*6 There is no data to support the use of an antimicrobial wash.
- 3 of 4 experts use a lap sponge to soak antibiotics up and wash the pocket.

Question Do you use the lap sponge to soak up the antibiotics or do you soak the lab sponges in an antibiotic solution and put in the pocket while tunneling??

Procedure 8. Making incisions & tunneling *

Electrophysiologist

NOTE: We did not go through all these steps.

QUESTION: How many are doing 2 vs. 3 incision technique? Do they believe that this reduces infection rate?

Pocket created, need to create incisions and tunnel lead

Move to a 2-incision approach? ** *** *4 *5

Already do procedure with 2-incisions

Still using 3-incisions

Create plan to become proficient with 2-incision method

*** "I would not move to a 2-incision technique until it is clear that it can be done well."*

**** "2-incision procedures reduce time, which allows, in theory, less risk of infection."*

*****4 "One of my infections was due to poor wound healing at the third superior incision."*

Notes, etc.

* There is a lot of tension on the sternal & xiphoid incisions, which is relevant to infection risk.

*5 A study comparing the 2 vs. 3 incision techniques is anticipated in 2019.
Also, this topic is mentioned in the Physician Skills section of this map.

EFFORTLESS Study
Erosion 1.7%
Hematoma 0.29%
Incision Infection 0.5%
System Infection 2.4%
2013 Knops Study: Heart Rhythm 2013 only 2 incisional infections & no erosions

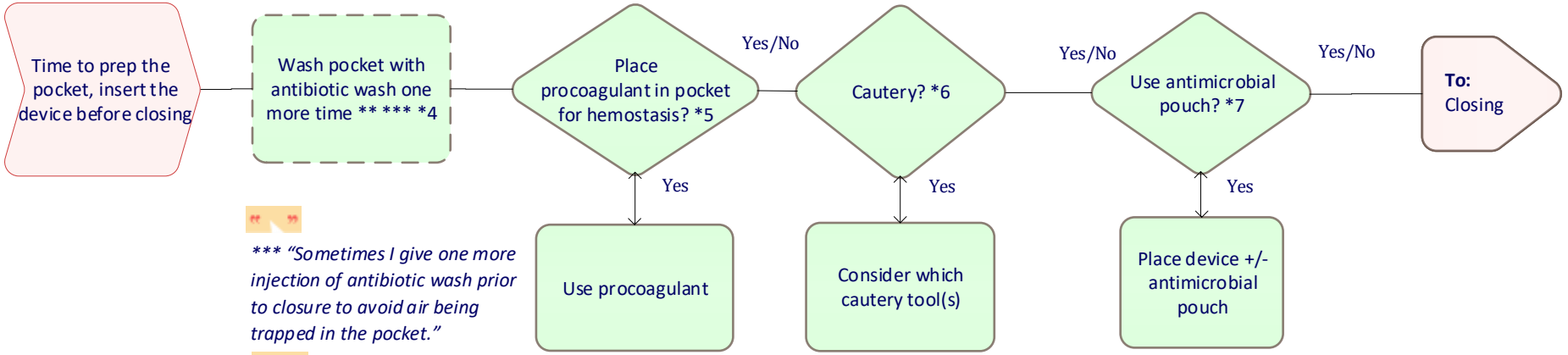
Knops, RE, Two-incision technique for implantation of the subcutaneous implantable cardioverter-defibrillator. Heart Rhythm, 2013. 10(8): p. 1240-3.

Boersma, L, BImplant and Midterm Outcomes of the Subcutaneous Implantable Cardioverter-Defibrillator Registry: The EFFORTLESS Study. J Am Coll Cardiol, 2017. 70(7): p. 830-841.

Procedure 9. Prepping the pocket for closure *

Electrophysiologist

* "The longer the pocket is open the higher the risk for infection."
"It is difficult to make small incisions when you are learning the technique."



*** "Sometimes I give one more injection of antibiotic wash prior to closure to avoid air being trapped in the pocket."

*4 "I do the wash after putting the device in the pocket and do it three times forcefully with the antibiotic solution."

Question
What is the antibiotic solution that they use and concentration?

** 4/4 EP's are doing an antibiotic wash. They recommended flushing before and after you put the device in-- even though there is no data to support this.
3 of 4 put a lap sponge in the pocket while they are tunneling.

*5 Consider for hemostasis placing a procoagulant in pocket; e.g., Surgicel (absorbable hemostat) or Arista (Bard)

Hemostatic agents may be helpful in S-ICD pocket, especially if there is a lot of bleeding.

*6 Consider tools for extensive cautery such as AQUA MANTIS, Medtronic. 1 expert uses Photon Blade for cautery. It goes deeper and also more gentle on the lead. Plus it has light unlike the Plasma Blade.
"For cautery we use photon blades that go deeper and are more gentle on the lead."

QUESTION Back when talking about creating the pocket they said Plasma blade was good for dissecting leads, but bad for cautery. This seems like a controversial area.

*7 There is no data to support use of an antimicrobial pouch. All new antimicrobial pouches require more vetting.
- Placement of an antibiotic envelope may prolong procedure (more time = increased infection risk).
- Antibiotic pouch options:
1) TYRX (Medtronic) pre-coated but shorter shelf life, or
2) Kangaroo (Biotronik) needs to soak in antibiotic solution, but it has a longer shelf life, bigger size
- WRAPIT Trial will provide antimicrobial pouch data in 2019 for current options.

Notes, etc.

Procedure 10. Closing the incisions (page 1 of 2)

Question
Isn't the closing done in layers and different techniques used for each layer?

Question
What order?
Same products for all incision?

Electrophysiologist

** "Closure is one of the most important steps to prevent infection."*

Time to close & dress each incision
* ** *** *4 *5

- Incision 1: Ancillary/ Pocket
- Incision 2: Xiphoid
- Incision 3: Sternal (only with 3-incision technique)

*** "These incisions are larger than typical EP procedure incisions, so take care to close properly."*

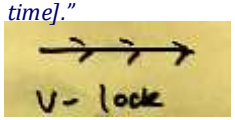
*** "It can be difficult to work in small spaces and deep pockets for novice implanters."*

**4 While some implanters will be very insistent that things be done in a certain way, the data doesn't exist to support one method is better than another"*

Closing the first two layers of pocket incision

Type of sutures for 1st two layers of pocket? *6 *7
- Yes → Use a suturing technique that minimizes infection risk
- Yes/No → Use some sort of glue to close final layer? *8 *9 *10

6 Hint
Consider using V-Loc sutures as it is a barbed suture that doesn't require knots [saves time]."



**7 "I use two layers of 2-0 to close, which is meant to be strong. Follow with one layer of 4-0 for cosmetic purposes."*

Closing the final layer of pocket incision

- Yes → Pick a glue to minimize infection risk
- Yes/No → Use sutures & steri-strips to close final layer? *11 *12 *13
- Yes → Use a suturing technique that minimizes infection risk
- Yes/No → Use Zipline to close final layer? *14
- Yes → Closed 1st incision
- **To:** Close next or next 2 incisions

**8 "I've outlawed Dermabond in our EP lab."*

**9 "I use Histoacryl vs Dermabond."*

**14 "I would like to use Zipline, but my hospital will not buy it."*

Question
What are the details for the best type of suturing technique to use?

Question
In addition to the type of suture, as well as absorbable or not, do you use continuous or interrupted suturing technique?

Question
Is there any data to show that one type of suture (absorbable or non-absorbable or closure methods (sutures, glue or zipline) is better at preventing infections or wound dehiscence?

Notes, etc.

*5
- Thorough closure reduces risk of dehiscence in case of hematoma

*10 2 of 4 experts use some sort of glue for closure other than sutures & steri-strips for the axillary incision.

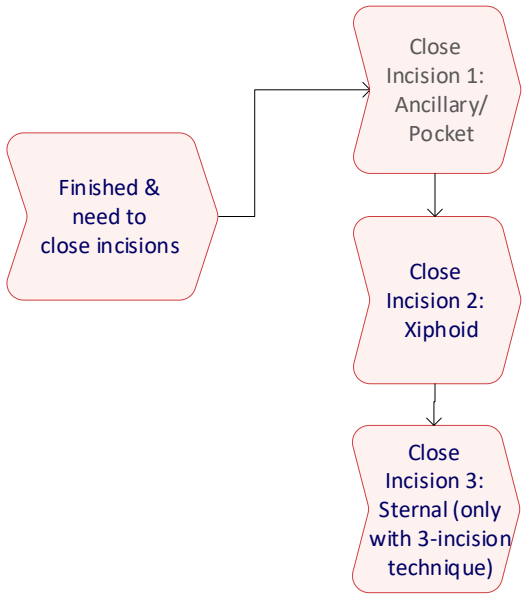
*11 it sounds like they use steri-strips only when they use sutures on the top layer and don't use steri-strips if they use glue or Zipline

*12 Superficial stitch abscess may start at suture knots.
- Consider an extra layer of interrupted sutures for the small incisions.

* 13 The reason they don't use steri-strips for the axillary incision (the pocket incision) is because this area is moist and steri-strips don't stick.
What about for the other 2 incisions?

Procedure 10. Closing the incisions (page 2 of 2)

Electrophysiologist



Closing the 1st layer of 2nd/3rd incisions

Closing the 2nd final layer of 2nd/3rd incisions

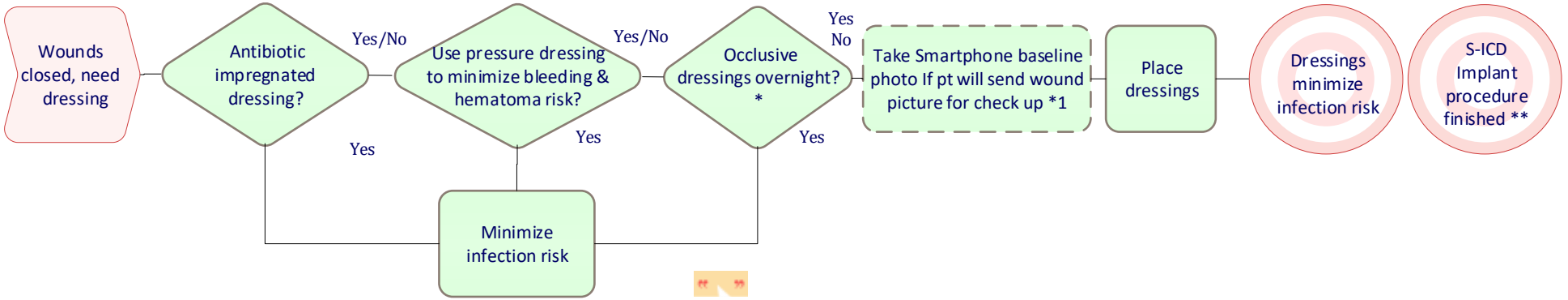
Closing minimized infection risk

Notes, etc.

? ***Question***
Our assumption is there are only 2 layers for the Xiphoid and/or Sternal incisions?

Procedure 11. Dressing the wounds

Electrophysiologist



* *"I recommend leaving dressings on for 48 hours, some recommend overnight."*

QUESTION: Is there data to support:
- one type of dressing over another,
- how long the dressings should stay on, and
- when a patient can shower?

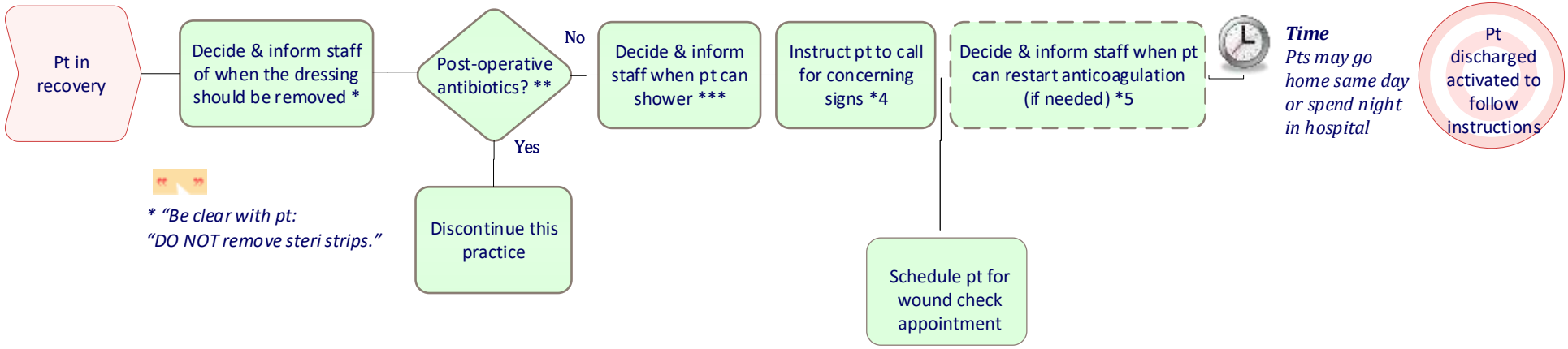
Notes, etc.

*1 *Infectious Disease specialist recommended taking photo of incisions after implant to provide a baseline photo to evaluate healing. This is done in other practices such as plastic surgery. The EP's were not comfortable doing this because of fear of wound contamination and HIPPA*

** Anesthesia creates low blood pressure. But when the procedure's done, the blood pressure rises can pop up to 150, and that can create a hematoma. While there's no data to support this belief-- the group thought it made sense.
SEE "Overall Prevention 4. Partnering with anesthesia to reduce infections" for more discussion.

Post Op Discharging patient with clear instructions for minimizing infection risk

Electrophysiologist



Notes, etc.

** Post-operative antibiotics should not be given. There is currently no data on postoperative antibiotics being helpful: in fact, they can cause harm.

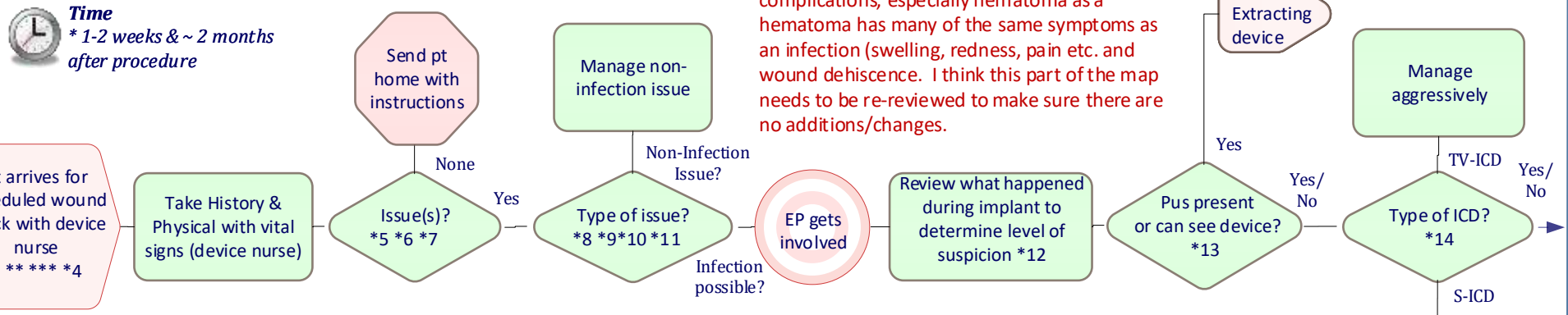
*** Time to shower postoperatively might be as soon as three days (if glue was used) or as long as seven days (if steri-strips were used).
-Also instruct the patient NOT to remove steri-strips if used.

*4
- Redness
- Swelling
- Heat or Warmth
- Fever
- Tender to Touch
- Pus
- Hematoma
- Incisions Break Down

*5 3 of 4 experts recommend waiting 48-hours before restarting anticoagulation medication. 1 of 4 experts recommended restarting anticoagulation medication after 24-hours postoperatively. Possibly up to a week if high risk.

Managing Infections 1. Conducting the patient wound check appointment

Electrophysiologist



QUESTION: We need a list of non-infectious complications, especially hematoma as a hematoma has many of the same symptoms as an infection (swelling, redness, pain etc. and wound dehiscence. I think this part of the map needs to be re-reviewed to make sure there are no additions/changes.

**** Idea***

Consider having pt send a picture of the wound instead of an office visit. If photographs are going to be used, take a baseline photo before placing the dressing at the end of procedure. Lots of discussion around this. The infectious disease specialist shared that taking pictures at baseline is routine in other practices (e.g., plastic surgery). An EP worried that bringing a camera in may increase infection risk. Another idea or perhaps compromise at a minimum was to take a picture of the wound at the 1 week wound check.

OP

***6 Hint**

Redness on S-ICD can be an infection indicator but often is not.

***7 Hint**

Never aspirate the pocket as part of an evaluation.

**** "We like the picture idea. Picture is worth a 1000 words."*

**4 "Difficult to get imaging information into EMR."*

**8"One of my infections was due to poor wound healing at the lead incision."*

**15 "There is no penalty for waiting for an infection to resolve on antibiotics with S-ICDs, unlike TV-ICDs."*

**14 "This is the beauty of the S-ICD, we almost never have a bloodstream infection."*

**16 "With the S-ICD the risk of endovascular infection is low, so we have the luxury of time to diagnose unknown infections."*

Notes, etc.

*5 Possible issues in order of likelihood:
- Erosion-extrusion of implanted electrode-pulse generator
- Hematoma
- Failure to convert spontaneous VF episode
- Inability to communicate with device
- Inappropriate shock: oversensing
- Incision / superficial infection
- Near syncope/dizziness/shortness of breath/confusion
- Pleural effusion
- Pneumothorax
- Premature battery depletion
- Shock delivered for Non VT / VF
- System infection
- Suboptimal electrode position/electrode movement
- Suboptimal pulse generator position
- Suture discomfort

*9 **Early** infection signs:
- Hot to touch,
- Tender to touch
- Swelling
- Redness
- Fever
- Hematoma

Signs of **late** infection:
- Broken down incisions
- Pocket swelling
- Unexplained fever
- Pocket pain
- Erosion

*10 It is usually the top incision when you do a 3-incision procedure that gets red/ infected.

*11 **Effortless Study:**
Erosion 1.7%
Hematoma 0.29%
Incision Infection 0.5%
System Infection 2.4%
2013 Knops Study:
Heart Rhythm 2013
only 2 incisional infections & no erosions

*12Review:
- Was there hematoma?
- A high risk of infection?
- Complicated procedure?
- Multiple DFT tests & repositioning?

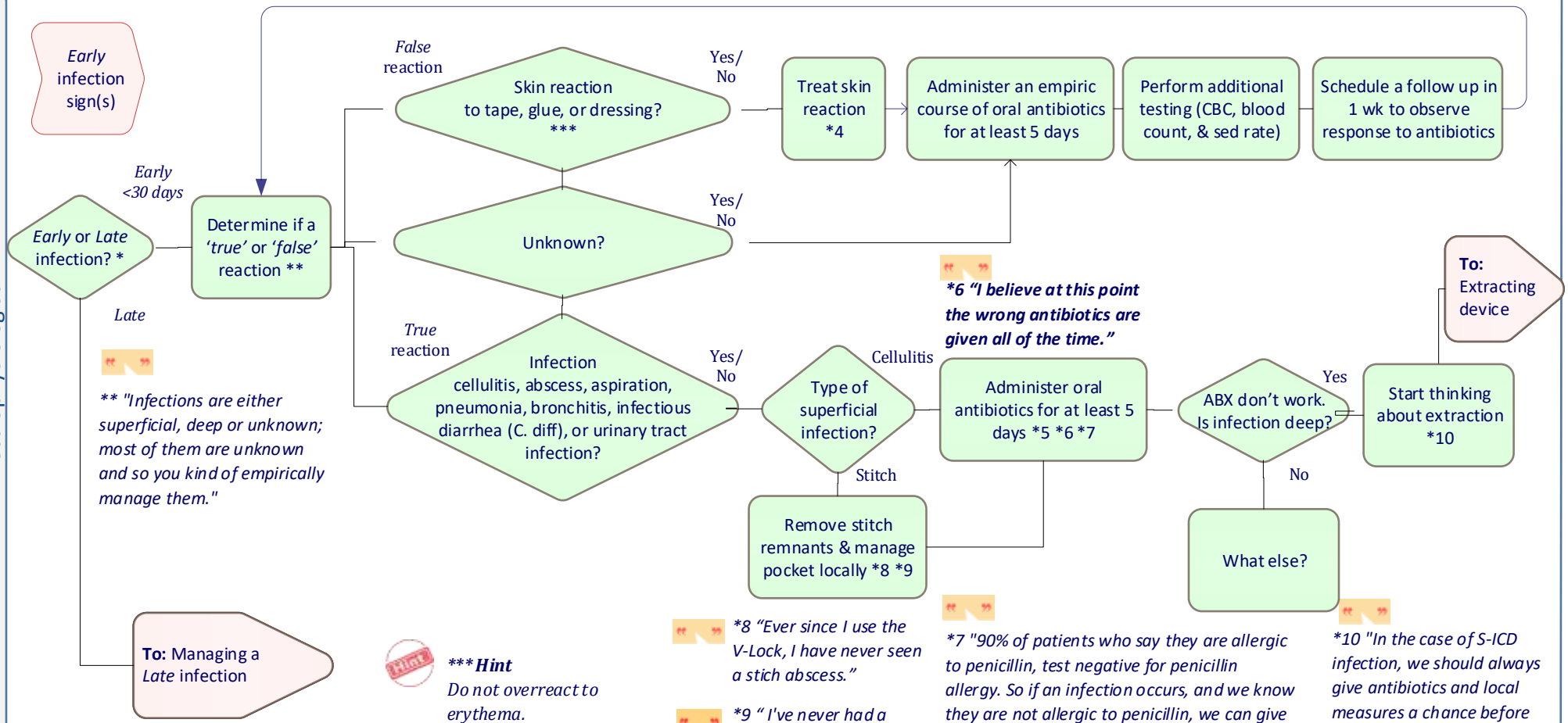
All of these may increase risk of infection now.

*13 If pus present, device has to come out.
If you can see device in any way, it has to come out.

Managing Infections 2: Diagnosing & managing an early S-ICD infection (<30 days)

QUESTION: We need to know how this diagnosing and managing an infection is the same or different for S-ICD vs TV-ICD?

Electrophysiologist



Notes, etc.

* Infections categorized as *Early* or *Late*. *Early* Infections occur between 18-48 hrs. up to 30-days postoperatively.
Effortless Study: *Early* 30-day peri-operative complication-free rate of 97% *Late* complication event rate of 6.4% (avg follow-up 558 days).

*4 Avoid corticosteroid creams to avoid accidentally masking true infections.

*5 Keflex is the antibiotic of choice for superficial infections. Other options are Cleocin or Bactrim if penicillin allergic. Keflex is the oral form of Cefazolin
Trimethoprim (TMP)/ sulfa is bactericidal. Clindamycin is bacteriostatic & may have more of a risk of C. diff.

QUESTION: Does everyone agree with 18-48 hours for early infection? Most EP's said they were thinking infections can't occur for at least 48 hours. We need to double check this or find out if there is data to support this timeframe?

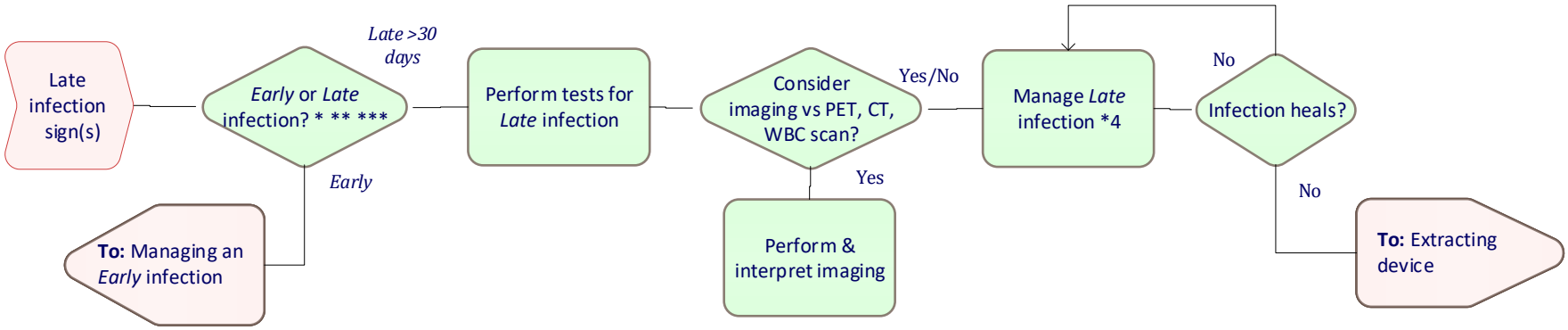
QUESTION: Panel considered late >6 wks. The study considered late >30 days.

Managing Infections 3: Diagnosing & managing a late S-ICD infection (>30 days)

Electrophysiologist

From: Managing a *Late* infection

Question: We need to know how this is the same or different for S-ICD vs TV-ICD. They only had 5 minutes to discuss this, so needs to be revisited



** " For late infections there is no yes or no, only suspicion which can be high or low."*

**4 "Sometimes on the late device infection it's not a yes or no, it's a level of suspicion. So sometimes the level of suspicion is high enough that you extract the device. Sometime it's not high enough and you choose to wait. "*

Notes, etc.

** *Late* infections are almost always device infections.
- *Late* infections can be from indolent local or "seeding" bacteria.
- Physicians may be more likely to recommend extraction as a low risk procedure with *late* infections.
- There is more uncertainty for the need to extract with late infections."

*** Signs of **late** infection:
- Broken down incisions
- Pocket swelling
- Unexplained fever *
- Pocket pain *
- Erosion *

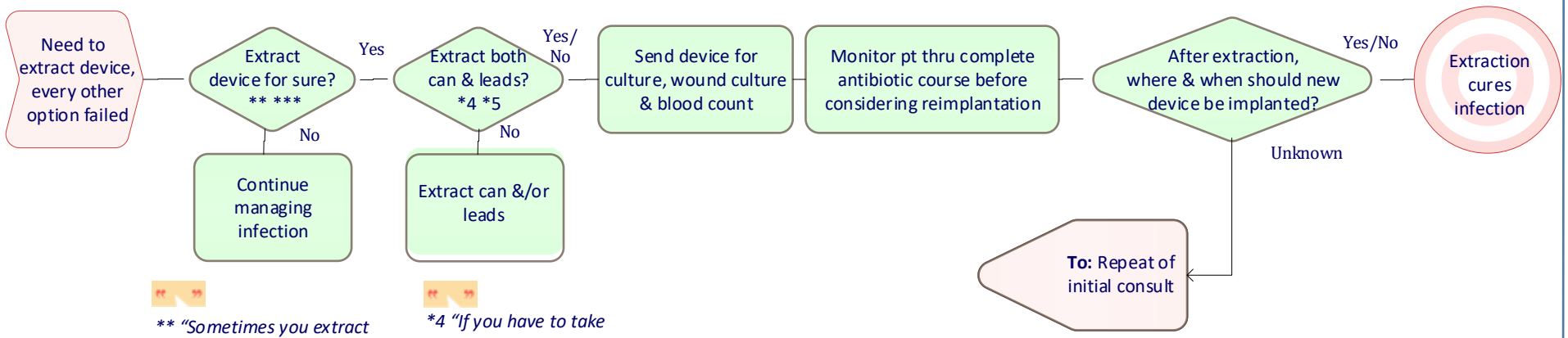
** Not on the original list*

Managing Infections 4: Extracting an S-ICD device *

Electrophysiologist

* "People are more likely to extract the S-ICD as it is easier to extract than a TV-ICD."

Client Note: We need a detailed map for every part of the device extraction for both S-ICD and TV-ICD



** "Sometimes you extract the device when you are not sure there is an infection."

*4 "If you have to take the can out, you have to take the lead out"

QUESTION: Are there any tools used for the extraction? Where is the extraction done? EP Lab? Do you put patient under GA or CS? Who does the extract? How long does it take? How long before you re-implant? Do you recommend a Zoll Life Vest? Do you implant another S-ICD or TV-ICD? Thoughts on paper from AMC? Brouwer, TF, Driessen, AHG, Olde Nordkamp, LRA, et al., Surgical Management of Implantation-Related Complications of the Subcutaneous Implantable Cardioverter-Defibrillator. JACC: Clinical Electrophysiology, 2016. 2(1): p. 89-96.

QUESTION: *** Is there a source for this data that 1 of 3 infections require extraction? Is this for TV-ICD or S-ICD

Notes, etc.

*** Infections leading to extractions are 1/3rd of all infections & a total of 2-3% of all procedures.
- Sometimes physicians are more likely to extract device as procedure is considered low risk.
- No special skill set or equipment required for extractions.
- Person who does implant likely to remove it even if they don't do TV-ICD extractions.

*5 Controversy among experts if you have manubrio-sternal incision infection, could we cut the lead and preserve the can?

Managing Infections 5: Re-implanting an S-ICD device

Electrophysiologist

Editor Note: We didn't get time to explore what happens after a device is extracted. How does this differ from TV-ICD?

- Complete antibiotic course before considering re-implant
- Determine when to re-implant
- Determine which device to re-implant
- Determine where to position/place device re-implant

Notes, etc.