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Perioperative Antimicrobial Prophylaxis in Vascular Surgery:

A Quality Assessment and Improvement Project

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Abstract

Introduction: Prophylactic antimicrobial selection and administration for the prevention of surgical site infections in vascular surgery is a recommended best practice. Non-adherence to published guidelines on the selection and administration of antimicrobials has been observed and may lead to reduced efficacy of antimicrobial prophylaxis.

Methods: An observational, descriptive design was used to study clinician knowledge and behavior and included a retrospective patient record review and provider knowledge survey. A clinical education intervention targeting providers responsible for the selection and administration of antimicrobial prophylaxis was conducted. A repeat patient record review and knowledge survey was completed following the education intervention.

Results: The rate of timely administration of all antimicrobials increased from 69.2% to 88.9% ($\chi^2 = 0.5640$, $df = 1$, $p = 0.4526$), and for vancomycin from 16.7% to 63.67% ($\chi^2 = 5.3158$, $df = 1$, $p = 0.0241$). Rate of appropriate selection increased from 76.9% to 83.8% ($\chi^2 = 0.5640$, $df = 1$, $p = 0.4526$). Knowledge and confidence among clinicians improved in some areas regarding the selection and administration of antimicrobial agents.

Conclusion: This quality assessment and process improvement study demonstrated that with targeted educational experiences and supportive clinical decision-making tools, clinicians responsible for vascular surgery patients can improve their knowledge, selection and timely administration of prophylactic antimicrobials. Implementing these processes into existing pre-operative patient screening/assessment clinics and surgery scheduling mechanisms would hardwire this process setting the stage for clinical outcome trials.

Key Words: Antimicrobial prophylaxis, vascular surgery, perioperative antimicrobial selection

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Background

Surgical site infections (SSI), defined by the Centers for Disease Control and Prevention (CDC) as “an infection that occurs after surgery in the area of the body where the surgery took place...” (CDC, 2016), are the second most common type of healthcare associated infection (Anderson et al., 2014; Culver, et al,1991). Approximately 140,000 vascular surgery procedures are performed annually in the United States (Calderwood et al, 2014; AHRQ-HCUPnet, 2016). Risk factors for vascular SSIs may be patient related, surgical (procedure) related, and/or environment related (Tatterton & Homer-Vanniasinkam, 2011). Patient factors that increase risk include: nasal colonization with methicillin sensitive staphylococcus aureus (MSSA) or methicillin resistant staphylococcus aureus (MRSA), end-stage renal disease, obesity, advanced age, smoking, and diabetes (Inui & Bandyk, 2015). Environmental factors that augment risk include the degree of operating room ventilation, environmental surface cleaning, surgical instrument and implant sterility, surgical attire, and sterile operative technique (Inui & Bandyk, 2015). Vascular procedures that are open/infrainguinal (infra-aortic) and those with prosthetic implantation are associated with the highest infection rates, and highest morbidity, respectively (Tatterton & Homer-Vanniasinkam, 2011; Vogel, et al., 2010; Stone, et al., 2010; Ryan, Calligaro, Scharff, & Dogherty, 2004).

Vascular surgery patients are at increased risk of developing surgery related infections (Tatterton & Homer-Vanniasinkam, 2011). When compared to overall SSI rates of 1-5%, reported by the Centers for Disease Control and Prevention’s National

Nosocomial Infections Surveillance Risk Category System, vascular surgery patients have SSI rates of 5-30% (Anderson et al., 2014; Calderwood et al, 2014; Culver, et al, 1991; NNIS, 2004; Tatterton & Homer-Vanniasinkam, 2011; Stone, et al., 2010). The institutional standardized infection ration (SIR) for SSI occurrence for colon surgery (95% CI [0.949, 1.947]) is no different than national benchmarks (SIR =1) (Medicare, 2019). For abdominal hysterectomy surgery institutional SIR for SSI occurrence (95% CI [0.009, 0.863]) are better than national benchmarks (SIR = 1) (Medicare, 2019). These are the only reported local SSI data by this institution. Local vascular surgery SSI rates are not readily published or systematic surveilled, however some vascular surgery attending physician receive a report on detected SSIs.

Patients who undergo vascular surgery have increased morbidity and mortality when they develop an SSI, vascular prosthetic graft infection (VPGI), or vascular access infections (Tatterton & Homer-Vanniasinkam, 2011). An increased risk of death following SSI has been described, with a relative risk (*RR*) of 2.2, 95% CI [1.1, 4.5] (Forbes & McLean, 2013). Mortality has been estimated as high as 13-58% when associated with vascular prosthetic graft infections (Young, Washer, & Malani, 2008).

Antimicrobial therapy continues to be strongly recommended by the CDC, National Surgical Infection Prevention Project, Surgical Infection Society and Society for Healthcare Epidemiology of America (Page et al., 1993; Bratzler & Houck, 2004; Tatterton & Homer-Vanniasinkam, 2011; Bratzler, et al., 2013; Hsu, 2014). Current best practice includes the screening of patients preoperatively for the appropriate antimicrobial prophylaxis. It is recommended that vascular surgery patients receive weight-based cefazolin, a second-generation cephalosporin, unless the patient has a

serious life-threatening allergic reaction to cephalosporins, is colonized with MRSA and/or is scheduled to undergo an infra-aortic prosthetic implantation for which vancomycin is recommended. Deviation from the current guidelines for the administration of the appropriate preoperative prophylactic antimicrobial therapy has been observed (Zaidi, Tariq, & Breslin, 2009; Hawn et al., 2008; Weber et al., 2008; Dull, Baird, Dulac, & Fox, 2008; Tatterton & Homer-Vanniasinkam, 2011), does not meet current best practice guidelines (Bratzler et al, 2013) and should be evaluated, measured and improved upon.

Review of Literature

Databases utilized to identify pertinent literature included the Cumulative Index to Nursing and Allied Health (CINAHL) complete, Ovid Medline, and PubMed Clinical Queries. Keywords and Medical Subject Headings (MeSH) included: surgical wound infection/*prevention & control, surgical wound infection/*microbiology, vascular surgical procedures/*adverse effects, drug administration schedule, antibiotic prophylaxis/*methods, anti-bacterial agents/*administration & dosage, anti-bacterial agents/*therapeutic use, surgical wound infection/epidemiology, anti-bacterial agents/*therapeutic use, vancomycin/*therapeutic use, vancomycin/administration and dosage, and practice patterns. Practical screens were used to focus the review and included publication dates of 2000-2017 and English language, peer reviewed articles. Landmark articles were included despite publication date limiters when five or more articles referenced the work, this totaled one landmark study by Classen (1992). Methodological screens applied included national and international guidelines, systematic review or meta-analyses of randomized controlled trials, randomized controlled trials,

case control studies, cohort studies and descriptive and qualitative studies. Articles selected for review were organized into patient / economic significance and scientific underpinnings categories. A table summarizing the articles reviewed can be found in the appendices (Appendix A)

Patient & Economic Significance

The impact of SSIs in the vascular surgery patient has a human cost as well as a financial cost (de Lissoy et al., 2009; Gagliardi, Fenech, Eskicioglu, Nathens, & McLeod, 2009; Stone et al., 2010; Salkind & Rao, 2011; Dua et al., 2014). A patient who develops an SSI, compared to a patient who does not, experiences increased pain, undergoes secondary operations, spends an average of 17 days more hospitalized, has a two-fold chance of mortality, and is five times more likely to be re-admitted to the hospital (Tatterton & Homer-Vanniasinkam, 2011).

The financial cost associated with infections in vascular surgery patients can be extrapolated from the above listed patient (human) costs and aggregate data on the cost of SSIs across all surgical services. In 2014, the Society for Healthcare Epidemiology of America reported the estimated annual cost associated with the development of an SSI ranges from \$3.5 billion to \$10 billion (Anderson et al., 2014). While estimates directly reflect the increased cost associated with vascular surgery patients, Engemann et al. (2003) found that surgery patients with a MRSA SSI had an additional cost of \$40,000 per hospital stay compared to those with MSSA SSIs.

Infection is the most common complication associated with vascular surgery (Tatterton & Homer-Vanniasinkam, 2011). Clinicians caring for these patients have a responsibility to design and implement systems based care models to meet guideline

recommendations in an effort to maximize adherence to best practices (van der Slegt, et al. 2013; Anderson et al., 2014; Waits et al., 2014; Sutherland, et al., 2014).

Scientific Underpinnings

Gram-positive microorganisms make up approximately 80% of vascular SSIs, most commonly identified as staphylococcus aureus and coagulase-negative staphylococci (Tatterton & Homer-Vanniasinkam, 2011). Gram-negative species are also found, yet to a lesser degree (20%), and include Escherichia coli, Pseudomonas aeruginosa, and Klebsiella pneumoniae (Tatterton & Homer-Vanniasinkam, 2011). Cefazolin, a fourth-generation cephalosporin, continues to be the most recommended antimicrobial agent, due to its gram-positive microbial coverage, low cost, with gram negative coverage which includes Escherichia coli and Klebsiella pneumoniae (Bratzler et al., 2013). When infrainguinal prosthetic implantation is anticipated in patients with known MRSA colonization or in patients with a true cephalosporin allergy, antibiotics such as vancomycin (a glycopeptide) or daptomycin (a cyclic lipopeptide) are recommended to be added or used as an alternative, respectively (Bratzler et al., 2013). These recommendations come from the 2013 American Society of Health-System Pharmacists report on the clinical practice guidelines for antimicrobial prophylaxis in surgery (Bratzler et al., 2013).

The efficacy of timely prophylactic antimicrobial administration was described in a landmark report by Classen et al. (1992). This report prompted the adoption of widespread guidelines for well-timed prophylactic use of antimicrobial agents to prevent surgery associated infections. Since then, there have been numerous reports that correlate, and a few that refute, the timing of antimicrobial agent administration to the occurrence

of SSIs (Hawn, Itani, Gray, Vick, Henderson, & Houston, 2008; Weber et al, 2008; Steinberg et al, 2009; Stone, et al., 2010; Fry, 2006; Anderson, et al, 2014; Dua et al, 2014; Stone et al, 2015).

The evidence that questions the importance of *timing* of administration is marginal. Two reports by Hawn and colleagues (Hawn et al., 2008; Hawn et al., 2013) challenge the importance of timing. However, methodological weaknesses can be identified in these works. In these reports, when two antimicrobial agents were used, only the one administered “closest to, but before incision” was recorded for timing of antibiotic (Hawn et al., 2013, pg. 650). The limitation of this approach centers on the selection for and reporting of an independent variable (timing of antibiotic) that excludes the considerable circumstances where more than one agent was used, thus overestimating the occurrence of timely administration. This is significant given that one agent can be administered rapidly (e.g., cefazolin) and the other often requires up to 60-120 minutes to be administered (e.g., vancomycin).

Despite any perceived controversy surrounding the timing of antimicrobial administration, current guidelines continue to recommend their timely routine use in high-risk procedures (Bratzler et al., 2013). However, despite these recommendations reports conclude that the timely administration of antimicrobial prophylaxis occurs only 50-80% of the time (Hawn et al., 2008; Weber et al., 2008; Dull, et al., 2008; Tatterton & Homer-Vanniasinkam, 2011), potentially resulting in sub-therapeutic antimicrobial tissue concentrations. In patients at high risk for developing an SSI, such as those receiving implanted graft material or with known MRSA colonization, low adherence to

antimicrobial guidelines have been shown to increase the occurrence of SSI (Classen, 1992; Garey et al., 2006).

Purpose Statement

The purpose of this project was to conduct a systematic analysis of current practice and improve upon the process of selection and timely administration of vancomycin for antimicrobial prophylaxis in the adult vascular surgery population. Pre-intervention assessment will identify the current state of vancomycin selection and administration and knowledge gaps among surgical and anesthesia clinicians caring for vascular surgery patients. Process improvement interventions composed of clinical education and decision support tools for clinicians who select (order) and administer the antimicrobial agents were implemented following the initial assessment. The aim was to improve adherence to established standards of practice and maximize the effectiveness of preoperative antimicrobial prophylaxis. Specific study questions included:

- (1) Will an educational program about recommended practice for the selection and administration of prophylactic antimicrobial agents in vascular surgery improve **appropriate selection** (agent and dosage) of antimicrobial prophylaxis?
- (2) Will an educational program about recommended practice for the selection and administration of prophylactic antimicrobial agents in vascular surgery improve **timely administration** (prior to surgical incision) of antimicrobial prophylaxis?

- (3) Will an educational program about recommended practices for the selection and administration of prophylactic antimicrobial agents in vascular surgery improve **clinician knowledge**?
- (4) Will an educational program about recommended practice for the selection and administration of prophylactic antimicrobial agents in vascular surgery improve **clinician confidence**?

Method

An observational, descriptive design was employed using retrospective record review and pre-/post-intervention clinician knowledge survey. One-group pretest-posttest and a two-group pretest-posttest methods were used to measure the knowledge, skill, and attitudes of perioperative clinicians about the prevention of nosocomial infection before and following the intervention. The one-group pretest-posttest data set was made up of a subset of clinicians that were identical before and after the intervention, this group was composed of the vascular surgery attending physicians and fellows. This subset is ultimately responsible for the selection and ordering of prophylactic antimicrobial agents. The two-group pretest-posttest data set was made up of all surgical and anesthesia clinicians before and after the intervention, this was not an identical group of participants, although there was some overlap.

The pretest-posttest clinician surveys were developed using key information from the literature review. Survey questions were written to assess the knowledge of clinicians required for determining the type and timing of prophylactic antimicrobial therapy in vascular surgery patients and were derived from published guidelines (Page et al., 1993; Bratzler & Houck, 2004; Tatterton & Homer-Vanniasinkam, 2011; Bratzler, et al., 2013;

Hsu, 2014). Additional survey questions were written to assess clinician attitudes about best practices and their confidence in adhering to them.

The effectiveness of this improvement process was assessed by comparing guideline adherence rates before and after the interventions. A clinician education plan was delivered using current best practice guidelines derived from the review of the literature. This included a slide show presentation delivered to the vascular surgery team during their grand rounds meeting (Appendix B). Anesthesiology personnel were provided with the same information in a printed form accompanied with a one to one tutorial in the perioperative setting. Learning objectives of the educational intervention included understanding the importance of selection and administration timing of antimicrobial prophylaxis as well as recognition of current barriers to adherence to best practices. Secondary learning objectives included the incidence of surgical site infections in vascular surgery, the microorganisms responsible for SSIs, as well as risk factors that impact SSIs in vascular surgery. Throughout and for one month after the educational intervention, dedicated time was spent in the perioperative environment with both anesthesiology and surgical team members to support clinical decision making. In person support was provided 2-3 days a week between September and November to reinforce the educational program's learning objectives.

Following the implementation of a curriculum aimed at improving peri-operative clinician's knowledge, skill, and attitudes about prescribing and administering antimicrobial prophylactics in vascular surgery, repeat retrospective record review and post-test surveys were performed. Variables of interest included the selection and administration timing of vancomycin in patients with a history of penicillin allergy,

incision prior to completed vancomycin administration, and planned infra-aortic prosthetic graft implantation in a patient with known MRSA colonization. Timely administration was determined by analyzing the time of initiation of each antimicrobial administered compared to the time of surgical incision. Timely administration was considered achieved when non-vancomycin agents were initiated five minutes prior to incision, timely vancomycin administration was considered achieved if initiated 60min prior to surgical incision. These variables were retrospectively evaluated in 76 cases of antimicrobial administration, 39 prior to project implementation and 37 afterwards.

Setting/Population

Conducted at a mid-western United States tertiary academic urban hospital, this study focused on patients scheduled for vascular surgery who were aged 18 years or older. Clinicians whose practice was analyzed included attending vascular surgeons, vascular surgery fellows, vascular surgery residents, general surgery residents, attending anesthesiologist, nurse anesthetists, and anesthesiology residents.

Sample

Two separate samples were targeted by this project. A patient sample set and a clinician sample set. The patient sample set was comprised of a convenience sample of those scheduled for vascular surgery during periods of time during the months of February 2018 and October 2018. Patients were excluded from evaluations if they were less than 18 years old or if they did not receive antimicrobial prophylaxis. The patient sample set was used to gain information about which antimicrobial agent was selected and the timing of its administration in relation to surgical incision time.

The clinician sample set was composed of clinicians with backgrounds in anesthesiology and surgery. The clinician sample set was divided into two sub-groups and underwent a one-group and two-group comparison (see Table 1). Due to the unpredictable nature of clinician coverage and the variability of clinical assignments, it was not possible to acquire a perfectly matched (identical) clinician sample. Inclusion criteria for clinicians included the cadre of anesthesiology (attending anesthesiologists, certified registered nurse anesthetists, and anesthesiology residents) and surgery specialists (vascular surgery attending physicians, vascular surgery fellows, and vascular surgery residents) that care for vascular surgery patients having various levels of experience.

Table 1: Clinician Sample Breakdown

Clinician	Two-Group Clinician Sample		One-Group* Clinician Sample	
	Pre Survey <i>n</i>	Post Survey <i>n</i>	Pre Survey <i>n</i>	Post Survey <i>n</i>
Surgeon Attending	6	6	6	6
Surgeon Fellow	4	4	4	4
Surgeon Resident	4	4	4	4
Anesthesiologist Attending	9	6		
Nurse Anesthetist (CRNA)	7	7		
Anesthesiology Resident	2	2		
Total	<i>n</i> = 32	<i>n</i> = 29	<i>N</i> = 14	
*Indicates identical group of pre- & post- survey respondents. This group holds primary responsibility for prophylactic antimicrobial medication ordering.				

The one-group sub-set comparison was conducted on those with the role of vascular surgeon. These individuals were made up of vascular surgery attending

physicians, vascular surgery fellows, and vascular surgery residents. This group of individuals have the primary responsibility of selection and ordering of surgical antimicrobial prophylaxis. This group was identical in the pre and post evaluations, thus permitting a one-group comparative analysis

A two-group comparison was completed for the entire pre- and post-intervention survey clinician sample sets. This group was composed of a mix of same individuals and unique individuals, necessitating a two-group analysis.

Data Collection

Collection of patient and case specific data (Appendix C) was conducted using electronic medical record (EMR) review. During the course of this project there was an institutional overhaul of the EMR systems, thus both MetaVision® (iMDsoft 2018) and EPIC® (EPIC systems corporation, Verona, WI, 2018) EMRs (post-intervention) were utilized. A fifteen-question knowledge, skill, and attitude survey (Appendix D) were utilized to query clinicians before and after the educational intervention. The surveys were conducted face to face by a single researcher on an individual basis in the perioperative areas. Post intervention surveys were performed approximately 2-3 weeks after the educational series.

Data Analysis

Descriptive statistics, cross tabulation and Chi-square were used to describe the observed characteristics in the subjects analyzed before and after the educational intervention. Wilcoxon rank sum test was performed to assess test assumptions, for non-normally distributed results, Wilcoxon signed rank analysis was performed. Statistical significance was set at 0.05 for statistical difference.

Results

Patient Sample Demographics: The pre-intervention patient sample ($n = 39$) included individuals aged 38 to 90 years old compared to post-intervention patient sample ($n = 37$) aged 19-78 years old. Age mean (m) and standard deviation (SD) for both pre- and post- samples were $m = 67.6$ ($SD = 12.4$) and $m = 59.4$ ($SD 14.0$), respectively.

Appropriate Antimicrobial Selection: In the pre-intervention patient sample there were no incidences of true life threatening allergies to cephalosporins. In the post-intervention patient sample, there were 4 cases of true life threatening cephalosporin allergy, in three of these four cases (75%) vancomycin was selected.

There were no cases (pre or post) of patients with a history of MRSA positive microbiological studies undergoing infra-aortic prosthetic graft implantation (another indication for vancomycin).

Clinician selection of the appropriate antimicrobial agent was performed 30 out of 39 cases, a rate of 76.9%, in the pre-intervention patient sample compared to 31 out of 37 cases, a rate of 83.8%, in the post-intervention group ($\chi^2 = 0.5640$, $df = 1$, $p = 0.4526$). Appropriate weight-based dosage of selected antimicrobial occurred at 35 out of 39 cases, a rate of 89.7%, in the pre-intervention group compared to 36 out of 37 cases, a rate of 97.3%, in the post-intervention group ($\chi^2 = 1.7654$, $df = 1$, $p = 0.1843$). While not statistically significant there is clinical significance in the selection of the proper antimicrobial agent and dosage for any specific patient.

Timely Administration of Antimicrobial: Administration of antimicrobials (including vancomycin) prior to incision (i.e. timely administration) was achieved 27 out of 39 times (69.2%) in the pre-intervention group compared to 32 out of 36 times (88.9%) in the post-intervention group ($\chi^2 = 4.3114$, $df = 1$, $p = 0.0379$).

In the pre-intervention group, completed vancomycin administration occurred prior to incision 2 out of the 12 times (16.7%) when vancomycin was selected for use. In the post-intervention group, completed vancomycin administration occurred prior to incision 7 out of the 11 times (63.6%) when vancomycin was selected for use. Chi square analysis of these results ($\chi^2 = 5.3158$, $df = 1$, $p = 0.0241$) suggests a statistically significant improvement in the timely administration of vancomycin in the post-intervention group.

Clinician Knowledge: A subgroup analysis (one-group pre/post-test) was performed using Wilcoxon signed rank test on those clinicians who currently have the responsibility for ordering the antimicrobial prophylactic, namely the vascular surgery attending physicians and their vascular surgery fellows. In one (Q6) of the three questions targeting clinician knowledge (Q6*, $S = -14.5$, $p = 0.0547$) a difference approaching statistical significance was noted. However when looking at all clinicians (two-group analysis), two (Q4 & Q8) of the three questions demonstrated a significant improvement in clinician knowledge following the intervention (Q4, $\chi^2 = 4.1112$, $df = 1$, $p = 0.0465$; Q8, $\chi^2 = 5.6509$, $df = 1$, $p = 0.0177$). (see table 2).

Clinician Confidence: One survey question was designed to assess clinician confidence in selecting the appropriate antimicrobial for surgical prophylaxis. Due to the non-normal distribution that was observed between the pre- and post- intervention surveys, non-parametric testing was performed. Chi square analysis applied to the entire

pre- and post- survey groups (two-group pre/post-test) found statistically significant differences in three specific questions. One such question targeted clinician confidence (Q3, χ^2 3.9936, $df = 1$, $p = 0.0465$), This question also demonstrated statistical significance in the sub-group analysis, i.e. one-group pre/post, ($\chi^2 = 3.8774$, $df = 1$, $p = 0.0325$) (see Table 2).

Table 2

Q#	Survey Question	Two-Group (<i>p</i> -value)	One-Group (<i>p</i> -value)
1	Antimicrobial prophylaxis for patients undergoing open vascular surgery is consistent with best practice.	0.2511	1.0000
2	Antimicrobial prophylaxis does not contribute to reductions in vascular surgical site infection.	0.2718	0.1875
3	I am confident in selecting the correct antimicrobial prophylaxis for vascular surgery.	0.0465*	0.0325*
4	I am able to identify a serious adverse reaction to PCN or cephalosporin.	0.0501*	0.4375
5	I am able to identify whether or not a prosthetic graft will be implanted prior to surgery.	0.8518	0.4375
6	I am able to identify whether or not a patient has a history of MRSA/MSSA colonization.	0.1352	0.0547
7	I am able to identify whether or not a patient has increased risk for MRSA/MSSA colonization.	0.2866	1.0000
8	The institution where I practice is considered to have a high prevalence of MRSA/MSSA.	0.0177*	0.1563
9	It is best practice to administer the antimicrobial prophylaxis prior to surgical incision.	0.8215	0.3750
10	Patients with known MRSA/MSSA colonization should always receive vancomycin antimicrobial prophylaxis (if not allergic to vancomycin).	0.6869	0.1484
11	Patients scheduled for infra-inguinal prosthetic graft implantation should receive vancomycin antimicrobial prophylaxis (if not allergic to vancomycin).	0.3654	0.4922
12	Patients with serious adverse reactions to penicillin/cephalosporins should receive vancomycin antimicrobial prophylaxis (if not allergic to vancomycin).	0.1505	0.1719
13	If a patient has serious allergic reactions to cephalosporins AND vancomycin, I am confident in determining the best antimicrobial prophylaxis for vascular surgery procedures.	0.0658	1.0000
14	Overall, our antimicrobial prophylaxis selection is adherent to current clinical guidelines for vascular surgery.	0.7549	0.7500

Q#	Survey Question	Two-Group (<i>p</i> -value)	One-Group (<i>p</i> -value)
15	Overall, antimicrobial prophylaxis administration is adherent to current clinical guidelines for vascular surgery.	0.0765	0.3750

Discussion

Appropriate Antimicrobial Selection: Potential clinical significance was also identified by the reduction of both inappropriately selected antimicrobial agent and inappropriate weight-based dosage of selected antimicrobial agent.

Timely Administration of Antimicrobial: Findings from this quality/process improvement study of a midwestern academic vascular surgery service division indicates that there was a statistically significant reduction in inappropriately administered vancomycin following a clinician education intervention.

Clinician Knowledge: Improvement in clinician knowledge was noted in their identification of serious, life-threatening allergic reactions to penicillins/cephalosporins, as well as, institutional MRSA/MSSA prevalence rates.

Clinician Confidence: Survey data suggest that among all clinicians surveyed there was a statistically significant improvement in clinician confidence in selecting the correct antimicrobial prophylactic for vascular surgery.

Limitations

Observing approximately 40 sequential pre- and post-intervention vascular surgery cases provided 12 and 11 vancomycin cases respectively for analysis. This small sample size lacks statistical power. Vancomycin was selected about 30% of the time when an antimicrobial prophylactic agent was indicated. This rate was observed for both pre- and post-intervention groups. This patient sample size was set by the time allocated to perform data collection and an estimation of frequency of surgical cases to be

evaluated. The frequency of vancomycin selection and administration was underestimated. Clinician samples sets were not controlled for with exception of the vascular surgeon subgroup, control of all clinician's studies would have permitted one-group parametric testing of all survey data.

Vancomycin is strongly indicated for vascular surgery patients in two instances (true life-threatening cephalosporin allergy and infra-aortic prosthetic graft implantation in patients with MRSA colonization). These two scenarios were not observed in both sample sets (pre & post) thus impairing the ability of this study to report on the effects of the intervention with respect to these two scenarios.

During the implementation of this quality assessment and improvement process the medical center where the data was being collected underwent an overhaul of their electronic health record systems. Due to this there were some differences in the manner by which some data points were recorded and ultimately measured. Although no obvious omissions or incorrect interpretations are suspected, they cannot be completely ruled out due to the possibility of user error with the implementation of a new software application.

Local institutional baseline SSI data for vascular surgery was not available thus only general assumptions about the state of SSI incidence in this specific population can only be assumed by evidence from studies in this field.

This study was also vulnerable to the Hawthorne effect as clinician participants were aware of the educational intervention they had participated in. To manage any instrumental threats, the pre/post tests were identical. There are no obvious regression threats as the population targeted is based on contact with the vascular surgery patient population alone. The one-group test for clinician knowledge and confidence was also a

small sample size, however was specific to the current paradigm for prescribing of pre-operative antimicrobial prophylaxis (is the purview of this subgroup). Those outside of this vascular surgery subset currently hold more of a supportive role on this variable.

Implications for Practice and Recommendations for Future Research

Practice implications identified by this project include the observed failure rate of timely vancomycin administration, a failure rate that persists despite an effective intervention. It is encouraging that a positive impact was observed, however there is still great need for practice change to reduce or eliminate this ongoing failure of timely administration of vancomycin. Also identified by the implementation of this project were challenges in SSI surveillance in the vascular surgery population. How SSI surveillance is routinely performed needs to be further assessed, redesigned and implemented in an effort to evaluate the efficacy of and degree of impact on patient centered outcome interventions such as this clinical scholarship project.

The ability of education and clinical support tools to improve selection and timely administration of pre-operative antimicrobial prophylactic agents was suggested by this project. While the overall incidence of vancomycin selection did not change between groups, there was a reduction in both the number of inappropriately selected agents (vancomycin was selected less frequently) and inappropriately chosen doses of vancomycin. This has the potential to enhance the clinical effectiveness of vancomycin (when selected) to prevent a surgical site infection due to increased likelihood of achieving levels above the minimal inhibitory plasma and tissue concentrations.

Furthermore, this process improvement study demonstrates that timely clinical decision support resources, delivered at the point of decision-making, may improve

processes to perpetuate appropriate clinician decision making. A key implication for clinical practice is to hardwire this process, this is the likely next step for this project. Specifically, to leverage pre-operative patient screening and surgery scheduling practices to select and time the administration of pre-operative antimicrobial prophylaxis. The overhaul of the electronic health record system at this institution creates the opportunity to further develop screening tools that support clinicians in the selection and timely administration of prophylactic antimicrobials.

Following further development and hardwiring of processes to support prophylactic antimicrobial decision-making, future research should focus on the ability of such process improvement activities to impact the patient centered outcomes i.e., rate of surgical site infections. Potentially answering the following question “Can process improvement strategies aimed at improving the selection and timely administration of antimicrobial prophylaxis reduce surgical site infections in the vascular surgery population?”.

Conclusions

This quality assessment and process improvement study demonstrated that with targeted educational experiences and supportive clinical decision-making tools, clinicians responsible for vascular surgery patients can improve their knowledge, confidence, and ability to select and timely administer antimicrobial prophylactic agents. Routine SSI surveillance is needed in this patient population prior to future outcome studies. Implementing these processes into existing pre-operative patient screening/assessment clinics and surgery scheduling mechanisms would hardwire this process setting the stage for clinical outcome trials.

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Appendices

Appendix A
Evidence Table

<u>#</u>	<u>First Author</u>	<u>Year</u>	<u>Level of Evidence</u>	<u>Sample Composition</u>	<u>Results</u>	<u>Limitations</u>
1	Classen	1992	II* Randomized controlled Trial	2847 patients Single center Across all lines of surgical services	0.6% SSI rate in those who received antimicrobial preoperatively 3.3% SSI rate in those who received antimicrobial postoperatively Those who received antimicrobial 1-2hrs prior to surgery had fewer (P<0.001) SSIs	Exclusion of patients admitted >48hr prior to surgery (an important subset) Single center
2	Engemann	2003	IV* Cohort Study	Patients undergoing surgery with SSI surveillance N = 479 Control group	MRSA resistance is independently associated with increased mortality MRSA resistance is independently associated with hospital expense / charges	Different types of antimicrobial therapy was not examined. Possible underestimation of cost due to

<u>#</u>	<u>First Author</u>	<u>Year</u>	<u>Level of Evidence</u>	<u>Sample Composition</u>	<u>Results</u>	<u>Limitations</u>
				MRSA group MSSA group		potential for outpatient treatment not captured
3	Fry	2006	V* Retrospective analysis Randomized	Multi center (national CMS SIP database) 788 randomly selected cases to establish baseline	Poor compliance with timely administration, 56% compliance Good performance on antimicrobial selection, 97% correctly selected Poor compliance with discontinuing therapy <24hrs, 41% compliant	Detailed patient population not reported Retrospective Variable data reporting accuracy across clinical sites (i.e database metrics)
4	Garey	2006	III* Prospective non-randomized	Patients undergoing coronary bypass grafting or valve replacement surgery 06/2002-06/2005.	SSI rates were lowest in those receiving vancomycin between 16-60min before surgical incision compared to the other four time groupings (3.4% vs. 26.7%, 7.7%, 6.9%, and	Single center Non-randomized No control group

<u>#</u>	<u>First Author</u>	<u>Year</u>	<u>Level of Evidence</u>	<u>Sample Composition</u>	<u>Results</u>	<u>Limitations</u>
				Five groups assigned based on timing of vancomycin dosing prior to surgical incision N = 2048	7.8%)	
				68% male, 53% Caucasian.		
5	Dull	2008	QA/QI report Exemplar of successful implementation	SCIP adherence at 2 acute care hospitals in MI	SCIP 1 = 64% to 90% SCIP 2 = 95% to 93% SCIP 3 = 60% to 95% General trend toward improved adherence	Not scientific SCIP has fallen out of favor
6	Hawn	2008	IV* retrospect cohort	VA-elective Procedures N=9,195 Mostly male	Timely admin occurred 86.4% Untimely SSI = OR 1.29, 95%CI 0.99, 1.67	Not all vascular surgery patients. VA pop. not representative (not generalizable)

#	First Author	Year	Level of Evidence	Sample Composition	Results	Limitations
						NSQIP used for outcome (limited to NSQIP collected information)
7	Weber	2008	IV* Prospect Observe cohort	Consecutive enrollment of visceral, Vascular, and Trauma sx 01/2000-12/2001 3836 cases 50.7% male 49.3% female 15.3% vasc cases	49% of the time anti-Biotic was admin Within the final 30min prior to incision Increased odds of SSI if Antibiotic admin <30 min prior. OR 1.95; 95%CI 1.4-2.8 Admin 59-30min prior to incision is more effective than during last 30min	Not RCT Post-discharge Monitoring not standardized Optimal timing not generalizable to all Antibiotic agents
8	De Lissovoy	2009	IV* Retrospective analysis	Data from 1054 hospitals in 37 states (accounting for ~90% of US	Average increase in cost associated with SSI = \$20,842	Use of administrative data can be imprecise.

#	First Author	Year	Level of Evidence	Sample Composition	Results	Limitations
				hospital discharges) Surgical Subsets: Neuro, cardiovascular, colorectal, GI, OB/GYN, Ortho	406,730 additional hospital days (\$900 million when extrapolated). 91,613 readmissions leading to additional 521,933 days of care (\$700 million when extrapolated)	
9	Gagliardi	2009	Scoping Review of the Literature	19 of 192 studies reviewed MEDLINE COCHRANE 1996-2007 7 = antibx use 12 = adherence	Factors that influence practice: -individual knowledge, Attitudes, beliefs & practices, institutional support Favor multi-disciplinary pathways, computerized order sets, and individualized performance data for QI strategies	Limited data (not comprehensive) Not scientific, although very systematic Not delineated by type of surgery No control (case control) for intervention (no

#	First Author	Year	Level of Evidence	Sample Composition	Results	Limitations
						matching by patient or type of surgery)
10	Steinburg	2009	IV* Prospective Cohort, multi-center	4472 surgical Cases 29 hospitals Cardiac hip/knee TAH	Surgical site Infection risk increased as the time interval between dose and incision increased OR 1.74, 95%CI 0.98-3.04	Not statistically significant (p = 0.04) Clinically significant Limited statistical power 2/2 low number of (+) cases. Post-discharge surveillance not standardized Truncated follow-up (due to parent study)...under ascertainment (lowered power) Vanco observations too low.

<u>#</u>	<u>First Author</u>	<u>Year</u>	<u>Level of Evidence</u>	<u>Sample Composition</u>	<u>Results</u>	<u>Limitations</u>
11	Patrick	2010	II* Prospective RCT Single center	18yo or > Vascular surgery N = 169	Adding anti-MRSA prophylaxis does not Reduce the incidence of MRSA infection in low-risk patients Groin procedures were 3x as likely to acquire infection (p = .0282) Groin procedures were associated with longer surgical times and higher intraoperative glucose (p = .0007)	66% power No standardized skin decontamination Dressing use/removal not standardized High-risk patients Excluded
12	Salkind	2011	Review Article	5 articles with class A evidence (Timing) 4 articles with class B evidence (consistent with guidelines/discontinued within 24hrs)	Review of evidence for timing of antibx therapy, when to discontinue use, and published guidelines (SCIP measures)	SCIP is falling out of favor Limited amount of identified evidence

<u>#</u>	<u>First Author</u>	<u>Year</u>	<u>Level of Evidence</u>	<u>Sample Composition</u>	<u>Results</u>	<u>Limitations</u>
13	Tatterton	2011	Review Article		Review of evidence and reports to describe the incidence and type of infections that occur in the vascular surgery population	Not scientific
14	Bratzler	2013	Clinical Practice Guidelines American Society of Health-Care Pharmacists	Multi-organizational collaborative panel of experts Primary literature published between 1999-2010 via MEDLINE, EMBASE, and Cochrane Database of Systematic Reviews.	Graded recommendation based on strength of evidence (I-VII) Stratification between different surgical procedures, i.e. specific recommendations for specific types of surgery	Limitation of available literature on antimicrobial prophylaxis Difficulty in establishing significant differences in efficacy among antimicrobial agents.

<u>#</u>	<u>First Author</u>	<u>Year</u>	<u>Level of Evidence</u>	<u>Sample Composition</u>	<u>Results</u>	<u>Limitations</u>
14	Hawn	2013	IV* Retrospective Cohort study	32,459 cases Orhtopedic Colorectal Vascular Gynecologic VA patient population	Higher SSI rates w/ administration >60min prior to incision (OR 1.34, 95%CI 1.08-1.66) Significant relationship between timing and SSI (p = .003)	Mostly male patients Not capture of intraoperative redosing Small group of non-timely administration
16	Van der Slegt	2013	IV* Prospective Quasi experimental Cohort study	720 vascular cases Continuous sample (3/2009-1/2010)	Bundle implementation Bundle compliance from 10% to 80% Use of bundle reduced SSI (33% reduction)	Lack of direct causal relationship (no randomized control) No performance of interrupted time series analysis

#	First Author	Year	Level of Evidence	Sample Composition	Results	Limitations
17	Anderson	2014	I* Systematic Review	Practice Recommendation Society for Healthcare Epidemiology of America Infectious Disease Society of America	(relevant): administer antibx prophylaxis according to EB standards and guidelines (LEVEL I) Administer with 1hr (2 hours allowed for vanc and flouroquinolones) Administer prior to tourniquet Vanco 15mg/kg	Not vascular specific
18	Dua	2014	VI* Retrospective analysis	National Inpatient Sample (NIS)- largest all-payer inpatient database Stratified 20%	No improvement in rate of SSI when SCIP measures implemented Increase in SSI rate with open AAAs	Retrospective design Use of national database compiled by ICD-9 codes

<u>#</u>	<u>First Author</u>	<u>Year</u>	<u>Level of Evidence</u>	<u>Sample Composition</u>	<u>Results</u>	<u>Limitations</u>
				random sample of all nonfederal inpatient admissions 2000-2010 Stratified by ICD-9 classification	Use of SCIP measures may not be achieving what was intended with prophylactic antimicrobial dosing	Only analyzed inpatients, no long term follow up data, potentially underreporting SSI rates.
19	Sutherland	2014	Process Improvement	Measure to improve SCIP compliance Descriptive Single center	Descriptive report on implementation of methods to surveil and adhere to SCIP inf 1,2,3 in a large academic institution Hundreds of thousands of dollars in cost savings	Not scientific No other limitations
20	Waits	2014	IV* Retrospective Cohort study	Data from 24 hospitals in MI 4,085 colorectal surgeries analyzed between 2008-	Multisite sampling (more generalizable than previous similar studies) Large sample size	Difficulty in inclusion of urgent/emergent surgeries (numerous incidents) may have

#	First Author	Year	Level of Evidence	Sample Composition	Results	Limitations
				2011.	Single surgical population (with exception)	led to selection bias Baseline education of clinicians not assessed
21	Stone	2015	II* Prospective double-blind randomized controlled trial	Adults undergoing groin or lower extremity vascular procedure N = 200	Randomization Use of Cohen’s delta coefficient 3, due to impaired adequacy of endpoint SSI evaluation in both groups	Single center No multivariate analysis to assess confounders

*Melnik Levels of Evidence: Melnyk, B.M. & Fineout-Overholt, E. (2015) Evidence-based practice in nursing & healthcare: A guide to best practice (3rd ed.). Philadelphia, PA : Wolters Kluwer Health

Appendix B

Education Tool



- ▶ Antimicrobial Selection
 - ▶ Cefazolin is most indicated
 - ▶ Vancomycin in some instances
- ▶ Antimicrobial Administration
- ▶ How Should we Select and Administer antimicrobial prophylaxis?
 - ▶ Patient evaluation
 - ▶ Severe Life Threatening PCN Allergy?
 - ▶ Known Colonization of MRSA/MSSA?
 - ▶ Comorbidities (SRD, Morbid Obesity, Diabetes, COPD)
 - ▶ Procedural evaluation
 - ▶ Intra- vs. topical
 - ▶ Open vs. endo
 - ▶ Temporal evaluation
 - ▶ In holding
 - ▶ In the OR
 - ▶ Before or after incision?

WHAT WE DO VS. WHAT WE MIGHT DO BETTER.

- ▶ Patient History of Life Threatening Allergy to cefazolin
 - ▶ Known cross reactivity with
cefezole, cefrazole, fezacef, or ceftozolo
- ▶ Patient with known MRSA colonization
 - ▶ +/- aztreonam for gram-negative coverage
- ▶ **ADMINISTRATION MUST START IN HOLDING AREA**
 - ▶ The decision to give vancomycin should not occur during the briefing!

WHEN SHOULD WE USE
VANCOMYCIN?

Appendix C

Data Collection Tool

Date:	Patient Weight (Kg): BMI:	Patient Age:
DOS:	Surgery:	

	YES	NO	
ESRD			
Hemodialysis			
Peritoneal Dialysis			
DM1			HgA1C:
DM2			HgA1C:
Smoking History			Pack year:
Serious PCN/Cephalosporin Allergy			Rxn:
Planned Infra-aortic graft implantation			
Known MRSA colonization			
Known MSSA colonization			
Antibiotic Vancomycin			
Antibiotic Cefazolin			
Antibiotic Other			Type:
Antibiotic Start Time			_____ : _____
Antibiotic Completed Time			_____ : _____
Pre-Incision "time-out" Time			_____ : _____
Surgical Incision Time			_____ : _____
Time from Antibiotic Complete to Skin Incision			Min:

Incision Prior to Completed Antibiotic Admin.			
Appropriately Selected Antibiotic			
Appropriately Administered Antibiotic			
Appropriate Weight Based Antibiotic Dosage			

Appendix D

Vascular Surgery Clinical Practice Questionnaire

Date: _____

Clinician Role: _____

	Strongly Disagree	Disagree	Neither Disagree or Agree	Agree	Strongly Agree
1. Antimicrobial prophylaxis for patients undergoing open vascular surgery is consistent with best practice.	1	2	3	4	5
2. Antimicrobial prophylaxis does not contribute to reductions in vascular surgical site infection.	1	2	3	4	5
3. I am confident in selecting the correct antimicrobial prophylaxis for vascular surgery.	1	2	3	4	5
4. I am able to identify a serious adverse reaction to PCN or cephalosporin.	1	2	3	4	5
5. I am able to identify whether or not a prosthetic graft will be implanted prior to surgery.	1	2	3	4	5
6. I am able to identify whether or not a patient has a history of MRSA/MSSA colonization.	1	2	3	4	5

	Strongly Disagree	Disagree	Neither Disagree or Agree	Agree	Strongly Agree
7. I am able to identify whether or not a patient has increase risk for MRSA/MSSA colonization.	1	2	3	4	5
8. The institution where I practice is considered to have a high prevalence of MRSA/MSSA.	1	2	3	4	5
9. It is best practice to administer the antimicrobial prophylaxis prior to surgical incision.	1	2	3	4	5
10. Patients with known MRSA/MSSA colonization should always receive vancomycin antimicrobial prophylaxis (if not allergic to vancomycin)	1	2	3	4	5
11. Patients scheduled for infra-inguinal prosthetic graft implantation should receive vancomycin antimicrobial prophylaxis (if not allergic to vancomycin).	1	2	3	4	5
12. Patients with serious adverse reactions to penicillin/cephalosporins should receive vancomycin antimicrobial prophylaxis (if not allergic to vancomycin).	1	2	3	4	5

	Strongly Disagree	Disagree	Neither Disagree or Agree	Agree	Strongly Agree
13. If a patient has serious allergic reactions to cephalosporins AND vancomycin, I am confident in determining the best antimicrobial prophylaxis for vascular surgery procedures.	1	2	3	4	5
14. Overall, our antimicrobial prophylaxis selection is adherent to current clinical guidelines for vascular surgery.	1	2	3	4	5
15. Overall, antimicrobial prophylaxis administration is adherent to current clinical guidelines for vascular surgery.	1	2	3	4	5