

**Figure 2. Management and outcomes of superficial device infections (n=15)**

	Device retention	Complete device extraction
Infection onset	14	1
3 months		
Cure	9	1
Failure	4 <sup>A</sup>	0
Lost to follow up	1	0
3-12 months		
Device removal	4	0
Re-implantation	2	1
13 months		
Cure	13	1
Failure	0	0
Re-implantation	0	0

**Figure 2.** Outlines the management and outcomes of 15 patients considered to have superficial skin and soft tissue infection associated with DBS device. Patients without device exposure or clinical evidence for deep infection as determined by physical exam, and radiography when available, were considered to have superficial infection. Outcomes definitions are outlined in figure 1.

<sup>A</sup> Subsequently underwent complete device removal

**Conclusion.** All patients who had complete extraction achieved clinical cure at 3-months follow-up, while high failure rates occurred in those with device retention. Most infections were polymicrobial and predominantly caused by gram-positive pathogens. Thirty percent of patients with re-implantation after complete device extraction developed re-infection within 1 year.

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**93. Early Recognition and Response to Increases in Surgical Site Infections (SSI) using Optimized Statistical Process Control (SPC) Charts – the Early 2RIS Trial: A Multicenter Stepped Wedge Cluster Randomized Controlled Trial (RCT)**

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**Session:** O-20. Infection Risks from Invasive Procedures

**Background.** Traditional approaches for SSI surveillance have deficiencies that can delay detection of SSI outbreaks and other clinically important increases in SSI rates. Optimized SPC methods for SSI surveillance have not been prospectively evaluated.

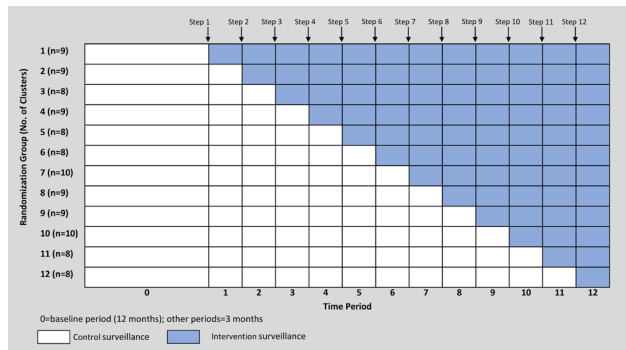
**Methods.** We conducted a prospective multicenter stepped wedge cluster RCT to evaluate the performance of SSI surveillance and feedback performed with optimized SPC plus traditional surveillance methods compared to traditional surveillance alone. We divided 13 common surgical procedures into 6 clusters (Table 1). A cluster of procedures at a single hospital was the unit of randomization and analysis, and 105 total clusters across 29 community hospitals were randomized to 12 groups of 8-10 clusters (Figure 1). After a 12-month baseline observation period (3/2016-2/2017), the SPC surveillance intervention was serially implemented according to stepped wedge assignment over a 36-month intervention period (3/2017-2/2020) until all 12 groups of clusters had received the intervention. The primary outcome was the overall SSI prevalence rate (PR=SSIs/100 procedures), evaluated with a GEE model with Poisson distribution.

Table 1

Cluster	Procedures
Cardiac	Coronary artery bypass graft Cardiac valve replacement
Gastrointestinal	Colon Herniorrhaphy
Joint	Knee arthroplasty Hip arthroplasty
Obstetrics and gynecology	Cesarean section Hysterectomy Vaginal hysterectomy
Spine	Spinal fusion Laminectomy
Vascular	Carotid endarterectomy Peripheral venous bypass

Surgical procedures included in each cluster.

Figure 1



Schematic for stepped wedge design. The 12-month baseline observation period was followed by the 36-month intervention period, comprised of 12 3-month steps.

**Results.** Our trial involved prospective surveillance of 237,704 procedures that resulted in 1,952 SSIs (PR=0.82). The overall SSI PR did not differ significantly between clusters of procedures assigned to SPC surveillance (781 SSIs/89,339 procedures; PR=0.87) and those assigned to traditional surveillance (1,171 SSIs/148,365 procedures; PR=0.79; PR ratio=1.10 [95% CI, 0.94–1.30]; P=.25) (Table 2). SPC surveillance identified 104 SSI rate increases that required formal investigations, compared to only 25 investigations generated by traditional surveillance. Among 10 best practices for SSI prevention, 453 of 502 (90%) SSIs analyzed due to SPC detection of SSI rate increases had at least 2 deficiencies (Table 3). Table 2

Outcome	SSIs, Intervention	Procedures, Intervention	Crude SSI PR, Intervention	SSIs, Control	Procedures, Control	Crude SSI PR, Control	PRR (95% CI)	P Value
All SSIs	781	89,339	0.87	1,171	148,365	0.79	1.10 (0.94–1.30)	.25
Complex SSIs <sup>a</sup>	472	89,339	0.53	739	148,365	0.50	1.09 (0.89–1.34)	.40
Superficial SSIs	309	89,339	0.35	432	148,365	0.29	1.26 (1.00–1.58)	.07

Models included effects for step and intervention phase, and were adjusted for hospital, median wound class, median American Society of Anesthesiology score, and operation time score. Compound symmetry working correlation structure was used for the outcomes of all SSIs and complex SSIs; independent working correlation structure was used for superficial SSIs.

Abbreviations: CI, confidence interval; PR, prevalence rate per 100 procedures; PRR, prevalence rate ratio. <sup>a</sup>Complex SSIs include deep incisional and organ-space SSIs.

Poisson regression models comparing surgical site infection (SSI) prevalence rates for procedure clusters receiving statistical process control surveillance to SSI rates for clusters receiving traditional control surveillance.

Table 3

Best Practice for SSI Prevention	Compliance with Best Practice, n/N (%)
Choice of prophylactic antibiotic(s)	445/502 (89%)
Timing of prophylactic antibiotic(s)	419/502 (83%)
Weight-based dose of prophylactic antibiotic(s)	445/502 (89%)
Re-dosing of prophylactic antibiotic(s) <sup>a</sup>	38/65 (58%)
Skin antisepsis with appropriate agent	403/502 (80%)
Maintenance of perioperative normothermia	379/502 (75%)
Operative and postoperative supplemental oxygen <sup>b</sup>	77/415 (19%)
Postoperative glucose monitoring and control	222/502 (44%)
Use of SSI prevention checklist	151/502 (30%)
Prophylactic oral antibiotics and mechanical bowel preparation <sup>c</sup>	28/217 (13%)
<b>Procedures with at least 1 best practice deficiency</b>	<b>499/502 (99%)</b>
<b>Procedures with 2 or more best practice deficiencies</b>	<b>453/502 (90%)</b>

<sup>a</sup>Analyzed for surgeries requiring re-dosing based on surgery duration and antibiotic chosen.

<sup>b</sup>Analyzed for surgeries requiring general anesthesia and mechanical intubation.

<sup>c</sup>Analyzed for colon surgeries only.

Compliance with 10 best practices for surgical site infection (SSI) prevention among 502 SSIs analyzed during SSI investigations generated by statistical process control surveillance.

**Conclusion.** SPC methods more frequently detected important SSI rate increases associated with deficiencies in SSI prevention best practices than traditional surveillance; however, feedback of this information did not lead to SSI rate reductions. Further study is indicated to determine the best application of SPC methods to improve adherence to SSI quality measures and prevent SSIs.

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#### 94. Infectious Complications of Left Ventricular Assist Devices

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**Session:** O-20. Infection Risks from Invasive Procedures

**Background.** Left ventricular assist devices (VAD) have significantly increased survival for patients with advanced heart failure. While advancements in devices during the past 10 years have improved thrombotic and bleeding complications, infection remains a significant cause of morbidity and mortality. We assessed the incidence and risk factors of VAD infections at our institution.

**Methods.** A single center, retrospective study of patients who had VAD implanted between January 2007 and December 2020 was performed. Patients with concurrent right sided mechanical circulatory support devices were excluded. Patient demographics, clinical characteristics, labs, microbiology data, and antimicrobials were obtained from the electronic medical records. Clinical outcomes were adjudicated by 2 independent physicians. VAD infections were classified using the ISHLT 2011 guidelines.

**Results.** 241 patients had durable VAD implanted in this 14-year period, with a median time of 3 years follow-up. 134 (56%) patients had a clinically significant infection; 42 (31.3%) were VAD specific infections, 42 (31.3%) were VAD related, and 50 (37.4%) were non-VAD related. 95% of VAD specific infections were driveline site infections. 98% of patients with VAD related infections had a concurrent blood stream infection. Of the 50 non-VAD infections, 72% involved either a lower respiratory, urinary tract, or *Clostridium difficile* infection. Median time from VAD implantation to infection was 5 months. 44 (32.8%) had their first infection during the index hospitalization, of which 27 (61.4%) were non-VAD infections. 78 (58.2%) had one infection, compared with 38 (28.4%) who had two or more infections. 17 (12.7%) had recurrence of their initial infection and 6 (35%) occurred despite being on suppressive antibiotics. 48 of 134 (36%) infected patients were transplanted. 57 of 134 (42.5%) died compared to 33 of 107 (31%) without an infection.

Table 1 Patient Demographic and Characteristics of VAD patients with and without infection

Characteristic	Infection, n=134	No Infection, n=107
Age (median, range, years)	58 (21-76)	58 (18-73)
Sex		
Male	111 (82.8%)	87 (81.3%)
Race		
White non-Hispanic	113 (84.3%)	90 (84.1%)
Black non-Hispanic	11 (8.2%)	13 (12.1%)
Asian non-Hispanic	3 (2.2%)	3 (2.8%)
Hispanic	7 (5.3%)	1 (0.9%)
Smoking		
Current	6 (4.5%)	3 (2.8%)
Former	72 (53.7%)	59 (55.1%)
Never	56 (41.8%)	45 (42.1%)
Diabetes	55 (51.4%)	37 (27.6%)
CKD ≥stage 3	41 (30.6%)	27 (25.2%)
HTN (pre-VAD)	81 (60.4%)	62 (57.9%)
BMI (Median)	28.8	28.6
Etiology of LV Failure		
ICM	51 (38.1%)	34 (31.8%)
NICM	6 (4.5%)	72 (67.3%)
Mixed	77 (57.4)	1 (0.9%)
ICD present at time of VAD placement		
Yes	114 (85.1%)	97 (90.7%)
Preoperative support (IABP/ECMO)	29 (21.6%)	23 (21.5%)
Reason for VAD placement		
Bridge to transplant	55 (41.0%)	65 (60.7%)
Bridge to decision	9 (6.7%)	8 (7.5%)
Destination therapy	70 (52.2%)	34 (31.8%)
Type of VAD		
HeartMate II	82 (61.2%)	51 (47.7%)
HeartMate III	32 (23.9%)	37 (34.6%)
HeartWare	20 (14.9%)	19 (17.7%)
Length of index hospitalization, (days, median)	24	24

**Conclusion.** More than half of VAD patients at our center during a 14-year time period had an infectious complication and higher mortality rate compared to those without an infectious complication. Further studies are needed to assess the immunologic risk factors for the increased risk of non-device associated infections in VAD patients.

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#### 95. Impact of Penetrating Trauma on Surgical Site Infection Standardized Infection Ratio (SIR) for Colon Procedures

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**Session:** O-20. Infection Risks from Invasive Procedures

**Background.** Colon surgery (COLO) is one of the focus areas for the the Centers for Medicare and Medicaid Services (CMS) Hospital Inpatient Quality Reporting (IQR) Program. Standardized criteria from the National Healthcare Surveillance Network (NSHN) are used to define surgical site infections (SSI) and to assess and weight standardized risk variables, so that all organizations can be judged to the same standard. Performance is compared through use of a standardized infection ratio (SIR), which is the observed number of infections, divided by the "predicted" number of infections, given the number and type of surgeries performed.

**Methods.** A retrospective review of medical records and NHSN documentation was conducted for 778 COLO procedures that were performed at a large academic and level 1 trauma center between January 2019 and December 2020. Initial review of the data showed that the increases in SIR were primarily concentrated in trauma patients with intestinal injury and fecal spillage. SIR for adult procedures were calculated using the NHSN Complex 30-Day SSI Data for IQR Report model, which the metric used by the CMS IQR. The CDC NHSN Statistics Calculator was used to compare SIR for