**Application**

**Residency Grant Project 2016-2017**

**Section I**

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| Current Residency program | Est. completion date |
| Neurosurgery | June 2018 |
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| Additional Project Team Members |
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**Section II**

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| Personal Statement: Please indicate how this grant, if funded, will help your career desires and focus. Outline your expected career path and how this aligns with the Residency Research Grant program objectives and criteria. (500 words max.) |
| I am a neurosurgery PGY4 and have a particular interest in Quality Improvement measures, which include working on designing a surgical site infection bundle with one of our spine attendings, Oren Gottfried. This is the focus of this grant application. Over the past year, our department has been working on protocolizing many various aspects of clinical care via a resident-led initiative to define best practice guidelines that work within the framework of our institutional practices. As residents, we gather interdisciplinary support and buy-in for these protocolized modifications to ensure easy adoption across service lines. We also define the individual metrics used to grade success of our interventions and are beginning to track related outcomes. The SSI bundle is part of this initiative and has already been vetted by our department for attending support across our subspecialities. I view this grant as valuable to improving the quality of care provided by our department in the immediate future, but also providing an educational framework for establishing, funding, and measuring quality outcomes on a departmental scale. These are skills which are not necessarily part of the current neurosurgery curriculum at Duke, but are instrumental for my future practice. This work will serve as the basis for a QI concentration curriculum design by my graduate medical education that I will take part in during my chief year. I hope to play a significant role in hospital wide QI development and administration in my future attending position. Lastly, these principals can be modeled in other surgical specialties outside of neurosurgery, including but not limited to orthopedic surgery, general surgery, gynecology, and trauma surgery. Thus the potential for significant impact on patients is vast and inter-disciplinary.  |

**Section III – Details of the proposal**

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| Abstract summary |
| Surgical site infections (SSI) significantly impact the cost and quality of patient care in the surgical spine community. Evaluation of “bundled”, rather than individual, interventions with regards to surgical infection reduction has recently gained popularity outside of the neurosurgical sphere. Adoption of a similar technique not only for the reduction of infection rates but also for homogenization of care to assist cross-covering providers in delivering up-to-date evidence based care is a possible benefit of this method. As such, we propose a bundle of infection reduction methods within our spine population that reflect departmental consensus on the most recent evidence-based infection interventions. We will track patient outcomes, overall compliance, and associated economic effects to assess bundle efficacy.  |
| Outline of the problem |
| Surgical site infections (SSI) are a major cause of increased cost, readmission, reoperation, and morbidity associated with surgery 1. Specifically, there is a noted correlation between SSIs and increased risk of ICU admission, increased length of stay, and a doubled risk of morbidity. In general surgery and neurosurgery literature, evaluation of individual interventions to decrease SSI have led to varying results that can be difficult to implement and interpret in combination. Moreover, a multitude of factors may contribute to SSIs and using a bundled approach may be a more successful strategy for reducing SSIs rather than targeting individual risk factors. However use of a bundled method of many best practices or a standardization of preoperative, intraoperative, and postoperative interventions has been gaining popularity with seemingly better success in many papers particularly in the cardiac, colorectal, trauma, and orthopedic literature 1-3. Most notably this exact procedure of bundling has been implemented at Duke by the colorectal department with reduction in SSI rates and promising economic data, 1 leading to national attention. At out institution, the infection rate for fusion cases is approximately 3% (internal institutional data, Duke University Medical Center, Infectious Disease Department). While these figures are reflective of the national averages in neurosurgery of approximately 1-5%, it is noted that significant attending variability in perioperative preferences to in care exists within our department particularly in regards to infection prevention and wound care. This creates confusion for patients, nursing staff, and cross-covering physicians, leading to preventable errors in recommendations and care. Therefore, we aim to identify a mutually-agreed upon set of best practice guidelines based on current literature to create consistency and improvement in infection outcomes.  |
| State of the art in this field |
| Often infection reduction interventions are limited to a single intervention within a specific field and the combined results associated with these studies are equivocal. It can also be argued that individual interventions may be too granular given the multi-modal nature of wound care and infection prevention. As such, “bundled care” as representative of the total patient care protocol has recently gained popularity. As seen in fields outside of neurosurgery, “bundles” often represent evidence based measures unique to the specific field as well as interventions recommended for all surgical specialties, such as the Surgical Care Improvement Project recommendations (SCIP). Areas of importance according to SCIP include: euglycemia, normothermia, antibiotics choices, and hair shaving 3. Literature almost uniformly in the field has consisted of a few hundred patients in cohort studies where pre- and post- implementation figures have been compared, with varying though generally positive results. In neurosurgery specifically, the use of the bundled approach is limited in the literature and confined mostly to antibiotic regimens in MRSA patients as well as some aspects of postoperative wound care 4,5. MRSA positive patients continue to increase in number and infection increases with prolonged hospitalizations. Furthermore, neurosurgical literature demonstrates that the MRSA positive subset is at high risk for SSI as compared to their uninfected counterparts 4. Hair shaving is another area of some study in the neurosurgical literature. While SCIP recommends as minimal of a hair shave as possible, neurosurgery literature supports that a minimal shave does not lead to worse infection outcomes 6. Aside from these areas, many parts of the standard bundles now proposed in general and orthopedic literature including euglycemia, normothermia, dressing/wound care, closure types, etc. remain unstudied in the neurosurgery literature. In addition, evaluating the economics of bundle implementation in neurosurgery– thus far not reported in the literature – would be an important contribution to the literature in our field1.  |
| Past research of the applicant in this field |
| We have previously performed two departmental presentations (one to departmental administration and one to neurosurgery/infectious disease representation) proposing various aspects of the current bundle to gather attending buy-in for the proposed changes in patient care. These presentations have required literature review of the best practice guidelines in the literature, as well as internal survey of current interdepartmental practices currently utilized at our institution. Infectious disease input was obtained for antibiotic recommendations and department specific infection rates. In its current iteration, departmental support by attendings, residents, and mid-level providers has been obtained. We have begun gathering the resources to implement the various interventions and identifying the resources for data input and tracking.  |
| Open questions |
| 1. Does implementation of a neurosurgical SSI bundle lead to a reduction in SSI?
2. Does homogenization of patient care improve SSI outcomes and ability of providers (residents/mid-level providers) to deliver care complaint with attending recommendation?
3. Is implementation of a neurosurgery SSI bundle cost effective?
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| Hypothesis |
| We hypothesize that the implementation of a perioperative bundle to standardize care will decrease SSI rates and create a favorable economic profile. Standardized care will also avoid errors by providers secondary to various “attending preferences” leading to unfavorable outcomes.  |
| What are the aims you want to reach with this study? |
| The specific aims of the project are therefore three-fold: **1)** To implement perioperative cranial and spinal neurosurgical bundles based on SCIP and most recent neurosurgical SSI literature review in an effort to standardize perioperative care; **2)** To demonstrate SSI reduction with the use of such an evidence based bundle using a retrospective cohort study; and **3)** To evaluate the economics of the SSI bundle in neurosurgery and to evaluate if these are valuable in lowering healthcare costs.  |
| Anticipated results |
| We anticipate a reduction in SSI post intervention at 1 year follow up with associated favorable economics |
| Study subjects, specimen or materials |
| All neurosurgical patients age 18-90 undergoing spinal surgery.  |
| Effect and outcome variablesBased on the figure the CDC definition of SSI in the updated January 2015 Module, we will define infection based on Table 1 criteria below 7. **Table 1: Definition of Types of SSI**

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| **Type of Infection** | **Definition** | **Signs and Symptoms** |
| **Superficial SSI (does not include pin site infection or stitch abscess)** | 1. Occurs within 30 d of surgery AND | a. Purulent drainage **OR** |
| 2. Involves skin of subcutaneous tissue AND | b. Organisms isolated from aseptically obtained culture **OR** |
| pt has one of the following:  | c. Incision explored and culture positive or not cultured and opened with one of the following: Pain, tenderness, localized swelling, redness, and warmth **OR** |
|   | d. Otherwise deemed by attending physician to be superficial  |
| **Deep incisional SSI** | 1. Occurs within 30 d (non- instrumented spine or CEA) or 90 d (all other procedures) after surgery if no implants and within 1 year with implant **AND** | a. Purulent drainage from deep incision but not organ space **OR** |
| 2. Involves deep tissues (fascial and / or muscle layers) **AND** | b. Spontaneous deep dehiscence past fascial or is deliberately opened by surgeon with positive culture or not cultured but has fever, localized pain, tenderness **OR** |
| pt has one of the following:  | c. Abscess found on direct examination |
|   |   |
| **Organ/ Space SSI** | 1. As above for 30 d or 90 d criteria **AND** | 1. Purulent drainage from drain **OR** |
| 2. Infection involves organs/spaces other than the incision opened or manipulated during the original procedure **AND** | 2. Organisms isolated from aseptically obtained cultures of fluid or tissues in the space **OR** |
| pt has one of the following:  | 3. Abscess on direct examination |

As shown in the table above, infection types will be classified as superficial, deep incisional or deep organ space. Based on review of the bundle literature across all specialties as mentioned above as well as a literature review of surgical site infection interventions in neurosurgery, a comprehensive intervention list for the proposed bundle was created. Please see the attached excel table for further details. |
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| **Methods for taking measurements** |
| Please see the attached excel table for further details. Compliance data for preoperative measures and data gathering for operative variables would likely require a part-time employee for collection. Post-operative variables could be recorded by the APP staff during perioperative care, with intermittent quality and completeness checks by the study personnel.  |
| **Methods for data management and analysis (including biostatistical check)** |
| Data would be collected in a RedCap database, and include other pertinent information including patient identifiers, type of surgery, primary or secondary surgery, surgical complications, other major complications. Database management would require part-time personnel support. Before and after implementation rates of SSI (both superficial and deep) will be evaluated using standard statistical methods per the institutional statisticians.Data collection period will end at the end of 1 year or reaching 1306 samples, whichever comes first. We will then compare the SSI rate of these patients receiving new care bundles with the rate at Duke Clinic in the past 2 years. Because the community around Duke Clinic is very stable, and there will be no major change in diagnosing patients in the coming year, it is reasonable to assume that the patients at Duke Clinic in the past two years and in the coming year come from the same population, so that they are comparable in terms of other factors, such as age, gender, race, pre-health conditions, symptoms severities, etc. Therefore, a two sample proportion test will be performed to see if the new care bundle has successfully decreased the SSI rate. Further, we will collect the health expenditure of these patients, and fit a regression model to study the effect of the new care bundle on the health expenditures, adjusting for other factors, such as age, procedure, previous general health conditions, symptom severity before the surgery, type of surgery etc.  |
| **Estimation of sample size and power** |
| From 7/1/2014 to 5/31/2016, in total 2332 spine surgeries were performed at Duke Clinic. Among them, 69 had deep incisional or organ space infections. The SSI rate is about 3%. Existing references suggest that adopting the new care bundle is likely to decrease the SSI rate significantly. For example, in cranial neurosurgery SSI reduction pre and post bundles rates were 23.8% and 2.8% respectively with respect to cranioplasty (p = 0.0217) (5). In a multi-institutional study regarding hip, knee, and cardiac surgery the mean rate of SSI per 10,000 operations was 36 for pre-intervention and 21 for post-intervention, with a rate ratio of 0.58 [95% CI, 0.27 to 0.92] (2). It is reasonable to expect that the new care bundle will reduce the spine surgery SSI rate at Duke Clinic. Assume there will be at least a 25% drop, i.e., the SSI rate after having the new bundle is no larger than 2.2%. To detect such a decrease with type I error controlled at 5% and at least 90% power, we need to collect results for at least 1306 spine surgeries. Within the past 22-month period, we have in total 2332 spine surgeries performed. It is likely that we can collect 1306 spine surgeries in the upcoming year. Conservatively speaking, if only 1000 spine surgeries are performed at Duke Clinic at the end of 1 year, we can still reach power at 88%. |
| **Animal model** If an in vivo animal model is used in the planned research work, please describe the model in detail. The description should include: anesthesia protocols, treatment protocols, pain management, surgical techniques, post-operative care, criteria for removal from the study if necessary, and euthanasia protocols.AAALAC accreditation (Association for assessment and accreditation of Laboratory Animal Care International) www.aaalac.orgPlease indicate whether the institution (main applicant and co-applicants) is AAALAC accredited and specify in which institution the animal research will be carried out. If the institution is not AAALAC accredited, please detail what agency and standards are used to oversee animal use and care. |
| No animal research will be necessary for this project |
| **Relevance of the project** |
| The project is relevant to the current literature as there is an interest in SSI reduction and use of bundles across surgery, but a paucity of information specific to neurosurgery. Our results will be of relevance to our neurosurgical department, infectious disease, intensive care, and patient care providers (mid-level providers and nursing involved with wound care).  |
| **Time schedule** |
| **July – August 2016** – Project initialization, gathering of resources and ancillary staff/stakeholder buy-in. Recruitment of personnel for compliance checking and data base management. **August 2016 –** Resident and APP training. Floor/ICU In-service and OR nursing in-service sessions.**September 2016 –** roll out of program. Compliance tracking begins and data collection begins.**October 2016** – October 2018 – continued data collection and compliance tracking**December 2016** – 3 month check in, review of collected metrics and data. Review of modifications necessary for improved compliance. **March 2017** – 6 month check in**June 2017** – 9 month check in, begin preparatory work for reporting of results to grant, including preliminary statistical analysis. Revision of duration of study as needed.**October 2017** – possible project completion and begin manuscript drafting. |
| Relevant literature by the investigators |
| None |
| Relevant literature by other authors |
| 1. Keenan JE, Speicher PJ, Nussbaum DP, et al. Improving Outcomes in Colorectal Surgery by Sequential Implementation of Multiple Standardized Care Programs. *Journal of the American College of Surgeons.* 2015;221(2):404-414.e401.2. Schweizer ML, Chiang HY, Septimus E, et al. Association of a bundled intervention with surgical site infections among patients undergoing cardiac, hip, or knee surgery. *Jama.* 2015;313(21):2162-2171.3. Tanner J, Padley W, Assadian O, Leaper D, Kiernan M, Edmiston C. Do surgical care bundles reduce the risk of surgical site infections in patients undergoing colorectal surgery? A systematic review and cohort meta-analysis of 8,515 patients. *Surgery.* 2015;158(1):66-77.4. Akins PT, Belko J, Banerjee A, et al. Perioperative management of neurosurgical patients with methicillin-resistant Staphylococcus aureus. *Journal of neurosurgery.* 2010;112(2):354-361.5. Le C, Guppy KH, Axelrod YV, et al. Lower complication rates for cranioplasty with peri-operative bundle. *Clinical neurology and neurosurgery.* 2014;120:41-44.6. Broekman ML, van Beijnum J, Peul WC, Regli L. Neurosurgery and shaving: what's the evidence? *Journal of neurosurgery.* 2011;115(4):670-678.7. CDC Procedure associated Module for Surgial Site Infection, January 2015 Update. 2015:26.8. Savage JW, Anderson PA. An update on modifiable factors to reduce the risk of surgical site infections. *The spine journal : official journal of the North American Spine Society.* 2013;13(9):1017-1029.9. Draelos ZD, Rizer RL, Trookman NS. A comparison of postprocedural wound care treatments: do antibiotic-based ointments improve outcomes? *Journal of the American Academy of Dermatology.* 2011;64(3 Suppl):S23-29. |

**Section IV – Budget for proposed project period**

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| **Personnel** | **Amount** |
| Surname / First name | Academic qualification | Effort in % |  |
| Compliance personnel (x1) | RN, pre MD or MD | 15% | 2,000 |
| Statisitical support |  | 5% | 500 |
| **Total cost for personnel** |  |  | **2,500** |

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| **Material**  | **Amount** |
| Devices, equipment, extension to existing equipment, etc. |  |
| RedCap database management and data entry | 3,000 |
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| **Total cost for material** | **3,000** |

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| **Supplies**  | **Amount** |
| Itemize below |  |
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| **Total cost for supplies** |  |

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| **Rental of equipment**  | **Amount** |
| Itemize below |  |
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| **Total cost for rental equipment** |  |

**Section V**

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| If selected for participation in the program, the grantee agrees to conduct herself/himself professionally according to the principles of medical ethics and to be governed by the Bylaws of the North Carolina Spine Society.  |
| Applicant’s signature: |  | Date: |  |
| Program Director’s signature: |  | Date: |  |

To be considered for the 2016-2017 grant year,
**this application and the applicant’s CV are due by 5:00 pm on July 13, 2016.**

**Please sign your completed form and return it along with your CV by email, mail or fax to:**

NCSS, PO Box 27167, Raleigh, NC 27611 | Fax: 919-833-2023 | ncspine@ncmedsoc.org