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Damon Michaels, BS, CCRP
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1. Background and Significance:

Surgical site infection (SSI) following spinal surgery is a frequent complication and results in higher morbidity, mortality and healthcare costs. SSI following adult spinal surgery is a frequent complication that has been reported to occur in 0.7–12.0% of patients and result in higher postoperative morbidity, mortality and health care costs. Vanderbilt University Medical Center SSI rate is 7%. Treatment for SSI can be challenging often requiring revision surgery, long-term antibiotics, and prolonged hospitalization. The accurate identification of risk factors is thus important in the development of strategies to prevent these potentially devastating infections.

The New CDC-definitions for surveillance of surgical site infections (1992) take into account 3 classes of surgical site infections (SSI): superficial incisional SSI, deep incisional SSI, and organ/space SSI. The most prevalent host-related risk factors for development of SSI are advanced age, morbid obesity, disease severity, an ASA score > 2, prolonged preoperative hospital stay, and infection at distal sites. Microbial contamination of the surgical site occurs mainly during the surgical intervention.
Although exogenous contamination from the surgical suite may be of concern, especially in clean operations, most surgical site infections are caused by microorganisms of the patient's own skin flora. SSI rates vary according to the type and duration of the surgical procedure. Proper surgical technique is probably the most important factor in the prevention of SSI.
Modification of patient risk factors should be attempted whenever possible through use of adequate protocols for antimicrobial prophylaxis with antibiotics should be followed. Routine surveillance of surgical site infections is beneficial for SSI prevention and early detection. Additional prevention aimed at decreasing number of microorganisims on patient's skin pre-operatively may decrease rates of SSI. Prior studies have reported daily use of 2% chlorhexidine gluconate (CHG) cloths has decreased rates of nosocomial bloodstream infections in those with central line catheters. Another study reported decreasing SSIs up to 50% when nursing staff instituted utilization of CHG cloths pre-op and daily post-op cleansing in-hospital. However, use of CHG cloths pre-operatively has not been routinely instituted. Many hospitals and service lines do not have a protocol for their use. Therefore study of such a population may prove worthy, as currently VUMC neuro-spine patients do not routinely utilize preoperative skin cleansing with CHG cloths.

This study proposes a randomized, controlled trial of neuro-spine patients of 2% chlorhexidine gluconate skin preparation cloths for the prevention of post op surgical site infections in spine patients.

2. Hypothesis:

Use of CHG cloths the night before and morning of surgery (neckline to toes) will affect (decrease rates) of SSI compared to patients who receive routine standard of care (soap and water pre-op, day of surgery and daily post-operative).

3. Study Objectives:

- Randomize consented patients pre-operative to either study group (of 2% chlorhexidine gluconate cloths the night before and morning of surgery) or control (standard of care cleansing with soap and water) with follow-up through discharge for evaluation of SSI
- Evaluation for SSI development at 6 week (+/-) 1 week post-op visit.

- Measure change in skin flora by comparing skin swab cultures of those using the cloths and those who do not on day of surgery, post-op day 4 or hospital discharge and postop day 30

4. Methods:

Pre-operatively patients scheduled for neurosurgical spine cases will be evaluated and approached for interest, if consenting process completed, patients will be randomized to one of 2 arms in 1:1 through a block randomization table.

Those enrolled into the study arm will receive the CHG cloths and instructions for use from research personal. Those randomized to the control arm will receive standard of care skin cleansing by nursing staff.

All subjects who have signed consent will have a skin swab culture taken the day of screening and prior to cleansing with Chlorhexidine gluconate wipes close to the intended incision line. We will also obtain skin swab cultures at site of incision preoperatively on the day of surgery, post-op day 4 or time of discharge (which ever comes first) and at the 30 day follow up.

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Neurosurgical spine patients at Vanderbilt University Medical Center

6. Enrollment:

170 patients will be enrolled.

7. Inclusion/Exclusion Criteria:

Inclusion Criteria

Patients scheduled for a neuro-spine procedure and have 2 of the following risk factors: Diabetic OR BMI>30 OR ASA$\geq$2 OR pre-operatively hospitalized OR >60 years old OR chronic steroids/immunosuppressive medications OR prior history of SSI

Exclusion Criteria

1) Unable to consent
2) Non English speaking
3) Known allergy to any of the ingredients contained in SAGE chlorhexidine gluconate cloths
4) Current infection or history of spine infections.
5) Patients with tumors or intradural spinal pathology.

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Data regarding demographics, health history and status, surgical course and hospitalization will be collected and entered into an electronic database. Patient data will be de-identified once entered into the database. Shared data will always be de-identified and accessed through Redcap, a secure web-based system.

9. Reporting of Adverse Events or Unanticipated Problems involving Risk to Participants or Others:

Events determined by the Principal Investigator (PI) to be unanticipated problems involving risks to subjects will be reported by the PI or sub-investigator to the IRB within 10 working days of the Investigator's knowledge of the problem.

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We are planning a study of independent cases and controls with 1 control(s) per case. Prior data indicate the rate of infection in the control group (those with risk factors, including superficial SSI) is 0.5, then just 150 evaluable subjects are needed to detect a 50% or greater reduction, with 80% power. We can also design a statistical analysis plan that uses the grade of SSI instead of binary yes/no to indicate presence of SSI. This should increase the power as well, for instance, if the SAGE cloths reduce the severity of (but does not completely prevent) infection in some patients.

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Through these interventions, we expect risks to privacy to be minimized.

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Research Records will be retained by the Nursing Research Office for a period of six (6) years after the submission of the final report and close-out procedures on the research project for which the Research Records were prepared.

The retention of the original Research Records shall be the responsibilityNursing Research Office .

Study Schema

Procedure	screening	Day of surgery	POD 1	POD 2	POD 3	POD4 or discharge	6 weeks ± 1 week follow up visit
Written informed consent	X						
Medical history	X						
Urine pregnancy test		X					
BMI	X						
Vital signs (HR, RR, BP, T)	X	X	X	X	X	X	X
Randomization	X						
SAGE cloths for treatment arm[1]	X	X					
Standard of care; soap and water for control arm	X	X	X	X	X	X	
Skin culture	X	X				X	X
Post surgical assessment			X	X	X	X	X
Blinded assessor to evaluate for s/sx of SSI							X
Assess for adverse events	X	X	X	X	X	X	X
medications	X	X	X	X	X	X	X

[1]Supplies will be given to participants at screening visit. Application will be done by the participant on the evening before surgery.

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Vital signs (HR, RR, BP, T)	X	X	X	X	X	X	X
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Standard of care; soap and water for control arm	X	X	X	X	X	X	
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Post surgical assessment			X	X	X	X	X
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Assess for adverse events	X	X	X	X	X	X	X
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[1]Supplies will be given to participants at screening visit. Application will be done by the participant on the evening before surgery.

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