Outpatient Preoperative Prophylactic Antimicrobial Use and Surgical Site Infection Rates

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Abstract

In the United States, most postoperative orthopedic surgical site infections (SSIs) and prophylactic antimicrobial use research are hospital-based. However, 50% of the orthopedic procedures occur outpatient and postoperative SSI research is lacking (Berríos-Torres et al., 2017). Hospital-based preoperative prophylactic intravenous antibiotics administration supports decreased SSI rates (Al-Mulhim, Baragbah, Sadat-Ali, Alomran, & Azam, 2014). The research question posed was: For the adult patient undergoing an orthopedic surgical procedure at an outpatient facility, what is the effect of preoperative prophylactic antimicrobials on postoperative surgical site infection rates within the first 30-days? This descriptive study examined a convenience sample of adults, following an orthopedic procedure, administered a preoperative prophylactic intravenous antimicrobial for a postoperative SSI at an outpatient surgical facility. Guiding the research was Meleis' transitions theory which examines the transitional experience throughout the surgical encounter to reduce associated risks (Omar, 2017). Of the 149 orthopedic cases reviewed between January 1, 2019-April 30, 2019, N = 103 patients met the inclusion criteria. The various intravenous antimicrobials and the doses administered were Cefazolin 1 gram, Cefazolin 2 grams, Clindamycin 600mg, Clindamycin 900mg, Vancomycin 1 gram, and Rocephin 1 gram. The study found 1 (0.01%) SSI documented for a patient administered Rocephin; significantly, 99.9% administered a preoperative prophylactic antimicrobial experienced no SSI within 30-days postoperatively. Future research recommendations include investigating the type, dose, and time of preoperative antibiotic administrations, and all surgical procedures performed at an outpatient surgical facility.

Keywords: preoperative prophylactic antimicrobials, surgical site orthopedic infections

Outpatient Preoperative Prophylactic Antimicrobial Use and Surgical Site Infection Rates

With evidence-based guidelines deficient, preoperative prophylactic antimicrobial practices varying amount surgeons, and lack of research performed in the outpatient surgical setting, research focus on postoperative surgical site infection (SSI) rates within this setting is essential. Most research surrounding postoperative SSIs and prophylactic antimicrobial use are hospital-based with patients undergoing orthopedic procedures in the outpatient setting going unnoticed after being sent home from the facility (Berríos-Torres et al., 2017). Nearly 50% of outpatient SSIs are unaccounted for after discharge from the facility (Berríos-Torres et al., 2017). Results from hospital-based studies demonstrate a significant reduction in postoperative SSI rates when prophylactic antimicrobials are given effectively (Al-Mulhim, Baragbah, Sadat-Ali, Alomran, & Azam, 2014). Yuasa, Yamakawa, Maezawa, and Kaneko (2015) found when preoperative antibiotics were used on patients undergoing a total hip arthroplasty, there was a significant reduction in the prevalence of SSIs, confirming the rationale that prophylactic antibiotic use is effective.

Data from this study aimed to reduce the gap in knowledge between hospital-based and outpatient facility-based SSI rates. This study provides baseline data on postoperative SSI rates within the outpatient setting for future research to expand upon and potentially initiate a quality improvement plan within the outpatient surgical setting. To encapsulate applicable data and help close this gap, postoperative SSI rates within an outpatient facility were examined using a retrospective, descriptive, non-probability sampling design. The research design, setting, sample, consent and data collection procedures, demographic and data collection forms, data analysis, risks and benefits, potential benefits, confidentiality protection, and expected results were thoroughly reviewed for a detailed understanding of the study methodology and goals.

Background/Significance

The knowledge of SSIs concerning operation mortality was first published in 1841 and has become a prevalent topic in healthcare today (Sabbatani et al., 2016). SSIs are those infections related to an operative procedure occurring at the site of surgical incision, tissues, muscles, or tendons under the surgical incision, the organ or body system involved in the surgery, or the implanted material or prosthetic within 30 days of the surgery or 90 days if implanted material was used such as screws, nails, plates, pins, or complete prosthetic joint (Anderson & Sexton, 2018; Centers for Disease Control and Prevention [CDC], 2012). The risk for SSI per every 100 TJAs is 0.7-2.4% for hip prothesis and 0.6-1.6% for knee prosthesis with the most common pathogens seen in research being *Staphylococcus aureus*, gram-negative bacilli, coagulase-negative staphylococci, and beta-hemolytic streptococci (Edwards et al., 2009; Trampuz & Zimmerli, 2006).

These infections can lead to increased mortality and morbidity rates, unnecessary hospital admissions, extended inpatient stays, the need for skilled nursing care, and an economic burden related to added healthcare costs (Al-Mulhim et al., 2014). SSIs are the most common postoperative complication and reasoning for a revisional surgery (Anderson et al., 2014). Eliminating or decreasing these SSI rates decreases the subjects' risk for the above hindrances. Prophylactic intravenous antibiotics, given correctly preoperatively, have demonstrated a significant decrease in SSIs in the hospital setting. The goal of antibiotic prophylaxis is the prevention of SSIs acquired from pathogens at the site of surgery which includes potential bacterial growth on the surface of orthopedic devices used during surgery.

In the United States, most research surrounding postoperative SSIs and prophylactic antimicrobial use are hospital-based with patients undergoing orthopedic procedures in the

outpatient setting going unnoticed after being sent home from the facility (Berríos-Torres et al., 2017). The total number of SSIs for outpatient patients are not accounted for as nearly 50% of them are unknown after discharge from the facility (Berríos-Torres et al., 2017). The total number of these orthopedic procedures including total joint arthroplasties is expected to increase 51% nationally by 2026 due to insurance mandates and the capability of these procedures to now be performed in an outpatient facility (Crowe, 2014). A 47% increase in outpatient TJAs occurred between 2012 to 2015, and over the next 8-10 years, a 77% growth in outpatient TJAs is expected versus only a 3% growth inpatient (Bert, Hooper, & Moen, 2017; Crowe, 2014). Due to this, a significant need for strict protocols, improved strategies, and recommendations including the use of prophylactic antibiotics to decrease postoperative SSIs in the outpatient setting.

Healthy People 2020 supports the concept of administering prophylactic antimicrobials preoperatively as their goal is that individuals live longer, better-quality lives without suffering from preventable disease, disability, injury, premature death, eliminate disparities, and create a social and physical environment promoting positive and beneficial health to all (Centers for Disease Control and Prevention [CDC], 2015). One of the Graduate Quality and Safety Education for Nurses [QSEN] (2018) competencies is quality improvement which directly correlates to necessary prophylactic antimicrobial use preoperatively (Graduate Quality and Safety Education for Nurses [QSEN], 2018).

The benefit of the antibiotic regime can present a constant challenge due to the sequence of protocols failing, adverse events occurring unexpectedly, providers being uneducated in proper antibiotic treatments, wrong antibiotics or dosages given, refusal by the patient of preoperative antibiotics, and/or nurses failing to give an ordered antibiotic due to understaffing

or exhaustion (Institute of Medicine [IOM], 2011). This can create chaos and uncertainty for the patient, family members, and healthcare team. As providers, avoiding those errors and giving prophylactic antibiotics before surgery per protocol and best practice measures will help avoid potential consequences including SSIs. Health care providers need to make decisions and proper interpretations about maintaining, changing, and implementing practice techniques according to evolving theories to avoid a potential consequence of failure, a postoperative SSI (IOM, 2011). The modern-day practitioner should have the knowledge to precisely interpret variation and increase responsiveness with apt reactions to patient outcomes (IOM, 2011).

Research Purpose

The purpose of this study was to examine postoperative SSIs for adults undergoing an orthopedic procedure in the outpatient setting who were given a prophylactic antimicrobial in the preoperative phase of surgery. Infection rates were monitored for the first 30 days post-operatively and compared to existing inpatient postoperative infection rates. The orthopedic procedure, antibiotic given, and if the patient experienced a postoperative SSI within 30 days of surgery were evaluated. Data from this study aimed to close the gap in knowledge, evidence, and research between hospital and outpatient facility-based SSI rates and if prophylactic antimicrobial use affects these rates. This posed the research question utilizing the population, intervention, comparison, outcome, and time (PICOT) format. The research question was for the adult patient undergoing an orthopedic surgical procedure at an outpatient facility, what is the effect of a preoperative prophylactic antimicrobial on postoperative surgical site infection rates within the first 30 days following surgery?

Introduction of Literature Review

The Cumulative Index to Nursing and Allied Health Literature (CINAHL) Complete, MEDLINE Complete via EBSCO, UpToDate, and DynaMed Plus database searches established literature for this review. The search terms included "prophylactic antibiotics and surgery," "preventative antibiotics and surgery," "preventative antimicrobials and surgery," "prophylactic antimicrobials and joint replacements," "preventative antimicrobials and joint replacements," "total joint arthroplasty and preventative antibiotics," "preoperative antibiotics," "preoperative prophylaxis," "outpatient preoperative antibiotics," "outpatient surgery prophylactic antibiotics," "outpatient total joint arthroplasty," "outpatient surgery," "outpatient orthopedic surgery," "ambulatory surgical center preventative antibiotics," "surgical site infections," "tracking surgical site infections," "tracking surgical site infections outpatient surgery," "surgical site infections outpatient surgery," "surgical site infections joint arthroplasty," "surgical site infection orthopedic surgery," "postoperative infection prevention," "outpatient surgery protocols," outpatient surgery infection," "antimicrobial prophylaxis," "transitions theory," and "transitions theory and surgery." For these databases, the search limitations included only those articles published in English language from 2006 to 2019. Twenty-nine articles within CINAHL, 21 articles on MEDLINE, 17 articles within UpToDate, and 7 articles within DynaMed Plus search met the criterion for inclusion. Abstracts were thoroughly examined and eliminated if not evidenced based, were only meta-analyses, had limited study participants (< 50), or presented with methodology, population, or specific setting concerns. The CDC, World Health Organization, and Google databases were also used sparingly to help define and clarify concepts for the reader, but only reliable, valid resources were applied.

After eliminating the nonapplicable articles, a complete copy of each article was obtained and reviewed. Articles were highlighted with facts that supported and would be useful for the research proposal. The main reasons certain articles were not utilized was due to wrong population or surgical procedures or not enough relevant data to support the specific PICO.

Gaps in Knowledge

Knowledge and research are lacking with postoperative infection rates at Ambulatory Surgical Centers (ASCs) as most data support hospital acquired infection rates. Most of the research surrounding SSIs are combined with other healthcare acquired infection data obtained primary from hospitals. There are a few existing SSI studies on ASC's specializing in orthopedic surgical procedures regarding definitions and infection protocols, but more evidence-based research is needed in the safe development of effective protocols for the prevention of SSI in the ASC setting (Heuer, Kossick, Riley, & Hewer, 2017).

Another gap with this research problem is that nearly 50% of outpatient SSIs go unknown following discharge from the facility (Berríos-Torres et al., 2017). SSI tracking is vital to prevent further complications and implement change but also difficult. In the outpatient setting, patients do not return to that facility for postoperative follow ups and/or management of postoperative complications, so the prevalence of SSI monitoring presents a challenge (Anderson et al., 2014). With many of the proposed guidelines to prevent SSIs, comes unresolved issues warranting a need for further research on the implementation of SSI protocols in outpatient settings. Since the implementation of antimicrobial prophylaxis, stricter infection control protocols have been put in place regarding preoperative antibiotics (Anderson et al., 2014: Centers for Disease Control and Prevention [CDC], 2018).

Consequences of the Problem

SSIs are one of most common and costly preventable hospital acquired infections leading to increased mortality and morbidity rates, hospital admittance, extended inpatient stays, skilled nursing facility care, and compounded healthcare costs (Al-Mulhim et al., 2014). Anywhere from 160,000-300,000 SSIs are documented every year in the United States with nearly 60% of them labeled preventable per evidence-based guidelines (Anderson et al., 2014). Patients that experience a SSI are found to extend their hospital stay by 7-11 days, have up to an 11 times higher risk for death, and have an increased risk for hospital readmission than those without a SSI (Anderson et al., 2014). SSIs account for nearly 75-77% of deaths of those who die following the operation, account for a mortality rate of 3%, and create a financial burden of $3.5-$10 billion on healthcare in the United States annually (Anderson et al., 2014; CDC, 2018). Infection rates are on track to triple from 2.18% to 6.8% or about 221,500 cases a year with the cost of these infections more than $1.62 billion for total knee arthroplasties alone indicating a need for modification (Berríos-Torres et al., 2017).

Antimicrobial resistance, a popular discussion in modern day healthcare, may pose a debate with preoperative prophylactic antimicrobial use. This refers to the pathogen resisting the effects of antimicrobial therapy. However, the likelihood of developing this resistance from a TJA is uncommon unless the patient is undertaking frequent procedures requiring similar antibiotics (Cohen et al., 2017). A large study performed by Cohen et al. (2017) confirmed that the use of antibiotic prophylaxis was not associated with the risk for postoperative antimicrobial resistant infections.

Proposed Solutions

The CMS Surgical Care Improvement Project (SCIP) is a national organization with a goal of reducing surgical complications including the decrease in postoperative SSIs (Heuer, Kossick, Riley, & Hewer, 2017). As of 2013, the SCIP guidelines suggest intravenous antibiotics to be administered within one hour of surgery or two hours if a quinolone or Vancomycin is given to maximize tissue and serum concentration (Heuer et al., 2017). According to Berríos-Torres et al. (2017), preoperative antimicrobial agents are to be given when indicated based on clinical practice guidelines and timed appropriately so that bactericidal concentration of the agents is established in the serum and tissues upon surgical incision initiation. The antibiotic of choice should be based on microbial characteristics such as level of expected contamination and strength of pathogen, patient characteristics such as comorbidities, allergies, and immunity, and surgical characteristics such as the type of operation, tissue and organs involved, or the need for prosthetic implantation (Anderson et al., 2014).

The recommended agent for an orthopedic procedure involving implantation of hardware is Cefazolin but if the patient has a beta-lactam allergy, Vancomycin or Clindamycin should be used as alternates with the strength of evidence to support this at the highest level (Bratzler et al, 2013). Vancomycin alone is effective at preventing deep SSIs and can reduce the chance of gram-positive pathogens and methicillin-resistant Staphylococcus aureus after a TJA or hardware implantation procedures (Tan, Springer, Ruder, Ruffolo, & Chen, 2016). If the SSI is at risk for gram-negative pathogens, an additional antibiotic such as an aminoglycoside, aztreonam, or a fluoroquinolone may be needed (Anderson & Sexton, 2018). The dosing of antibiotics varies on patient age, weight, comorbidities, length of surgery, and blood loss (Bratzler et al., 2013; de Beer et al., 2009).

Research has confirmed that healthcare facilities implementing these protocols have improved compliance with SCIP performance goals and reduced rates of SSIs (Anderson et al., 2014). Some healthcare facilities using computer-assisted support and automated reminders have improved the effective management of prophylactic antibiotics as well (Anderson et al., 2014). Compliance and surveillance monitoring with antimicrobial prophylactic protocols and postoperative monitoring of infections is critical in the avoidance of unwarranted SSIs.

S. Moessner stated one protocol his outpatient surgery facility implemented was a mandatory verbal timeout between the patient, preoperative nurse, operating room (OR) nurse, surgeon, and anesthesiologist before the patient could enter the OR to make sure all preoperative interventions, orders, and measures were accounted for (personal communication, June 7, 2018). Over his last 12 years at this facility, he has seen a reduction in surgical errors including prophylactic antibiotics since this protocol was initiated and strictly followed (S. Moessner, personal communication, June 7, 2018).

Infection control programs optimizing the policy and procedure of preoperative prophylactic antimicrobial use have proven effectiveness supported with research (Finkelstein et al., 2014). For the outpatient surgical patient, doing chart reviews of the surgeon and primary care physician documentation including International Classification of Diseases (ICD) and Current Procedural Terminology (CPT) codes monthly for the first three months postoperatively may help in the tracking and investigating of SSIs (Rhee et al., 2015). Physicians use ICD and CPT coding to classify and code diagnoses, medical problems, and procedures for billing. Direct patient phone calls made monthly for the first 90 days may also help with SSI tracking.

The use of a successful surveillance program has demonstrated importance in reducing the risk of postoperative SSIs. The CDC and Healthcare Infection Control Practices Advisory

Committee (HICPAC) has developed a new guideline in 2017 to aid in the prevention of surgical site infections in both inpatient and outpatient settings (CDC, 2018). The surgical procedure and surgical site infection whether it be superficial, deep, and/or organ/space that may have developed must be monitored for at least one month to meet requirements (CDC, 2018). The CDC and HICPAC advise post discharge surveillance is necessary to detect SSIs for outpatient procedures (2018). The use of electronic record triggering and monitoring may enable improved efforts in monitoring for postoperative SSIs after orthopedic surgeries (Menendez, Janssen, & Ring, 2016). Unfortunately, these newly mandated requirements have limited supportive research findings.

Theoretical Framework

The theoretical framework of Dr. Afaf Ibrahim Meleis' transitions theory guides this research study. Meleis' transition theory analyzes the transitional experience and care practice interventions prior to, during, and after the surgical transition to reduce risks that may negatively affect his or her health such as an SSI (Omar, 2017; Penn Nursing, n.d.). This theory first developed in the 1960's, evolved between 1970-1990's due to Meleis' shifts in theoretical thinking and research, and was officially published in 2000 (Meleis, Sawyer, Im, Messias, & Schumacher, 2000; Omar, 2017). The main concepts of the transitions' theory are types and patterns of transition, properties of the transition experience, facilitators and inhibitors of the transition, process and outcome indicators of the transition, and therapeutic nursing for successful transition (Omar, 2017). The types of transitions are developmental, health and illness, situational, and organizational with this research proposal focusing on the health and illness transition although multiple transitions happen simultaneously and overlap during the

surgical event (Meleis et al., 2000; Omar, 2017). The properties of effective transition include awareness, engagement, and change (Meleis et al., 2000; Omar, 2017).

The medical team caring for these surgical patients need to be aware and have the knowledge and recognition of the appropriate processes and policies for the patient to safely transition from the preoperative, perioperative, and the postoperative phases. Each member needs to demonstrate involvement in making sure all preoperative requirements including the ordering and administering of a prophylactic antibiotic are completed before the patient can successfully transition to the next phase of the surgical experience. If this is overlooked, the risk for a SSI during the postoperative phase increases resulting in failed transition. This can cause significant hindrances in not only the health and illness transition but also the developmental and situational transition.

Conclusion of Literature Review

With the focus on preoperative prophylactic antibiotic use in the outpatient or ASC setting for orthopedic procedures, the literature review provided an array of articles relevant to the research proposal to define key concepts, give valid and applicable statistics, support the proposal, and provide recommendations for future research and protocol implementation. After assessing the literature, gaps in knowledge solidified that research is lacking in the effective management, monitoring, and tracking of SSIs in the outpatient setting with many infections unknown (Anderson et al., 2014; Berríos-Torres et al., 2017; Heuer et al., 2017). Research confirmed that SSIs are the most common and costly preventable infection accounting for an increase in mortality, hospitalizations, and financial burden validating that SSIs pose an immense consequence for the patient and healthcare team (Anderson et al., 2014; Berríos-Torres et al., 2017). Antimicrobial resistance is not an associated risk regarding prophylactic antimicrobials

preoperatively (Cohen, 2017). The proposed solutions focused on methods that have proven to be effective such as the administration of the correct dose, strength, and timing of intravenous antibiotics per SCIP guidelines, implementation of stricter protocols within outpatient settings including computer assisted programs and reminders, verbal timeouts prior to surgery, employing infection control programs to perform chart reviews and patient phone calls, and surveillance programs in the outpatient setting (Anderson et al., 2014; Anderson & Sexton, 2018; Berríos-Torres et al., 2017; Bratzler et al., 2013; CDC, 2018; de Beer et al., 2009; Finkelstein et al., 2014; Heuer et al., 2017; Rhee et al., 2015; S. Moessner, personal communication, June 7, 2018; Tan et al., 2016). Theories were explored and the theoretical framework of Dr. Afaf Ibrahim Meleis' transitions theory was most pertinent for the research study (Meleis et al., 2000; Omar, 2017).

Methodology

Research Design

The researcher used a retrospective, descriptive, non-probability sampling study design. With retrospective studies, the results have already occurred at the time the study has commenced with the goal being to study a specific outcome (surgical site infections), promptly estimate the effect of a certain exposure (use of prophylactic antimicrobials) on an outcome (post-operative surgical site infections) or obtain preliminary measures of association (The National EMSC Data Analysis Resource Center [NEDARC], 2016b). The researcher performs chart reviews and/or examines medical records to obtain needed data about events that have already happened (NEDARC, 2016b). With this data, the researcher can then convey associations and consider potential relationships between variables (NEDARC, 2016b). The

participants included within this study already had a known condition, in this case, the need for an orthopedic surgery.

With a descriptive study, the goal was to assess a population at a specific point of time with a goal being to identify areas needed for future research, to aid in the planning of resource provision, and/or provide valuable information about a certain condition (The National EMSC Data Analysis Resource Center [NEDARC], 2016a). All these goals are consistent with the study methodology, and study participants were studied at a specific point of time.

The population includes adults age 19 or older who underwent an orthopedic procedure at this facility between January 1, 2019-April 30, 2019 (per orthopedic surgeon discretion of preoperative antimicrobial use). The independent variable for the study was prophylactic antimicrobial administration in the direct preoperative area. The dependent variable for the study was postoperative surgical site infection rates.

Setting

The research was a single-site study conducted at an outpatient surgical facility where varying orthopedic procedures are performed. This outpatient facility was a physician owned, Medicare certified, and state licensed Ambulatory Surgical Center (ASC) with specialties focused on orthopedics, pain management, ear, nose, and throat, podiatry, and plastic surgery. The orthopedic surgeons entered their surgical documentation into the facility database.

Sample

For this study, participants were part of the study because they just happened to be situated or had a procedure performed where the researcher obtained data during the study dates. This plan supports convenience sampling criteria (Etikan, Musa, & Alkassim, 2016). Inclusion of participants were dependent on the orthopedic surgeon discretion; the patient, surgery, and if

an antibiotic was administered. The number of anticipated participants was determined to be at least 40, dependent on approval and study start dates. Specific criteria for subject inclusion was:

a. an adult 19 year of age or older, male or female

b. any nationality, race, ethnicity, or culture,

c. any educational level,

d. any socioeconomic status,

e. no history or current diagnosis of an infection either at the site of surgery or elsewhere,

f. no history of or current methicillin-resistant staphylococcus aureus (MRSA) infection,

g. underwent an orthopedic surgical procedure by one of the orthopedic surgeons at the outpatient facility, and

h. received an antimicrobial in the direct preoperative area within one hour of incision time.

Specific criteria for subject exclusion was:

a. an adult under the age of 19, male or female,

b. a specified nationality, race, ethnicity or culture;

c. a specified educational level,

d. a specified socioeconomic status,

e. a current diagnosis of an infection either at the site of surgery or elsewhere,

f. a history of or current methicillin-resistant staphylococcus aureus (MRSA) infection, or

g. did not undergo an orthopedic surgical procedure by one of the orthopedic surgeons at the outpatient facility, and

h. did not receive a prophylactic antimicrobial in the direct preoperative area within one hour of incision.

Steps to Protect Confidentiality and Privacy

The researcher successfully completed the Collaborative Institutional Training Initiative (CITI) Certification (See Appendix C) prior to study commencement. Each subject was assigned a research code number (001, 002, 003, etc.) with only his or her medical record number documented next to the coded number (Form 1). Next to each research code, the corresponding orthopedic procedure, antibiotic given and dose, and if the individual experienced a post-op infection within 30 days post-op was written down (Form 2). Neither of these forms had any personal identifying information included.

As mentioned earlier, the researcher utilized a private office within the surgery center facility where the door remained closed at all times during data collection to decrease risk of exposure of the study data. This private office provided computer access to gather information needed only for participants that met inclusion criteria to complete the study to reduce any breaches in confidentiality. Study data was secured in a locked cabinet within the private office and only accessed by the researcher. The researcher did not have any subject identifying information taken home as the data collection form utilized outside the facility only contained the participants research code numbers. Due to this, the researcher was able to communicate about subjects by their coded number outside of the facility to further protect them when research analyzation and paper generating was performed outside the facility. During the data collection process, the data collection forms were kept in a safe cabinet within the private office

that remained locked and only accessed by the researcher. The researcher kept her nursing employment and researcher duties separate to avoid Health Insurance Portability and Accountability Act (HIPAA) violations that could have led to legal conflicts.

Waiver of Consent

Direct consent for study participation was not needed as all subjects signed a surgical consent stating that their information may be used for research purposes without exposure of personal identifiers or protected health information. Each subject, again, was identified by a research code number for analysis.

A waiver of consent was obtained from the institutional review board. With a waiver of consent, there is a desire to avoid written documentation linking the study subject to the research study with an adequate plan to protect subject health information identifiers from misuse or disclosure (U.S. Food & Drug Administration [FDA], 2017). This was congruent with this study protocol. According to the FDA (2017), a waiver of informed consent is permitted if the study involves little to no risk to the subjects, will not adversely affect the rights and well-being of the subjects, could not feasibly be performed without the waiver, and subjects would be notified as needed with any pertinent information the study results may validate.

Data

Data Collection

After obtaining successful approval from the business administrative manager at the outpatient surgical facility and Clarkson College Institutional Review Board (IRB) to perform the study, the study commenced (See Appendix A). There was no recruitment of subjects to the study as every individual who underwent an orthopedic procedure performed between January 1, 2019, and April 30, 2019, and who met the qualifying, inclusion criteria were included. Access

to the sample was then obtained via chart reviews following the orthopedic surgeon documentation inclusive of a current diagnosis of an infection either at the site of surgery or elsewhere, any history of or current methicillin-resistant staphylococcus aureus (MRSA) infection, the type of orthopedic procedure performed, antibiotic given, and if a post-operative infection occurred within 30 days post-operatively. There were two data collection forms:

a. Master Code List included the subjects medical record number with an assigned research code.

b. Data Collection Form (Appendix B) listed each subject by their research code such as 001, 002, 003, etc. Next to each research code number, the corresponding type of orthopedic procedure, antibiotic given (name/dose), and if the research participant experienced a post-op infection within 30 days post-op (yes/no) was documented. The orthopedic procedures and antibiotics given were then categorized for evaluation.

Only the researcher knew the medical record number correlating to the research code number. A 30-day phone call and/or subject visit occurred by the surgeons or their nurses at the clinic to assess for postoperative SSIs. This was documented within the medical outpatient surgical facility database record and reviewed by researcher. At the end of the study, the data collection forms were analyzed with appropriate statistics.

Data Analysis

The data collected included the orthopedic procedure performed, antibiotic given, and if a postoperative infection occurred 30 days after surgery via a chart review during the study dates. Statistical Package for Social Sciences (SPSS) was used for effective data analysis. Descriptive statistics was utilized to identify common trends, make summarizations, organize data results,

and visualize data in table and/or graph format. Percentages of the overall SSI rates was calculated. Frequencies and percentages were also calculated for the type of antibiotic given.

Distribution and Disposal of Data Collected

The data collected was recorded, analyzed, and assimilated into a research paper for the purpose of the researcher's completion of the evidence-based practice project to obtain the Master of Science in Nursing degree through Clarkson College. The results were shared with Clarkson College peers, fellow students, and the team at the outpatient surgical facility. The project was presented at the Graduate Capstone Symposium prior to graduation. The research study may be published within a peer-review journal related to orthopedics.

The researcher plans presentations to the orthopedic surgeons at the next quarterly meeting following completion of the study via a power point with all statistics, graphs, and tables all visible. Statistical comparison includes data studied within the hospital setting. The study results could potentially initiate a quality improvement program at the facility. The study results could lead to the future development of evidence-based protocols or recommendations for outpatient facilities regarding prophylactic antimicrobial use to decrease infection rates. Ultimately, the benefit for the subjects was to decrease preventable, unwarranted postoperative SSIs within the outpatient surgical facility and effectively track SSIs following discharge from the facility.

Potential Psychological, Social, Economic, Ethical, or Legal Risks

Due to the study design, it imposed minimal to no potential psychological, social, economic, or legal risks to all participants. The subjects involved in the study were scheduled for the orthopedic procedure for treatment purposes. They were not recruited strictly for study purposes with treatment and control groups which could have led to potential harm. There were

no undesired or unexpected changes in psychological processes or emotions grounded solely on the study as the subjects underwent the same surgical procedure and process with or without the researcher overseeing it. There were no social or economic stigma or labeling of the subjects due to the data collection and analyzation process. The confidentiality safeguarded the subjects to minimize the legal risks.

The potential of harm or discomfort within this study design was little to none. The study presented no increase in risk than an average, healthy individual would expect to encounter on any typical, given day (Clarkson College Institutional Review Board [IRB], 2018). The data collection and monitoring plan incorporated adequate precautions and practices protecting the confidentiality of subject data via sufficient research coding methods. The researcher utilized a private office within the surgery center facility where the door remained closed at all times during data collection to decrease risk of exposure to study data. This private office provided computer access to gather information needed only for participants that meet inclusion criteria to complete the study. The researcher kept nursing employment and researcher duties separate to avoid Health Insurance Portability and Accountability Act (HIPAA) violations that could have led to legal conflicts.

Standard of care for orthopedic procedures was the focus of the study with all subjects receiving prophylactic treatment as ordered by surgeon to avoid unnecessary risks (i.e. There will no one group that receives prophylactic antibiotic and one that does not).

Benefits of the Study

Benefits to the Subjects

Postoperative SSIs lead to increased mortality and morbidity rates, unnecessary hospital admissions, extended inpatient stays, the need for skilled nursing care, and an economic burden

related to added healthcare costs (Al-Mulhim et al., 2014). Eliminating or decreasing SSI rates decreases the subjects' risk for the above hindrances. The study results aimed to develop evidence-based protocols for outpatient facilities regarding prophylactic antimicrobial use to decrease infection rates. The results demonstrated that antimicrobial use may not be beneficial for certain procedures as the surgery being performed was included on the data collection form. With the name of antibiotics recorded on the data collection form, the study aimed to differentiate between the actual antibiotic given prior to surgery. Ultimately, the benefit for the subjects decrease preventable, unwarranted postoperative SSIs within the outpatient surgical facility.

Benefits to Society

This study provides advanced evidence as a basis for clinical recommendations regarding the use of prophylactic antibiotics in the preoperative phase before an orthopedic procedure. The study findings potentially impact future clinical guidelines and practice techniques for outpatient surgical facilities regarding antimicrobial use in the preoperative phase of an orthopedic procedure. This study serves as a foundation for future studies that involve specific focus on the varying types of outpatient procedures, the age of subjects, specific comorbidities the subjects possess, the actual antibiotic given, the exact timing, dose, and route of antibiotics given, if the antibiotic was completely infused prior to tourniquet inflation, the incision cut time in relation to the antibiotic administration time, the length of surgery, if redosing of an antimicrobial was needed during or after surgery, and/or if an infection was suspected during surgery, all in relation to postoperative SSIs.

Decreasing SSI rates can decrease overall healthcare costs which prominently impact society. SSIs are one of most common and costly preventable acquired infections with most

research concentrated within the hospital setting (Al-Mulhim et al., 2014). SSIs account for nearly 77% of deaths of those who die following the operation and create a financial burden of $3.5-$10 billion on healthcare in the United States annually (Anderson et al., 2014). Those are just the observed, reported, and documented SSIs typically within the hospital setting whereas those in the outpatient facility are rarely accounted for in the literature.

Discussion of Findings

Of the 149 orthopedic cases performed at the outpatient surgical facility between January 1, 2019-April 30, 2019, 103 patients met the inclusion criteria for the study. Only 1 (0.01%) surgical site infection was reported and documented out of the 103 cases. This means 99.9% of the orthopedic procedures performed at the outpatient facility who had a preoperative prophylactic antimicrobial given did not experience a surgical site infection within 30-days post-operatively. This data was based on both follow up appointments and 30-day post-operative phone calls made by the surgeon and documented in the chart. The 30-day post-operative phone call confirmed that the patient was having no signs or symptoms of a SSI and that they did not see any other provider for a SSI within the 30-days.

The full list of orthopedic procedures performed, and the antimicrobial given can be found in Appendix B. The antimicrobials given were Cefazolin 1 gram (36 subjects), Cefazolin 2 grams (54 subjects), Clindamycin 600mg (6 subjects), Clindamycin 900mg (3 subjects), Vancomycin 1 gram (3 subjects), and Rocephin 1 gram (1 subject). The dose of Cefazolin and Clindamycin was based on weight with Cefazolin 1 gram or Clindamycin 600mg given to those individuals weighing < 180lbs and Cefazolin 2 grams or Clindamycin 900mg given to those patients weighing ≥ 180lbs per facility policy.

The one surgical site infection reported and documented was a Left Ankle Hardware Removal with Debridement and Wound Closure who was given Rocephin 1 gram IV prophylactically in the preoperative phase of surgery. No documented infection prior to the surgery per the surgeon report was indicated. This was the only subject within the study that received this antimicrobial. Recommendations do not consider the use of Rocephin preoperatively for orthopedic procedures in the prevention of SSIs (*DynaMed Plus,* 2019). No SSIs were documented for those subjects who received Ancef, Clindamycin, or Vancomycin preoperatively. The other 102 subjects involved in the study who had various orthopedic procedures as listed in Appendix B did not experience a post-operative SSI within 30-days of the surgery.

Per *DynaMed Plus* (2019), current guidelines indicate prophylactic antimicrobials are not needed for clean orthopedic procedures of the hand, knee, or foot that require no involvement of prosthetic or foreign material insertion. Antimicrobials are recommended for spinal procedures with and without instrumentation, hip fracture repairs, implantation of internal fixation devices, and total joint arthroplasties (*DynaMed Plus*¸2019). Antimicrobials should be given preoperatively for procedures with clean-contaminated, contaminated, or dirty/infected surgical wounds or procedures that are clean but require insertion of prosthetic material (*DynaMed Plus*, 2019). The recommended antimicrobial regime is Cefazolin 2 grams intravenously for individuals < 120kg and 3 grams intravenously for those ≥ 120 kg given in a single dose within 60 minutes of the surgical incision (*DynaMed Plus,* 2019). If the patient has an allergy or sensitivity to beta-lactams, Clindamycin 900mg intravenously within 60 minutes of the surgical incision or Vancomycin 15mg/kg intravenously within 120 minutes of the surgical incision may be used (*DynaMed Plus,* 2019).

Conclusions, Application to Practice, and Limitations

Preoperative prophylactic antimicrobials significantly influence post-operative surgical site infection rates in the outpatient setting. Results from this study demonstrated that patients who received a prophylactic antimicrobial prior to an outpatient procedure had little to no risk for a post-operative SSI. Only one SSI was accounted for with this subject receiving a pre-operative prophylactic antimicrobial not supported by current guidelines for orthopedic procedures. This was the only subject within the study that received this antimicrobial which serves as a limitation as there were no other subjects receiving this antimicrobial to compare results. Effective monitoring of these SSIs was exhibited via direct observation of the surgical site in the office or a phone call at the 30-day post-operative point to determine if a post-operative SSI was or had been present. These findings support a recommendation for outpatient post-operative SSI monitoring in that the surgeon needs to monitor patients at or near the 30-day post-operative time or provide a courtesy phone call to assess and monitor for a SSI.

One of the goals of this study was to close the gap in knowledge, evidence, and research between hospital and outpatient facility-based SSI rates and if prophylactic antimicrobial use affected these rates. The results from this research alleviated and fulfilled aspects of this gap in knowledge and evidence within the outpatient surgical facility. However, this study served as a basis for future, more advanced research to be manifested within outpatient surgical centers to further close this gap. Future research recommendations include comparing infection rates of subjects who did and did not receive administration of a preoperative prophylactic antimicrobial, comparing different age categories, determining if various comorbidities such as those with diabetes, heart disease, arterial or vascular deficiencies, chronic obstructive pulmonary disease, or those who are immunocompromised affected infection rates, or examining outpatient

procedures separate from the orthopedic focus. Infection rates between those subjects who were given a preoperative antimicrobial versus those who did not for the same procedures could lead to the reduction of unnecessary antimicrobial administration depending on results. The inclusion and exclusion criteria could be varied in future studies to expand on outpatient surgical research. Future studies of this nature could close the gap between inpatient and outpatient post-operative surgical site infection rates and monitoring following discharge.

Research from this study is beneficial to both patients undergoing an orthopedic procedure in the outpatient facility and healthcare providers involved with orthopedic procedures in the outpatient setting. Results can positively reduce anxiety levels for those unsure about having various orthopedic procedures done in the outpatient setting and for those nervous about post-operative complications including SSIs. Results from this study could initiate quality improvement programs or preoperative prophylactic recommendations within ambulatory surgical centers regarding type, strength, and time of antibiotic given and procedure performed. Results could be used as a reference when surgeons choose to opt out of ordering preoperative prophylactic antimicrobials. The results boosted confidence levels with surgeons in that they are providing evidence-based care and achieving significantly positive surgical outcomes for their patients.

One limitation of the study was that data was gathered from only one remote outpatient surgical facility with the team of orthopedic surgeons typically following similar protocol and rationale for prophylactic antimicrobials. At this outpatient facility, the anesthesiologists thoroughly evaluate each patient pre-operatively to ensure the patient is an appropriate candidate for outpatient surgery based on his or her medical history and past surgical experiences. This is a stand-alone facility so patients with a complex, multifaceted medical history are not accepted as

surgical patients due to their risk for intra-operative or post-operative complications. Therefore, this study consisted of relatively healthy patients considered low to minimal risk of post-operative complications including SSIs. This could potentially skew results which is why recommendations for future research including those patients with complex medical histories was indicated.

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Appendix A: Approval Letters

Appendix B: Data Collection Form

Appendix C: CITI Certification and Score Sheets

Appendix A: Approval Letters

101 South 42 St. Omaha, NE 68131-2739 PH 402 552 3100 TF 800 647 5500

Clarkson College
Prepare to be the best.

January 22, 2019

Principal Investigator: Jane Langemeier, Ph.D., R.N.
Co-Investigator: Ashlie Zima, R.N, B.S.N
Clarkson College

Dear Dr. Langemeier:

Clarkson College's Institutional Review Board office has received and reviewed your application for exempt review of the quality improvement, evidence-based practice class research project "Outpatient Preoperative Prophylactic Antimicrobial Use and Surgical Site Infection Rates." The Clarkson College IRB office assigned #2019.01.03 to the exempted application.

Please add the words "This project has been exempted from full-board review by the Clarkson College Institutional Review Board as IRB #2019.01.03" (as applicable).

Best wishes on the successful completion of this study. If for some unforeseen reason the project extends beyond one year, you will need to complete additional paperwork to the IRB office.

Please feel free to contact us if you have any questions regarding the process or need any other assistance from Clarkson College's IRB office in the future.

Sincerely,

Patricia Brennan, Ph.D.
IRB Chair
Clarkson College

101 South 42 St. Omaha, NE 68131-2739 PH 402 552 3100 TF 800 647 5500

Clarkson College
Prepare to be the best.

11/01/18

Ashlie Zima
Master of Science in Nursing Student
Clarkson College
101 South 42nd Street
Omaha, Ne 68131

Greetings Ashlie,

The Medical Director, Human Resources Administrator, and Orthopedic Surgeons at Outpatient Surgical Specialties Center (OSSC) give full permission for you to perform your Graduate Evidence-Based Practice Research Project for your Master of Science in Nursing Degree through Clarkson College at our facility. We look forward to learning the results of the study findings to potentially improve practice methods at OSSC.

Sincerely,

Leah Eppenbach
Human Resources Administrator

Appendix B: Data Collection Form

Data Collection Form

Research Code Number	Current diagnosis of an infection either at the site of surgery or elsewhere (yes/no)	Any history of or current methicillin-resistant staphylococcus aureus (MRSA) infection (yes/no)	Orthopedic Procedure (Type)	Antibiotic Given (Name/Dose)	Postoperative Surgical Site Infection Within 30 days of Surgery (Yes/No)
001	no	no	ORIF of Patella with Patellectomy	Cefazolin 1g	No
002	no	no	ORIF Left Patella	Clindamycin 600mg	No
003	no	no	ORIF Left Ankle (with hardware)	Cefazolin 1g	No
004	no	no	Left Knee Arthroscopy with Tibial Osteotomy and Arthroscopy (with hardware)	Cefazolin 1g	No
005	no	no	ORIF Right Ankle (with hardware)	Clindamycin 600mg	No
006	no	no	Left Long Finger Amputation	Cefazolin 2g	No
007	no	no	Left Thumb Ganglion Cyst Excision	Cefazolin 2g	No
008	no	no	Right Wrist Scaphoid Excision and Right Carpal Tunnel Release	Cefazolin 2g	No
009	no	no	Percutaneous Skeletal Fixation of Unstable Phalangeal Shaft Fracture, Middle Phalanx	Cefazolin 1g	No
010	no	no	Synovial Cyst Removal of Left Forearm	Clindamycin 600mg	No
011	no	no	Right Carpal Tunnel Release	Cefazolin 2g	No
012	no	no	Left Knee Arthroscopy	Cefazolin 2g	No
013	no	no	Right Knee Arthroscopy	Cefazolin 2g	No
014	no	no	Right Shoulder Arthroscopy with Rotator Cuff Repair	Cefazolin 2g	No
015	no	no	Left Knee Arthroscopy and Synovectomy	Cefazolin 2g	No
016	no	no	Right Knee Arthroscopy	Cefazolin 2g	No
017	no	no	Right Knee Arthroscopy	Cefazolin 2g	No
018	no	no	Right Carpal Tunnel Release, Right Ulnar Nerve Transposition	Vancomycin 1g	No
019	no	no	Left Shoulder Arthroscopy with Debridement and Labral Repair	Cefazolin 2g	No
020	no	no	Right Carpal Tunnel Release and Right shoulder Arthroscopy	Vancomycin 1g	No
021	no	no	Arthroplasty, Interposition, Intercarpal Joints, with Tendon Transfer	Vancomycin 1g	No

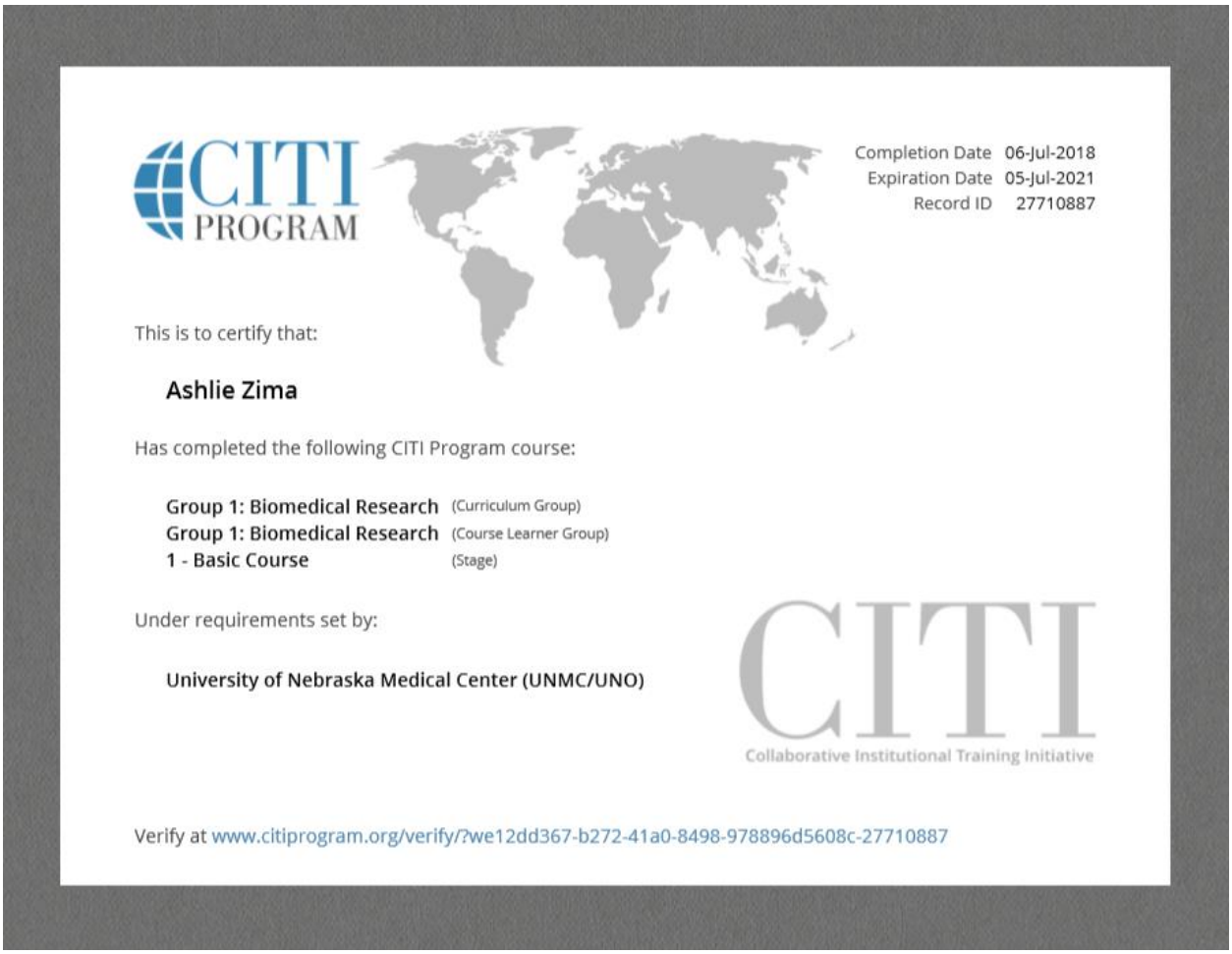
022	no	no	ORIF Radial Head of Elbow Fracture (with hardware)	Clindamycin 600mg	No
023	no	no	External Fixation System Application of Distal Radial Wrist Fracture (with hardware)	Cefazolin 2g	No
024	no	no	ORIF Right Ankle (with hardware)	Clindamycin 900mg	No
025	no	no	Left Achilles Tendon Repair	Cefazolin 1g	No
026	no	no	Meniscus Cyst Removal of Left Knee	Cefazolin 2g	No
027	no	no	Flexor Tendon Release of Right Long and Index Fingers	Cefazolin 1g	No
028	no	no	ORIF Left Distal Radius (with hardware)	Cefazolin 1g	No
029	no	no	Right Carpal Tunnel Release and Right First Dorsal Extensor Compartment Release	Cefazolin 2g	No
030	no	no	Left Carpal Tunnel Release	Cefazolin 2g	No
031	no	no	Tendon Transfer of Carpometacarpal Joints to Left Hand	Cefazolin 1g	No
032	no	no	Left Shoulder Arthroscopy with Rotator Cuff Repair (with hardware)	Cefazolin 2g	No
033	no	no	Right Shoulder Arthroscopy with Rotator Cuff Repair (with hardware)	Cefazolin 2g	No
034	no	no	Left Knee Arthroscopy	Clindamycin 900mg	No
035	no	no	Right Shoulder Arthroscopy with Surgical Debridement (with hardware)	Cefazolin 2g	No
036	no	no	Right Thumb Carpometacarpal Suspension Arthroplasty with Tendon Transfer	Cefazolin 1g	No
037	no	no	Right Thumb Metacarpophalangeal Arthrodesis (with hardware)	Cefazolin 1g	No
038	no	no	Left Knee Arthroscopy	Cefazolin 2g	No
039	no	no	Left Knee Arthroscopy with ACL Reconstruction	Cefazolin 1g	No
040	no	no	Right Knee Arthroscopy	Cefazolin 1g	No
041	no	no	ORIF Left Ankle (with hardware)	Cefazolin 2g	No
042	no	no	Left Knee Arthroscopy	Cefazolin 1g	No
043	no	no	Left Knee Arthroscopy	Cefazolin 2g	No
044	no	no	Left Wrist Arthroscopy with Triangular Fibrocartilage Complex Repair	Cefazolin 2g	No
045	no	no	Closed reduction Percutaneous Pinning of Right Small Finger Proximal Phalanx	Cefazolin 1g	No
046	no	no	Right Carpal Tunnel Release	Cefazolin 2g	No
047	no	no	Percutaneous Pinning Right Ring Finger Intermediate Phalanx	Cefazolin 2g	No

048	no	no	Right Ulnar Nerve Decompression with Anterior Transposition	Clindamycin 900mg	No
049	no	no	Left Knee Arthroscopy	Cefazolin 2g	No
050	no	no	Left Knee Arthroscopy with Removal of Loose Body	Cefazolin 2g	No
051	no	no	Right Knee Arthroscopy	Cefazolin 2g	No
052	no	no	Left Carpal Tunnel Release	Cefazolin 2g	No
053	no	no	ORIF Right Patella (with hardware)	Cefazolin 2g	No
054	no	no	Suture of Infrapatellar Tendon (with hardware)	Cefazolin 2g	No
055	no	no	Right Shoulder Arthroscopy with Rotator Cuff Repair and Debridement (with hardware)	Cefazolin 2g	No
056	no	no	Left Ankle Hardware Removal with Debridement	Rocephin 1g	Yes
057	no	no	Left Knee Arthroscopy with Proximal Tibial Osteotomy (with hardware)	Cefazolin 1g	No
058	no	no	Left Wrist Volar Cyst Excision	Cefazolin 2g	No
059	no	no	Left Knee Arthroscopy	Cefazolin 2g	No
060	no	no	Right Knee Arthroscopy	Cefazolin 2g	No
061	no	no	Left Foot Neuroma Excision/Arthrocentesis	Cefazolin 1g	No
062	no	no	Right Knee Arthroscopy	Cefazolin 1g	No
063	no	no	Removal of Hardware Right Ankle and Excision of Tumor to Right Ankle	Cefazolin 1g	No
064	no	no	Right Thumb Carpometacarpal Suspension Arthroplasty and Right Carpal Tunnel Release	Cefazolin 1g	No
065	no	no	Neuroplasty of Major Peripheral Nerve to Right Arm	Cefazolin 2g	No
066	no	no	Right Ring Finger Radial Collateral Ligament Repair (with hardware)	Cefazolin 1g	No
067	no	no	Right Shoulder Arthroscopy with Labral Repair (with hardware)	Cefazolin 1g	No
068	no	no	Left Thumb Carpometacarpal Suspension Arthroplasty with Tendon Transfer	Cefazolin 2g	No
069	no	no	Left Knee Arthroscopy with ACL Reconstruction	Cefazolin 1g	No
070	no	no	Left Knee Arthroscopy	Cefazolin 2g	No
071	no	no	ORIF of Distal Intra-articular Fracture of Left Distal Tibia (with hardware)	Cefazolin 2g	No
072	no	no	ORIF of Right Bimalleolar Ankle Fracture (with hardware)	Cefazolin 2g	No

073	no	no	Right Distal Bicep Repair (with hardware)	Cefazolin 2g	No
074	no	no	ORIF of Left Metatarsal Fracture (with hardware)	Cefazolin 1g	No
075	no	no	Left Knee Arthroscopy with ACL Reconstruction (with hardware)	Cefazolin 2g	No
076	no	no	Left Knee Arthroscopy	Cefazolin 2g	No
077	no	no	Right Knee Arthroscopy with ACL Reconstruction (with hardware)	Cefazolin 1g	No
078	no	no	Right Femur Hardware Removal	Clindamycin 600mg	No
079	no	no	Right Index, Long, and Ring Finger Pulley Releases	Cefazolin 1g	No
080	no	no	Left Shoulder Arthroscopy with Surgical Capsolorraphy (with hardware)	Cefazolin 2g	No
081	no	no	ORIF Left Ring Metacarpal (with hardware)	Cefazolin 2g	No
082	no	no	Right Carpal Tunnel Release	Cefazolin 2g	No
083	no	no	ORIF Right Trimalleolar Ankle Fracture Repair (with hardware)	Cefazolin 2g	No
084	no	no	Right Ankle Irrigation and Debridement with Wound Closure	Cefazolin 2g	Yes
085	no	no	Right Shoulder Arthroscopy with Rotator Cuff Repair (with hardware)	Cefazolin 1g	No
086	no	no	Right Knee Arthroscopy with ACL Reconstruction (with hardware)	Cefazolin 2g	No
087	no	no	Right Knee Arthroscopy	Cefazolin 2g	No
088	no	no	Right Long, Ring, Little, and Palmar Fasciectomy	Cefazolin 1g	No
089	no	no	Right Ulnar Nerve Release at Elbow	Cefazolin 2g	No
090	no	no	Corrective Osteotomy (with hardware)	Cefazolin 1g	No
091	no	no	Right Thumb Carpometacarpal Suspension Arthroplasty with Tendon Graft	Cefazolin 1g	No
092	no	no	Right Thumb Carpometacarpal Suspension Arthroplasty and Right Thumb Flexor Tendon Pulley Release	Cefazolin 1g	No
093	no	no	Palmar Fasciectomy with Tendon Transposition	Cefazolin 1g	No
094	no	no	Incision Right and Left Thumbs Flexor Sheaths	Cefazolin 1g	No
095	no	no	ORIF Distal Phalangeal Fracture	Cefazolin 1g	No
096	no	no	ORIF Right Ring Metacarpal and Percutaneous Skeletal Fixation Metacarpal Fracture (with hardware)	Cefazolin 2g	No
097	no	no	ORIF Distal Phalangeal Fracture	Cefazolin 1g	No

098	no	no	ORIF Right Ring Finger Versus Amputation (with hardware)	Clindamycin 600mg	No
099	no	no	Right Carpal Tunnel Release	Cefazolin 2g	No
100	no	no	Capsulodesis, Metacarpophalangeal Joint Single Digit Repair (with hardware)	Cefazolin 1g	No
101	no	no	Right Shoulder Arthroscopy with Rotator Cuff Repair	Cefazolin 1g	No
102	no	no	Right Knee Arthroscopy with ACL Reconstruction (with hardware)	Cefazolin 2g	No
103	no	no	Right Knee Arthroscopy	Cefazolin 2g	No

Appendix C: CITI Certification and Score Sheets



CITI PROGRAM

Completion Date 06-Jul-2018
Expiration Date 05-Jul-2021
Record ID 27710887

This is to certify that:

Ashlie Zima

Has completed the following CITI Program course:

Group 1: Biomedical Research (Curriculum Group)
Group 1: Biomedical Research (Course Learner Group)
1 - Basic Course (Stage)

Under requirements set by:

University of Nebraska Medical Center (UNMC/UNO)

CITI
Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?we12dd367-b272-41a0-8498-978896d5608c-27710887

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 1 OF 2
COURSEWORK REQUIREMENTS*

* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- **Name:** Ashlie Zima (ID: 7267464)
- **Institution Affiliation:** University of Nebraska Medical Center (UNMC/UNO) (ID: 417)
- **Institution Email:** Zima.Ashlie@clarksoncollege.edu
- **Institution Unit:** Student
- **Phone:** 4026412532

- **Curriculum Group:** Group 1: Biomedical Research
- **Course Learner Group:** Same as Curriculum Group
- **Stage:** Stage 1 - Basic Course

- **Record ID:** 27710887
- **Completion Date:** 06-Jul-2018
- **Expiration Date:** 05-Jul-2021
- **Minimum Passing:** 75
- **Reported Score*:** 98

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
Belmont Report and Its Principles (ID: 1127)	02-Jul-2018	3/3 (100%)
Avoiding Group Harms - U.S. Research Perspectives (ID: 14080)	02-Jul-2018	3/3 (100%)
Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research (ID: 14777)	02-Jul-2018	5/5 (100%)
Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)	05-Jul-2018	5/5 (100%)
Conflicts of Interest in Human Subjects Research (ID: 17464)	05-Jul-2018	4/5 (80%)
Informed Consent (ID: 3)	05-Jul-2018	5/5 (100%)
History and Ethics of Human Subjects Research (ID: 498)	05-Jul-2018	7/7 (100%)
Social and Behavioral Research (SBR) for Biomedical Researchers (ID: 4)	05-Jul-2018	4/4 (100%)
Records-Based Research (ID: 5)	06-Jul-2018	3/3 (100%)
Genetic Research in Human Populations (ID: 6)	06-Jul-2018	5/5 (100%)
Research and HIPAA Privacy Protections (ID: 14)	06-Jul-2018	5/5 (100%)
Cultural Competence in Research Training Module (ID: 14350)	06-Jul-2018	5/5 (100%)

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

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COMPLETION REPORT - PART 2 OF 2
COURSEWORK TRANSCRIPT**

** NOTE: Scores on this Transcript Report reflect the most current quiz completions, including quizzes on optional (supplemental) elements of the course. See list below for details. See separate Requirements Report for the reported scores at the time all requirements for the course were met.

- **Name:** Ashlie Zima (ID: 7267464)
- **Institution Affiliation:** University of Nebraska Medical Center (UNMC/UNO) (ID: 417)
- **Institution Email:** Zima.Ashlie@clarksoncollege.edu
- **Institution Unit:** Student
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- **Curriculum Group:** Group 1: Biomedical Research
- **Course Learner Group:** Same as Curriculum Group
- **Stage:** Stage 1 - Basic Course

- **Record ID:** 27710887
- **Report Date:** 06-Jul-2018
- **Current Score**:** 98

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
History and Ethics of Human Subjects Research (ID: 498)	05-Jul-2018	7/7 (100%)
Informed Consent (ID: 3)	05-Jul-2018	5/5 (100%)
Social and Behavioral Research (SBR) for Biomedical Researchers (ID: 4)	05-Jul-2018	4/4 (100%)
Belmont Report and Its Principles (ID: 1127)	02-Jul-2018	3/3 (100%)
Records-Based Research (ID: 5)	06-Jul-2018	3/3 (100%)
Genetic Research in Human Populations (ID: 6)	06-Jul-2018	5/5 (100%)
Research and HIPAA Privacy Protections (ID: 14)	06-Jul-2018	5/5 (100%)
Avoiding Group Harms - U.S. Research Perspectives (ID: 14080)	02-Jul-2018	3/3 (100%)
Cultural Competence in Research Training Module (ID: 14350)	06-Jul-2018	5/5 (100%)
Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research (ID: 14777)	02-Jul-2018	5/5 (100%)
Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)	05-Jul-2018	5/5 (100%)
Conflicts of Interest in Human Subjects Research (ID: 17464)	05-Jul-2018	4/5 (80%)

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