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Protection against infection in epidural stimulation implantation: a program evaluation.

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Protection Against Infection in Epidural Stimulation Implantation: A Program Evaluation

by

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Dedication

I would like to dedicate this project to my late mother and father, Mr. and Mrs. Joe Ingram. They instilled in me the drive and perseverance I needed to continue this journey. I would also like to dedicate this project to my husband Charles and my three children K'daya, CJ, and Cameryn. Your patience and unconditional love were priceless during those long days of work and studying. Thank you for always motivating and cheering me on.

Abstract

Background: Spinal surgical site infection (SSI) is the third most common complication after spinal surgery. Complications of surgical site infection can increase hospital length of stay, associated health care costs, mortality, and produce unfavorable surgical outcomes (Janssen et al., 2019). The need to decrease the incidence of surgical site infections (SSIs) is a primary concern for the Kentucky Spinal Cord Injury Research Center (KSCIRC) organization. To decrease the risk of infection with epidural spinal cord implantation, a pre-operative quality improvement plan was implemented for KSCIRC to follow.

Setting: The project took place at the University of Louisville's Kentucky Spinal Cord Injury Research Center inside Frazier Rehabilitation Hospital. KSCIRC serves the spinal cord injury community by providing scientific and clinical research.

Purpose: The purpose of this project was to evaluate the efficacy of pre-operative protocol in decreasing the risk of post-surgical infection or complications of epidural implantation in spinal cord injury participants.

Procedures: KSCIRC medical core (clinical research nurses) ordered pre-surgery labs and tests as directed by the study physician. Results of tests were reviewed by the study physician and study neurosurgeon with the clinical research nurse for surgical clearance. The clinical research nurse completed the protections against infection checklist as recommended by Infection Prevention and Control Department.

Measures: Outcomes measured in this project were surgical infections, non-infectious complications, return to the operating room, and complications within 30 days of operation/hospitalization or 90 days of implantation.

Keywords: spinal cord injury, SCI (Spinal Cord Injury), infection, surgical site infection, SSI, post-operation infection, SSI prevention, neurostimulator, epidural spinal cord stimulation, epidural stimulation complications

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Protection Against Infection in Epidural Stimulation Implantation: A Program Evaluation

Background

The National Spinal Cord Injury Association states there is an average of 450,000 people living with a Spinal Cord Injury (SCI) in the United States with an estimated 17,000 spinal cord injuries occurring every year. According to the Centers for Disease Control and Prevention, the cost to treat SCI is an estimated $9.7 billion each year (Spinal Cord Injury, 2019). Acute SCI is a traumatic incident that interrupts the sending and receiving of signals from the body's systems that control sensory, motor, and autonomic functions (some of the body's internal organs) below the level of injury. There is the suggestion that the interruption of the autonomic function may cause decrease immune responses in people with spinal cord injury leading to an increased risk of infection. Due to the decreased immune responses, a state of chronic inflammation leads to an increased number of secondary health complications (Allison & Ditor, 2014). The leading cause of re-hospitalization and death in the post-acute phase after SCI is complications from an infection.

The spinal cord stimulator (SCS) is a device with electrodes implanted in the epidural space. It consists of a pulse generator connected to one or more stimulating leads. Spinal cord stimulators were first used as a treatment for pain. They are now also being used to treat failed back surgery syndrome, complex regional pain syndrome, intractable angina, peripheral vascular disease, chronic abdominal pain, cancer-related pain, etc. (Hoelzer, et al., 2017, p. 558). As part of research at the University of Louisville, epidural stimulation is being used in an attempt to recover levels of autonomic regulation of cardiovascular and respiratory function, bladder,

bowel, and sexual function as well as to control voluntary leg movement below the level of injury in spinal cord injuries.

Although the SCS has aided many in the treatment of pain and chronic illnesses and is now being used to return function in those with longstanding paralysis, many complications have been associated with its placement. Reported complications of SCS include but are not limited to lead migration, lead fracture, pulse generator site discomfort, neurologic injury, system failure, allergic reactions to components of the implant, and infection. All reported complications range from 30% to 40% (Hoelzer et al., 2017). An epidural spinal stimulation implant is surgically inserted to provide electrical stimulation of the lumbosacral part of the spinal cord to facilitate recovery of nervous system functions.

Spinal surgical site infection (SSI) is the third most common complication after spinal surgery. Complications of surgical site infection can be fixation failure, osteomyelitis, pseudoarthrosis, increased hospital length of stay, unfavorable surgical outcomes, increased health care costs, and mortality (Janssen et al., 2019). Infection rates related to spinal cord stimulator implantations range between 3% and 6%. Infections due to their placement, lead to increased direct and indirect costs, prolonged antibiotic exposure, and loss of therapy time (Hoelzer, et al., 2017, p.559). The treatment for SSI can be challenging requiring prolonged antibiotics, multiple revision surgeries, prolonged hospital stay, and in some patients, advanced soft tissue reconstructions. SSIs are defined by the Centers for Disease Control and Prevention (CDC) as an infection related to the procedure that occurs at or near the surgical incision within 30 days of the procedure or within 90 days if prosthetic material is implanted. They are categorized by the depth and tissue involved. SSIs incidences range from an estimated 160,000 to 300,000 annually in the United States. The annual cost is estimated at $3.5 to $10 billion. SSIs

increase the cost of hospitalization by more than $20,000 per admission and extends hospital stays by 9.7 days. An estimated 60% of SSIs are preventable with the use of evidence-based measures (Ban et al., 2017). Infection rates for spinal cord stimulation incisions are estimated to be 2.5-14%. Infections related to spinal cord stimulation implantation are usually more superficial and involve the skin and subcutaneous tissues around the incision site. Deep infections involving adjacent muscle and fascia are more significant as they usually include contamination of the spinal cord stimulator which may require hardware removal (Deer et al., 2017). The diagnosis and treatment of SSIs can be difficult and often require wound debridement and/or instrumentation removal (Deng et al., 2020).

Purpose

The purpose of this program evaluation project was to evaluate the efficacy of preoperative procedure changes initiated to decrease post-operative incision infections and complications. This program evaluation received de-identified data from an existing data set to determine if a more stringent perioperative process improved postoperative outcomes. This process change was based on the recommendations of a team put together by the University of Louisville Hospital (ULH) epidemiologist. The team consisted of Infection Prevention and Control and Quality Management Departments.

Due to an unacceptable number of SSIs in early study patients, a root cause analysis was performed by the interdisciplinary team. Medical records and study documents of eleven participants who had been implanted were reviewed. Of the eleven participants reviewed, two developed surgical site infections and three had wound dehiscence without developing an infection. Of the two who developed surgical site infections, one required the removal of the stimulator, the other lifelong antibiotic treatment per infectious disease recommendations. The

three participants with wound dehiscence were either taken back to the operating room for wound revision or incisional washout. At the end of the root cause analysis, the interdisciplinary team did not find a direct association for the incision complications, but it did provide pre-procedure guidance for improvement including increasing presurgical screening, cleaning of research peri- operative equipment, limiting traffic in the operating room using new sterile instruments for each stage of the implantation procedure, not applying vancomycin powder to the post-op dressing and using an antimicrobial envelope for the implantable stimulator (Arnold et al., 2019). The new process was placed in the manual of procedures for future epidural stimulator implantations at KSCIRC. The overall goal of the perioperative protocol change was to improve preoperative screening and prevent surgical site infections or complications in patients admitted to SCI research protocol who are undergoing epidural spinal stimulator implantation. The primary aim of this program evaluation is to determine if the recommended change in peri-operative management affected post-operative wound outcomes. The secondary aim is to evaluate other infections/ complications within 30 days of operation/hospitalization or 90 days of implantation according to the National Health Safety Network (NHSN).

Setting

This program evaluation project setting was the University of Louisville's KSCIRC. KSCIRC is located inside Frazier Rehab Institute and provides basic and translational research along with clinical care to patients with acute and chronic SCI. KSCIRC's research is conducted with a close association of clinical professionals in the Department of Neurological Surgery of the University of Louisville. It offers an integrated approach to spinal cord injury aiming to improve the health and motor function of the spinal cord injury community. Research activities and patient care are combined to improve patient outcomes.

Ethics

Approval for this project was received from KSCIRC's Professor and Associate Director, Dr. Susan Harkema. Human subjects were screened for medical eligibility by the study physician and neurosurgeon for the original SCS studies. Once medical eligibility was determined, the participant provided informed consent for clinical and neurophysiological assessments to determine further eligibility to participate in epidural stimulation. Additional consent was received for surgical implantation once the participant was deemed eligible to move forward in the study. All study procedures were approved by the University of Louisville IRB.

All primary data collected and analyzed is stored in the Neurorecovery Network database. The Neurorecovery Network database is managed by the University of Louisville's KSCIRC department. Permission to complete this program evaluation using de-identified data was requested and approved through the University of Louisville's IRB. Following IRB approval, data was requested from the Neurorecovery Network database by completing a Clinical Data Dissemination Request Form.

Funding

There was not a budget for this program evaluation project. Initial clinical studies were funded by the National Institute of Health, Craig H. Nelson Foundation, and Christopher and Dana Reeves Foundation. No additional funding or grants were received. The graduate student investigator reviewed and analyzed data sets already collected by KSCIRC and stored in the NRN Database. Existing resources and employee roles were used as approved by the PI (Principal Investigator) of the original studies.

Sample

The sample consisted of two cohorts. The two cohorts underwent epidural spinal cord stimulator implantation from December 2009 to December 30, 2020. Cohort A data is from December 2009 to August 2017 before the implementation of the peri-operative care bundle and Cohort B data is from September 2017 to December 2020.

Following the University of Louisville's Institutional Review Board (IRB) approval, the sample for this project was limited to spinal cord injury participants who met medical inclusion before implantation. Each participant was at least 18 years of age and in stable medical condition. The spinal cord injury was non-progressive with a neurological injury level between C1 and L6. Each participant had a neurological level of A, B, or C according to the American Spinal Cord Injury Association Impairment Scale (ASIA). The ASIA is a standardized neurological examination used to assess the sensory and motor levels affected by the spinal cord injury and to describe the severity of the injury. Each participant was enrolled in one of the following spinal stimulator studies according to their scientific inclusion: "Recovery of Cardiovascular function with Epidural Stimulation after human Spinal Cord Injury" (CVEpi), "Spinal Epidural Electrode Array to Facilitate Standing and Stepping after Spinal Cord Injury" (Original Epi), and/or "Task and Physiological specific stimulation for recovery of autonomic function, voluntary movement and standing using epidural stimulation and training after severe spinal cord injury" (TSEpi) studies.

Implementation

Project Design

This program evaluation was a secondary, retrospective review of data retrieved from the Neurorecovery Network (NRN) database. Data were collected on all participants that had epidural stimulation implantation. There were two cohorts of epidural stimulation patients

reviewed from December 2009 to December 2020. The standard preoperative laboratory panel included complete blood count, comprehensive metabolic profile, albumin, transthyretin, vitamin D, and urinalysis and urine culture were used for Cohort A (December 2009 – August 2017). For Cohort B (September 2017 – December 2020), the Department of Infection Prevention and Control added inflammatory markers such as C-reactive protein, procalcitonin, and erythrocyte sedimentation rate to the screening labs listed above. Methicillin-Resistant Staphylococcus aureus (MRSA) nasal swab, as well as multidrug-resistant Gram-negative bacteria MDRO (Multi-Drug Resistant Organism) peri-rectal swab. (Table 1). Urine samples collected were tested for creatinine, blood, bilirubin, glucose, ketones, protein, nitrates, leukocytes, pH, and specific gravity. A urine culture was performed if bacteria were present in the urinalysis. For those participants positive for urinary tract infection (UTI) or asymptomatic bacteriuria (ASB), treatment was devised according to antibiotic susceptibilities. After treatment, the participant was retested. The goal was to have the participant's urinalysis negative of bacteria before implantation. Following SCS implantation, all participants' surgical sites were evaluated and monitored according to the NHSN surveillance definition (see Appendix A for criteria).

Table 1.

Pre-operative testing to prevent surgical site infections

Test	Purpose
Nasal swab for MRSA	To determine if colonized or decolonized and identify the need for vancomycin as a preoperative antibiotic
Peri-rectal swab for MDRO; Gram-negative	To determine if colonized and based on organism consider decolonization and adjustment of preoperative antibiotic
Urinalysis Urine culture	To identify infection/ colonization for clearance before the procedure
C-reactive protein Erythrocyte sedimentation rate	Identify baseline inflammatory measures

Procalcitonin	
Prealbumin Albumin Transthyretin Vitamin D	To verify appropriate preoperative nutritional status to facilitate wound healing

Theoretical Framework

This program evaluation project combined research activities (translational research) and patient care to improve patient outcomes across the spectrum of care. A combination of two change theories, Lewin's Three-step Model for change and Lippitt, Watson, and Westley's Seven-step Theory will be used to help guide this program evaluation. Kurt Lewin's Three-Step Model for change was introduced in 1951. It is a framework highlighted in nursing literature known to aid healthcare providers in implementing evidence-based practices of care. Three concepts of the Change theory include driving forces, restraining forces, and equilibrium. Driving forces facilitate change by forcing a shift in equilibrium towards change. Restraining forces counter-driving forces causing a shift in equilibrium opposing change. Equilibrium is the stability between driving forces and restraining forces. Lewin's Theory consists of three steps (Mitchell, 2013):

- Unfreezing- educating (showing data), communicating, demonstrating issues
- Changing/movement- brainstorming, presenting ideas, training, implementation
- Refreezing- communicate, re-train, evaluate, monitor

A traditional clinical path or approach is altered (unfreezing), providers' behaviors are refined (movement) and changes in the behaviors are reinforced (refrozen). This process helps to understand how health professions' behavior is accepted and supported. Lippitt's Theory, introduced in 1958, extended Lewin's three-step theory by creating a seven-step theory that focuses on the role and responsibility of the change agent and not so much on the change. It uses

language like the nursing process and is made up of four elements: assessment, planning, implementation, and evaluation (Mitchell, 2013):

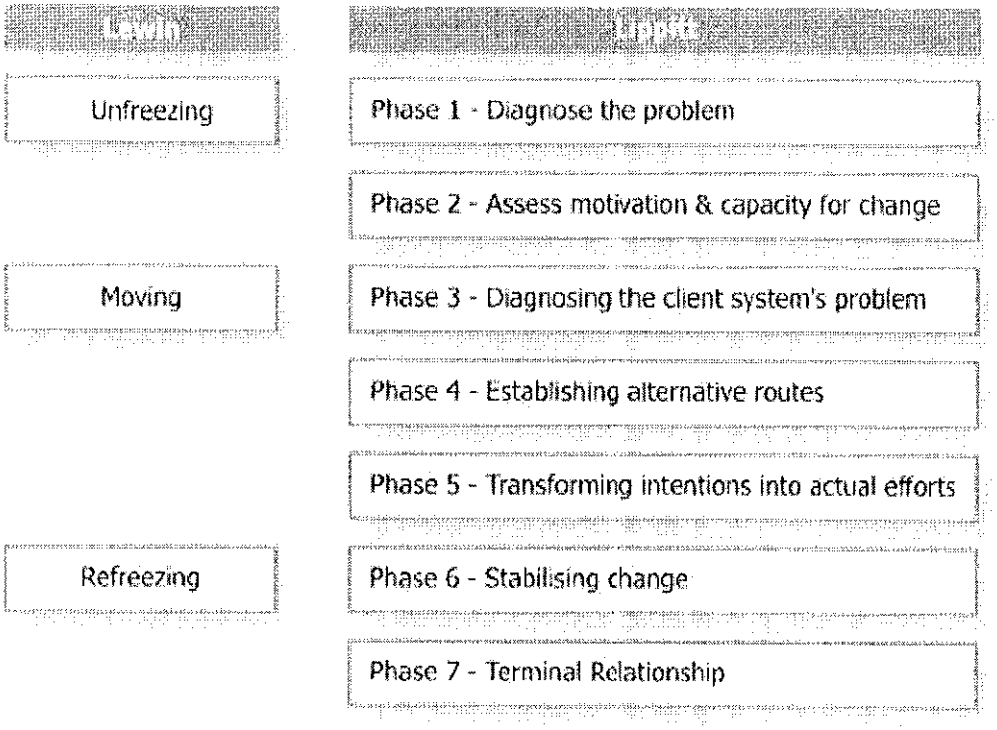
Table 2.

Lippitt's Theory

Nursing Process Elements	Lippitt's Theory
Assessment	**Phase 1.** Diagnose the problem (develop the need for change) **Phase 2.** Assess motivation/ capacity for change (establishment of a changing relationship) **Phase 3.** Assess change agent's motivation and resources (working toward change)
Planning	**Phase 4.** Select progressive change objective (the clarification or diagnosis of client systems problem) **Phase 5.** Choose the appropriate role of the change agent (the examination)
Implementation	**Phase 6.** Maintain change
Evaluation	**Phase 7.** Terminate the helping relationship

Figure 1

7 Stage Model of Change



Measurement

Analysis

The primary outcome measure was postoperative SSIs. Secondary outcomes were other infections or complications within 30 days of surgery and/or hospitalization or 90 days after implantation. Surgical site infection outcomes were evaluated using the NHSN Surgical Site Infection Checklist for superficial and deep incisional infection (Appendix A). The clinical diagnosis of infection was based on a record review of provider assessments.

Age at injury, time since injury to surgery, and surgery age were summarized using descriptive statistics with mean and standard deviation, median with 1st and 3rd quartiles were

compared across surgery protocol using the Wilcoxon Rank Sum test. Sex, injury level, AISA level, stimulation location, and presence of infection post-injury were summarized using frequency count and associated percentage. They were compared between the two cohorts using Fisher's exact test. All tests were 2-sided, and the significance level was set to 0.05. Analyses were calculated using SAS (Statistical Analysis Software) 9.4 (SAS Institute Inc, Cary, NC).

Results

Interpretation

Data retrieved from the NRN database was collected and analyzed on a total of thirty epidural stimulator implantations that occurred from December 2009 until December 2020. Thirteen stimulators were placed before the additional infection control testing was initiated and seventeen following the procedural change. The cohorts consisted of participants with the mean age at the time of surgery of 28 (Cohort A) and 35 (Cohort B). Males represented 77% and 76% respectfully of the total surgery occurrences (Table 4). Two participants (15%) were identified with infection and two others (15%) had dehiscence of their incision without becoming infected in Cohort A. Of those two with infections, one each was male and female. As part of treatment, the first participant would continue antibiotics as long as the stimulator remained in place. The second participant's stimulator was removed due to the infection contaminating the stimulator and wires. Cohort B had one participant (6%) develop an infection with three (18%) develop other complications from surgery (Table 3).

SSI incidence demonstrated no statistically significant difference between the two cohorts. There was a decrease in infection rates from 15% pre-implementation to 6% post-implementation ($p=0.56$). Years since injury to implantation showed a significant difference. Those who were implanted after the protocol had been injured longer with mean years since

injury to surgery date being 5 years for Cohort A and 9 years for Cohort B ($p = 0.0424$). The change in the placement of the stimulator from the abdomen to the mid or lower back did show significance ($p = <0.0001$). Although both the years since injury and implantation site were statistically significant, neither should have affected the outcomes.

Table 3.
Infection rates

	Cohort A	Cohort B	
	Pre (n=13)	Post (n=17)	p-value
Infection, n (%)	2 (15%)	1 (6%)	0.56
Other Infection/Complication, n (%)	2 (15%)	3 (18%)	1

Table 4.
Demographics

		Cohort		
		A (n=13)	B n=17)	p-value
Injury Age	Mean (SD)	23 (4)	27 (10)	0.7856
	Median	24 [20 - 26]	24 [19 - 29]	
	Range, min to max	17 to 31	16 to 53	
Surgery Age	Mean (SD)	28 (4)	35 (13)	0.1488
	Median	28 [24 - 32]	31 [27 - 43]	
	Range, min to max	23 to 35	20 to 61	
Years injury to Surgery	Mean (SD)	5 (3)	9 (8)	0.0424
	Median	3 [3 - 7]	7 [4 - 9]	
	Range, min to max	2 to 10	2 to 39	
Sex	Female, n (%)	3 (23%)	4 (24%)	1
	Male, n (%)	10 (77%)	13 (76%)	
Injury Level	Cervical, n (%)	7 (54%)	17 (100%)	0.0029
	Thoracic, n (%)	6 (46%)	0 (0%)	

AISA level	A, n (%)	8 (62%)	8 (47%)	0.2278
	B, n (%)	5 (38%)	5 (29%)	
	C, n (%)	0 (0%)	4 (24%)	
Stimulation Location	Abdomen, n (%)	12 (92%)	0 (0%)	<.0001
	Lower back, n (%)	1 (8%)	5 (29%)	
	mid back, n (%)	0 (0%)	12 (71%)	

Limitations

One of the main limitations to this project evaluation is that it was a retrospective analysis. It was expected that documentation of infection protocol was adhered to and complete. There was no direct monitoring of documentation. The data was also limited by the sample size. Since December 2009, there have been only 30 participants implanted in the epidural studies. The sample size in each cohort was different. There may be other risk factors unidentified that may affect the risk of infection in this patient population. Further evaluation into specific pre-operative labs such as CRP, ESR, and/or urinalysis with microscopic analysis may provide better predictive information than the overall preoperative order set. Also, other factors could affect surgical site healing such as poor nutrition (inadequate protein intake) and additional health conditions.

Summary

Due to immunologic and metabolic abnormalities, chronic spinal cord injury patients are at higher risk for surgery complications. Surgical site infections are unintentional and most often preventable outcomes of surgery. Treatment for SSIs is usually straightforward but may lead to significant morbidity, mortality, and/ or increased health care costs. Standardizing a screening protocol can assist in significantly decreasing SSI occurrence and is of importance for all stakeholders.

The primary aim of this program evaluation project was to evaluate the efficacy of preoperative procedure changes initiated to decrease post-operative incision infections and complications. It was hypothesized that the implementation of perioperative medical clearance protocol decreases complications in an SCI sample undergoing epidural stimulation placement. The results from this retrospective analysis were an early analysis to see if the protocol is working. It demonstrated no significant difference between the two cohorts but the decrease in infection rate is still important. The decrease of infections is significant to research because SSIs can temporarily or permanently lead to the removal of the device, which causes delay or cessation of stimulation halting the research. The decrease in SSIs is significant clinically because it may help in the decrease of hospital costs, length of stay, and decrease morbidity and mortality. Monitoring should continue to determine exactly how the infectious control protocol affects infection rates in the remaining participants in the epidural stimulation study and the spinal cord injury community.

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Appendix A

Surgical Site Infection Criteria	**Superficial incisional SSI** Must meet the following criteria: Date of event occurs within 30 days after any NHSN operative procedure (where day 1 = the procedure date) **AND** Involves only skin and subcutaneous tissue of the incision **AND** Patient has at least ***one*** of the following: a. Purulent drainage from the superficial incision b. Organism(s) identified from an aseptically- obtained specimen from the superficial incision or subcutaneous tissue by culture or non-culture-based microbiologic testing method which is performed for purposes of clinical diagnosis or treatment (for example, not Active Surveillance Culture/Testing (ASC/AST)). c. Superficial incision that is deliberately opened by a surgeon, attending physician* or designee and culture or non-culture-based testing of the superficial incision or subcutaneous tissue is not performed **AND** Patient has at least one of the following signs or symptoms: localized pain or tenderness; localized swelling; erythema; or heat. d. Diagnosis of a superficial incisional SSI by the surgeon, attending physician* or another designee

	There are two specific types of superficial incisional SSIs: 1. Superficial Incisional Primary (SIP)- a superficial incisional SSI that is identified in the primary incision in a patient that has had an operation with one or more incisions (for example, C- section incision or chest incision for CBGB) 2. Superficial Incisional Secondary (SIS)- a superficial incisional SSI that is identified in the secondary incision in a patient that has had an operation with more than one incision (for example, donor site incision for CBGB)
	Reporting Instruction for Superficial SSI: • Diagnosis/treatment of cellulitis (redness/warmth/swelling), by itself, does not meet criterion "d" for superficial incisional SSI. Conversely, an incision that is draining or that has organisms identified by culture or non-culture-based testing is not considered cellulitis. • A stitch abscess alone (minimal inflammation and discharge confined to the points of suture penetration). • For an NHSN operative procedure, a laparoscopic trocar site is considered a surgical incision and not a stab wound. • A localized stab wound or pin site infection is not considered an SSI; depending on the depth, the infection might be considered either a skin (SKIN or soft tissue (ST) infection.
Surgical Site Infection Criteria	**Deep incisional SSI** Must meet the following criteria: Infection occurs within 30 or 90 days after the NHSN operative procedure (where day 1 = the procedure date) **AND** Involves deep soft tissues of the incision (e.g., fascial and muscle layers) **AND** Patient has at least ***one*** of the following:

	a. Purulent drainage from the deep incision. b. A deep incision that spontaneously dehisces, or is deliberately opened or aspirated by a surgeon, attending physician * or other designee and organism is identified by culture or non-culture based microbiologic testing method which is performed for purposes of clinical diagnosis or treatment (e.g., not Active Surveillance Culture/ Testing (ASC/AST) or culture-based microbiologic testing method is not performed **AND** Patient has at least one of the following signs or symptoms: fever (>38C); localized pain or tenderness. A culture or non-culture-based test that has negative findings does not meet this criterion, c. An abscess or other evidence of infection involving the deep incision that is detected on gross anatomical or histopathologic exam, or imaging test Two types of Deep Incisional SSIs: 1. Deep incisional primary (DIP)- deep incisional SSI that is identified in a primary incision in a patient that has had an operation with one or more incisions (for example CBGB) 2. Deep incisional secondary (DIS)- a deep incisional SSI that is identified in the secondary incision in a patient that has had an operation with more than one incision (for example, donor site for CBGB)
Surgical Site Infection Criteria	**Organ/Space SSI** Must meet the following criteria: Date of event occurs within 30 or 90 days after the NHSN operative procedure (where day 1 = the procedure date) **AND**

	Involves any part of the body deeper than the fascial/muscle layers that are opened or manipulated during the operative procedure **AND** Patient has at least one of the following: a. Purulent drainage from a drain that is placed into the organ/space (for example, closed suction drainage system, open drain, T-tube drain, C-guided drainage). b. Organism(s) identified from fluid or tissue in the organ/space by culture or non-culture-based microbiologic testing method which is performed for purposes of clinical diagnosis or treatment (for example, not Active Surveillance Culture/Testing (ASC/AST)). c. An abscess or other evidence of infection involving the organ/space that is detected on gross anatomical or histopathologic exam or imaging test evidence suggestive of infection. **AND** Meets at least ***one*** criterion for a specific organ/space infection site

*The term attending physician for application of the NHSN SSI criteria may be interpreted to mean the surgeon(s), infectious disease, other physicians on the case, emergency physician, or physician's designee (nurse practitioner or physician's assistant)

**Because the epidural stimulator is being used as part of a research study, the surgery is not reportable to NHSN