A. Project Title: *Surgical Resident and Staff Engagement in Quality Improvement Related to Surgical Site Infections: The Effect of Real-Time Feedback*

Description of project goals: Surgical site infections (SSIs) contribute to significant morbidity and at times mortality in patients. SSI reduction has been identified as a significant focus of quality improvement (QI) programs for several years. US Department of Health and Human Services (HHS) has established a national prevention target to reduce SSI by 25% by December 31, 2013.[1] However, our current QI efforts have not reached desired goals (Figure 1). CDC's National Health Safety Network (NHSN) data shows a 10% reduction in SSI nationally at the end of the year 2010.[2] Surgical curricula with a QI focus have been described in the literature, but those related to involvement of residents in SSI prevention strategies have not been specifically described.[3,4] Indeed, among all the outstanding educational activities for the residency and fellowship programs in the surgical departments, quality improvement education related to SSI prevention is lacking. It is our intent to focus on QI in SSIs, engaging surgical residents through education in this process. We propose to provide real-time SSI data and integrate infection prevention experts into resident and medical staff education within the surgical departments. We believe these multidisciplinary teams, using this real-time data, can develop prevention strategies ultimately leading to reduction in SSI. The proposed studies will have the following objectives and hypotheses to meet the overall objectives:

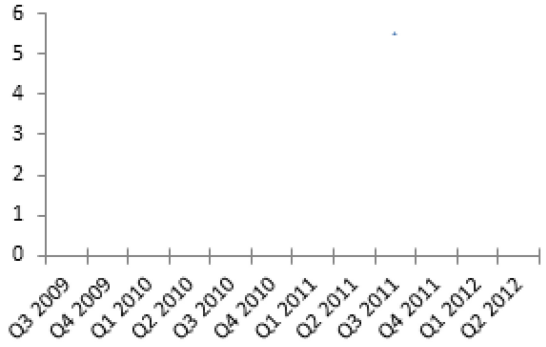

***Figure 1*: Surgical site infection rate per 100 procedures at University of Cincinnati. Includes a composite of coronary artery bypass grafting, hip and knee arthroplasties, Cesarean section, abdominal/vaginal hysterectomy, laminectomy and fusion (Infection Control database). Q=Quarter (3 mo period)**

Objective 1. To provide real time data and education on SSI prevention as they occur to surgical disciplines at the department level.

Hypothesis 1a: Surveillance for SSI can be conducted as soon as an SSI is detected clinically.

Hypothesis 1b: SSI data and education regarding SSI prevention can be provided to the surgical disciplines as soon as an infection is identified.

Objective 2. Design quality improvement strategies tailored to reducing SSI at the patient care unit level by engaging the residents and attending surgeons through objective 1.

Hypothesis 2: Residents and attending surgeons can be engaged in quality improvement strategies tailored to reducing SSI by providing real time SSI data and education to them.

Objective 3. Reduce SSI by 50% in a 2-year time frame by implementing objectives 1 and 2.

Hypothesis 3: SSI can be reduced by providing real time data to the stakeholders (residents and medical staff) and engaging them in quality improvement strategies thereby increasing their knowledge about prevention of SSI.

Technical Approach:

Current assessment of need to reduce SSI:

SSIs cause significant morbidity and mortality

In 2002, in the United States, an estimated 14 million NHSN operative procedures were performed (CDC unpublished data). SSIs were the second most common healthcare-associated infection, accounting for 17% of all hospital-acquired infections (HAIs) among hospitalized patients.[5] A similar rate was obtained from NHSN hospitals reporting data in 2006-2008 (16,147 SSI following 849,659 operative procedures) with an overall rate of 1.9%.[6]

While advances have been made in infection control practices, SSIs remain a substantial cause of morbidity and mortality among hospitalized patients.[7] In one study, among nearly 100,000 HAIs reported in one year, deaths were associated with SSIs in more than 8,000 cases.[8]

Patients with certain factors may be at greater risk for an SSI

Rates of SSI are higher for patients who have cancer, especially if they have received pre-operative radiotherapy or chemotherapy.[9] People between 20 and 40 years of age have lower rates of SSI, probably because the immune system functions optimally in people of this age.[10] Men are at higher risk especially for staphylococcal infection[10] possibly because they are more likely to carry staphylococci on their skin compared to women.[11] Obesity is a risk factor for SSI.[12,13,14] Risk of SSI is also higher for people significantly below their ideal body weight.[15] People with diabetes mellitus are at higher risk for SSI.[12,16] A well-established relationship exists between emergency procedures and the incidence of SSI.[14] For elective procedures it is possible to reduce the risk through intervention, however, implementation of these interventions maybe limited under emergency situations. It may still be possible to reduce the risk in emergency situations by strictly adhering to best practices. This may be achieved with constant assessment of current practices, and feedback with education to all surgical residents and staff.

Feedback of SSI data to surgeons is an important strategy in reduction of SSI risk

Surveillance of SSI with feedback of appropriate data to surgeons has been shown to be an important component of strategies to reduce SSI risk.[17,18,19,20] This feedback will help provide surgeons with insight into their infection rate but does not necessarily provide education related to SSI prevention or evaluate system barriers and provider opportunities. Engaging surgical staff in evaluating the root cause of SSI and in evaluating system barriers can result in process improvement strategies that correct deficiencies in best practices. This is necessary to prevent SSI, and at the same time helps improve the infrastructure to promote avoidance of future SSI.

Current surveillance mechanisms and sources of data

The Department of Infection Control conducts surveillance for SSIs (detects SSIs for tracking purposes) using CDC/NHSN definitions and collects data on the total number of surgeries performed using ICD-9 coding as recommended by the CDC.[7] These surveillance definitions used are shown in Table 1. Surgeries for which surveillance is performed include coronary artery bypass grafting, hip and knee arthroplasties, Cesarean section, abdominal/vaginal hysterectomy, laminectomy and fusion, and colectomy. All cases are reviewed by the infection preventionists and the hospital epidemiologist. The data is sent to the directors of the surgical departments *only once every three months*. This at times causes a delay of five to six months in surveillance for a given SSI depending on when the infection occurred during the surveillance period.

A **superficial incisional SSI** is defined as follows:
Infection occurs within 30 days after the operative procedure AND *involves only skin and subcutaneous tissue of the incision* AND *patient has at least **one** of the following:*

a. Purulent drainage from the superficial incision.
b. Organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision.
c. At least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat; AND superficial incisions are deliberately opened by surgeon, AND are culture-positive or not cultured. A culture-negative finding does not meet this criterion.
d. Diagnosis of superficial incisional SSI by the surgeon or attending physician.

A **deep incisional SSI** is defined as follows:
Infection occurs within 30 days after the operative procedure if no implant is left in place or within one year if implant is in place and the infection appears to be related to the operative procedure AND *involves deep soft tissues (e.g., fascial and muscle layers) of the incision* AND *patient has at least one of the following:*

a. Purulent drainage from the deep incision but not from the organ/space component of the surgical site.
b. A deep incision spontaneously dehisces or is deliberately opened by a surgeon and is culture-positive or not cultured and the patient has at least one of the following signs or symptoms: fever (>38°C), or localized pain or tenderness. A culture-negative finding does not meet this criterion.
c. An abscess or other evidence of infection involving the deep incision is found on direct examination, during reoperation, or by histopathologic or radiologic examination.
d. Diagnosis of a deep incisional SSI by a surgeon or attending physician.

An **organ/space SSI** is defined as follows:
Infection occurs within 30 days after the operative procedure if no implant is left in place or within one year if implant is in place and the infection appears to be related to the operative procedure AND *infection involves any part of the body, excluding the skin incision, fascia, or muscle layers, that is opened or manipulated during the operative procedure* AND *patient has at least **one** of the following:*

a. Purulent drainage from a drain that is placed through a stab wound into the organ/space.
b. Organisms isolated from an aseptically obtained culture of fluid or tissue in the organ/space.
c. An abscess or other evidence of infection involving the organ/space that is found on direct examination, during reoperation, or by histopathologic or radiologic examination.
d. Diagnosis of an organ/space SSI by a surgeon or attending physician.

***Table 1*: Criteria for diagnosing surgical site infections.**[7]

Compliance with Surgical Care Improvement Project (SCIP) Quality Measures

Our preoperative, intraoperative and postoperative institutional policies related to SSI prevention reflect CDC guidelines for prevention of SSI.[21] A national program, the Surgical Care Improvement Project (SCIP), is sponsored by the Centers for Medicare & Medicaid Services (CMS) in collaboration with a number of other national partners, including the American Hospital Association (AHA), Centers for Disease Control and Prevention (CDC), Institute for Healthcare Improvement (IHI), The Joint Commission (TJC) and others interested in improving surgical care by significantly reducing surgical complications.[22] The compliance with SCIP quality core measures in our institution has ranged from 95% to 100% since July 2009 to the current date (baseline period of the proposed study) (Table 2).

SCIP Indicator	Q1 2011	Q2 2011	Q3 2011	Q4 2011	Q1 2012
Antibiotic within 1 hour of incision	96.6%	96.6%	97.3%	94.8%	95.9%
Antibiotic selection	95%	95.5%	96.8%	96.9%	99%
Antibiotic discontinued within 24 hours	96.5%	91.4%	96.6%	95.9%	96.8%
Appropriate hair removal	100	100	100	100	100
Perioperative temperature management	98.7%	100%	100%	100%	100%

Table 2: **Surgical Care Improvement Project (SCIP) measures. Q = Quarter (three month period) of year noted**

Baseline data and gap in existing system

Despite compliance with SCIP measures, our SSI rates have been steady and high over several years[23] (Figure 1). Our SSI rate per 100 procedures for the surgeries on which surveillance is performed is listed in Table 3 for the baseline period (July 2009 to June 2012). Several ongoing efforts through these years have increased our compliance with SCIP measures but our SSI rates remain high. This suggests that there are system barriers and provider opportunities that may be contributing to SSI in our institution.

Through stakeholder interviews we have realized that a gap exists in our resident curriculum related to lack of built-in infection prevention education. The majority of the curricular training, particularly in residency/subspecialty training programs, focuses on the pathophysiology of disease, clinical diagnosis, and treatment.[24] Along with the principles of disease management, trainee education must be complemented by a curriculum that constructs a culture of quality improvement and patient safety (QI/PS) within the fabric of clinical practice. The need for such a change at the level of resident education is two-fold. First, improving quality and delivery of effective care by minimizing redundancy and waste is one of the cornerstones of bending the curve of healthcare costs. Second, trainees will face a changing environment – from a traditional fee-for-service reimbursement model to a pay-for-performance model. In essence, this requires a change in physician behavior without changing the doctor-patient relationship. Education in the Department of Surgery includes medical student clinical clerkships and electives, graduate medical education resident and fellowship programs, basic scientist training, and continuing medical education seminars and classes. At the core of the educational program are Surgical Grand Rounds, Morbidity and Mortality Conference, and Curriculum Conferences. In addition, each individual subspecialty within the Department of Surgery has its own M&M Conference along with other curriculum conferences. However, among all the outstanding educational activities for the residency and fellowship programs in the Department of Surgery, quality improvement education, especially related to SSI prevention, is lacking.

Primary audiences targeted for the intervention

The proposed intervention will be targeted toward surgical residents and surgical staff. This proposal, if funded, will provide us the opportunity to integrate infection prevention experts into the surgical resident education via the following described methods. This will not only

benefit patients by having an impact on SSI prevention through the quality improvement strategies described below, but will also benefit the institution and residents by integrating the education related to SSI prevention into the surgical curriculum while improving the infrastructure toward avoidance of future SSI.

We propose an aggressive intervention that identifies system barriers and provider opportunities as soon as they occur and involves trainees (residents and fellows) in the process to help prevent SSI. This comprehensive effort should include all stakeholders including trainees, as they play a crucial role in patient care in any academic institution.

Surgery Type	**No. of SSI**	**No. of Procedures**	**SSI rate/100 procedures**
Hip arthroplasty			
Knee arthroplasty			
CABG			
Cesarian section			
Laminectomies/fusion			
Colectomies*			
Hysterectomies			
Total			

***Table 3*: Overall surgical site infection rate SSI rate per 100 procedures for the surgeries that the surveillance is performed for the baseline period (July 2009 to June 2012). (SSI = Surgical site infections; CABG = Coronary artery bypass grafting)**

***Surveillance for colectomies was started in January 2012 and the data represents the time period of January 2012 to June 2012.**

B. Intervention Design and Methods:

1. Provide real time data and education on SSI as they occur to surgical disciplines at the department level.

a. Real time data transference: CDC/NHSN definitions will continue to be used to perform surveillance for SSI (Table 1).[7] Since infection preventionists currently review daily microbiology reports, readmission reports and Emergency Department reports to identify patients that may have developed an SSI, it is feasible to perform surveillance as soon as a potential SSI is suspected. This real-time surveillance will allow for an investigation very close to the time of surgery – much earlier than was possible with quarterly reports – which will subsequently permit a root cause analysis. Thus there will be an opportunity to correct any contributing factors related to system or provider deficiencies as soon as possible; which in turn could prevent other SSIs that may have occurred due to a delay in correcting those factors. It will also create a sense of urgency among the surgical providers to correct the contributing factors. [Investigators acknowledge that the CDC/NHSN definition for SSIs may change in calendar year 2013.[25] In the event of such a change, all surveillance from previous years will be revised to fit the modified new definition in order to be able to assess response to the proposed interventions.]

b. Presentation of subspecialty-specific SSI in M&M Conferences: SSI rates will be presented at each surgical specialty M&M Conferences on a monthly basis. These meetings are heavily attended by residents and attending surgeons. Five minutes of each monthly M&M conference will be allotted to reports from the infection preventionists. A summary of

epidemiologic characteristics of infected patients and other epidemiologic clues that may point to the cause of each specific SSI will be presented. We will be able to obtain this information through root-cause analyses performed for each case of SSI as described below.

2. Formation of multidisciplinary team to perform root cause analysis of an SSI: Within each surgical specialty, a team will be formed that includes the attending surgeon assigned by the surgical subspecialty, subspecialty-specific nursing director, nurse educator, infection preventionist and hospital epidemiologist/infectious diseases physician. This team will invite the resident physicians involved in the surgery to join the team for the root cause analysis. If any system or provider deficits are discovered during the root cause analysis, they will be shared at the next M&M conference as described above. While efforts are concurrently being undertaken to correct identified deficits, further discussion toward remediation will be encouraged in this conference. Any further suggestions from the M&M conference will be incorporated into the action plan. Key Driver Diagrams and SMART aims (**S**pecific, **M**easurable, **A**ttainable, **R**elevant, **T**imebound) will be developed, and PDSA (Plan, Do, Study, Act) cycles will be implemented.[26]

C. Design of Outcomes Evaluation: A total SSI rate per 100 procedures is the primary outcome measure. Secondary outcome measures will include subspecialty-specific SSI rates per 100 procedures, percentage of questions targeted toward SSI prevention answered correctly by all surgical residents, compliance with case reviews by the multidisciplinary teams, 90-day readmission rate for all surgical disciplines and hospital length of stay of all patients who underwent surgeries.

1. Sources of data: The University of Cincinnati Infection Control and quality database will be used as the source of data for the proposed study.

2. Collection of data: SSI data will be collected using the methods described in B1a and SSI rate will be obtained per 100 procedures. Co-morbidity information on all patients undergoing surgeries listed in this proposal will be obtained. Co-morbidities that will be recorded for the purpose of this study are listed in Table 4. An open ended questionnaire targeted toward SSI prevention (Table 5) will be presented to the surgical residents for completion before starting the intervention and again at the end of project. The difference in total percentage of questions answered correctly by all surgical residents combined, before and after intervention, will be measured. Department of Infection Prevention will keep a record of all case reviews, the date that the SSI information was sent to the multidisciplinary team electronically requesting a case review, and whether the case review was completed within two weeks of sending SSI to the team. The hospital already monitors the 30-day readmission rate per 100 patient encounters for all patients and this data will be obtained from the hospital's quality database. A 90-day readmission rate per 100 patient encounters will also be generated for all patients who underwent surgeries during the baseline period and those who will undergo surgeries during the intervention period using the same method. Hospital length of stay for all patients undergoing surgeries will be monitored before and after intervention.

Co-morbidities:
Diabetes mellitus
Obesity (BMI 30 or higher) or Overweight (BMI 25.0 to 29.9)
Underweight (BMI below 18.5)
Smoking
Age (>40)
Gender (Male)
Cancer
Chemotherapy (current or within last three months)

Table 4: **Co-morbidities that will be recorded for the study**

Surgical Site Infection (SSI) Questionnaire

1. Name at least five patient co-morbidities that increase the risk of SSI.
2. Name at least three modifiable risk factors in which the SSI risk can be reduced by addressing them appropriately before surgery.
3. Name the quality measures monitored by Surgical Care Improvement Project.
4. Which antiseptic was compared with povidone-iodine in a trial of 849 patients undergoing clean-contaminated surgery published in New England Journal of Medicine in 2010 in which the overall rate of SSI was significantly lower in the group that performed skin antisepsis with this antiseptic than in the povidone-iodine group (9.5 versus 16 percent)?
5. Timing of antibiotic prophylaxis: What is the time frame within which the antibiotic prophylaxis should be administered prior to surgical incision for
    a. Vancomycin and fluoroquinolones
    b. Other antibiotics
6. Name two conditions in which antibiotic prophylaxis should be repeated. In these cases, repeat dosing is indicated every one to two half-lives of the drug in patients with normal renal function.
7. Name two methods of hair removal that are associated with the lowest risk of SSI. The lowest rates of SSI were reported when hair was removed just prior to the surgical incision.

NOTE: *There is general agreement that good surgical technique reduces the risk of SSIs. Such practices include gentle traction, effective hemostasis, removal of devitalized tissues, obliteration of dead space, irrigation of tissues with saline to avoid excessive drying, use of fine, non-absorbed monofilament suture material, judicious use of closed suction drains, and wound closure without tension.*

Table 5: **Surgical Site Infection (SSI) Questionnaire**

3. Control group: We will measure the effect of the intervention by comparing the intervention data to the historic control group data (all patients who developed SSI prior to the intervention).

4. Expected amount of change: We expect a 50% reduction in the SSI rate per 100 procedures as a result of this intervention. Our plan to measure the compliance with case reviews will determine if the target audience (surgical residents and staff) are fully engaged in the process. Our plan to monitor responses on the pre- and post-training questionnaire will also assess whether we were able to impact their learning.

5. Statistical analysis: The project work is expected to begin in January, 2013. SSI rates are available specialty by specialty prior to the start of the project. Once the program is in place, SSI rates will be computed monthly starting from July, 2013 until December, 2014. This will be a time series data spanning 18 months. The pre- and post-rates will be statistically compared monthly. The time point at which the effectiveness of the program of dissemination started will be determined. Change point analysis will be carried out to determine time the point(s) at which the rates are shifting. A Poisson regression model will be fitted to the count data on the number of infections per 100 surgeries to identify risk factors. Co-variates tested will be age (>40), gender, diabetes mellitus, obesity (BMI 30 or higher) or overweight (BMI 25.0 to 29.9), underweight (BMI below 18.5), smoking, cancer and chemotherapy (current or within the last three months).

30-day and 90-day readmission rate per 100 patient encounters will also be analyzed using an interrupted time series analysis. The difference in LOS between the pre- and post-intervention period will be tested. LOS will be presented with mean and standard deviation, together with the median and range. Because of the expectation of a non-normal distribution of LOS, the differences between groups will be tested using Mann-Whitney rank sum test in the unadjusted analysis. In the multivariate analysis we will use the non-parametric percentile method after a multivariate linear regression with non-parametric bootstrap replicates. The differences in LOS will be adjusted for gender, age, co-morbid conditions (described above), and patient group (type of surgery). Categorical data will be analyzed with Fisher's Exact test. We will assess the percentage increase in the questions answered correctly pre- and post-intervention. We will transform the percentages by arc sine square root transformation and perform a two-sample t-test.

6. Plan for public sharing of methods and outcomes: An abstract will be submitted to the Society of Healthcare Epidemiology of America (SHEA) in the spring 2015. A manuscript will be submitted for publication.

D. Preexisting work: Innovative methods of this study propose to perform surveillance as soon as a potential SSI is suspected, as opposed to the current quarterly surveillance that is standard in programs across the country. Involving surgical residents in the process is also innovative and has not been described in the literature. The UC Department of Surgery has long been a pioneering force in surgical infections through the work of Drs. William Altemeier, Wesley Alexander and Joseph Solomkin and theirs efforts have contributed to current national guidelines on prevention of SSI.[6] This initiative will build upon the existing residency curriculum for the department of surgery and upon the existing spirit to reduce SSI within the UC Health culture. At the core of the resident educational program are Surgical Grand Rounds, M&M Conferences and Curriculum Conferences. This proposal, if funded, will provide us the opportunity to integrate infection prevention experts into the education curriculum. We will be

able to build on our existing surveillance mechanisms for SSI using historic control data as the baseline for the study (Figure 1). We have three infection preventionists and a full time clinical Epidemiologist/Infectious Diseases physician within the University hospital that currently perform surveillance and these resources will be utilized to carry out the proposed study. We are also hiring a data analyst/manager who will maintain the data as the infection preventionists and hospital epidemiologist perform surveillance of SSI. This person will also be responsible for timely dissemination of the detected SSI to the multidisciplinary teams prompting a case review, and for data mining related to length of stay and hospital readmission.

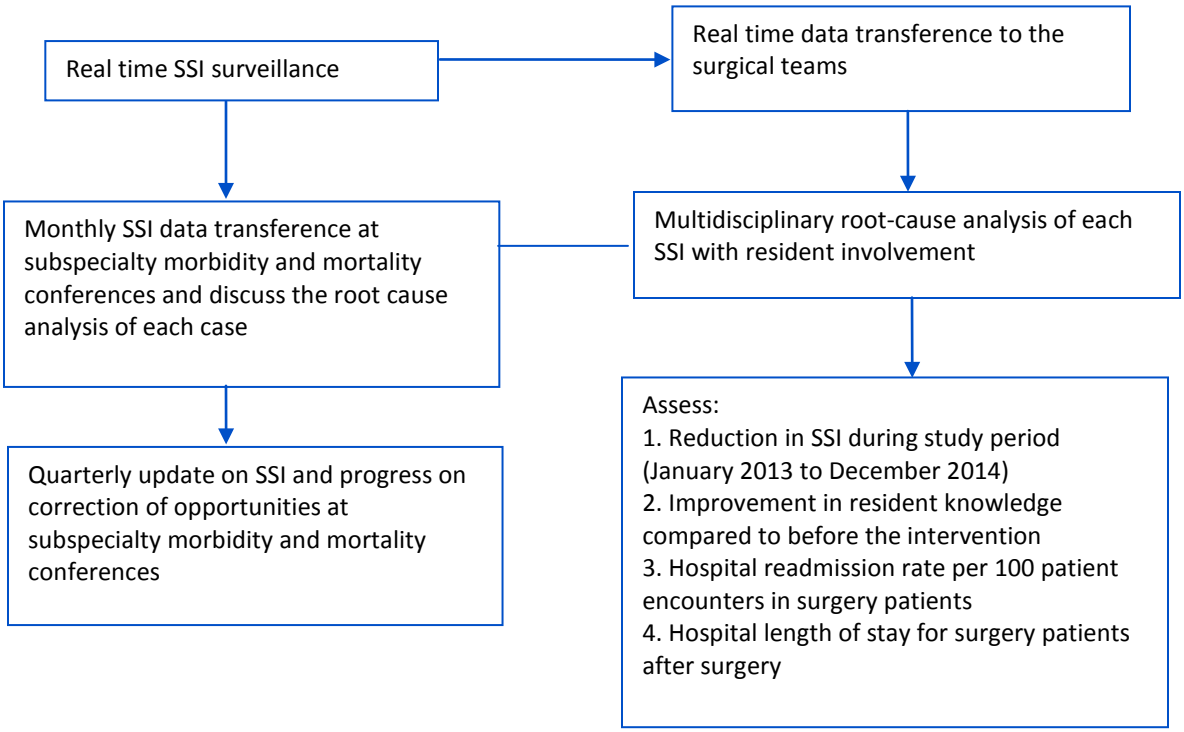

***Figure 2*: Flowchart of methods to be employed in this proposal.**

E. Detailed workplan, deliverables schedule and study timeline: This project will be undertaken from January 2013 to December 2014. Support has been obtained from the Department of surgery (a support letter from the Chairman of the Department of Surgery, Dr. Michael Edwards has been submitted with this proposal) to carry out the project. The Department of Infection Control will provide real time data as soon as an SSI is suspected. Multidisciplinary teams for each surgical discipline will be formed, as described in Section B2 above, in January 2013. SSI case reviews using the proposed protocol will begin in January 2013, including residents involved in each case in the team's review. The subspecialty-specific case review details and the subspecialty-specific SSI rate per 100 procedures will be shared in subspecialty-specific M&M conferences and the process will be repeated each month. A questionnaire assessing knowledge related to SSI prevention will be completed by all surgical residents at the first M&M conference of this study period (January 2013). The same

questionnaire will be completed by the surgical residents again in January 2014 and January 2015. The Principal Investigator will present at these M&M conferences in her capacity as the Medical Director of Infection Control. Statistical analysis will be performed from January to March 2015. An abstract will be submitted to Society of Healthcare Epidemiology of America (SHEA) to be presented in spring 2015. A manuscript will be prepared and submitted in spring 2015.

	Year 1 (January 2013 to December 2013)	**Year 2** (January 2014 to December 2014)	**Year 3** (January to March 2015)	**Year 3** Spring 2015
Research study*	Conduct of Objectives 1 and 2		Statistical analysis	Abstract presentation at Society of Healthcare Epidemiology of America and Manuscript submission

Table 5: **Deliverables schedule and study timeline**
***Ground work for this study has already been laid out in preparation for the start date. Support from the department of surgery has been obtained to carry out this project as described.**

F. Requested amount: A total of $50,000 is being requested. The majority of these funds will support a data manager who will be responsible for real time data transference and creating and maintaining the SSI rates, preparing graphs for presentation at M&M conferences and collating the data obtained for the study. Please see Detailed Budget for more details. The institution will provide the resources including the time spent by the infection preventionists and the investigators. The investigators will have access to the surgical M&M conferences and to the surgical residents and staff for this quality improvement project. Support letters have been submitted by Dr. Brian Gibler, CEO and President of University Hospital, UC Health, and Dr. Michael Edwards, Chair of the UC Department of Surgery.

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