

Surgical site infections are the third most common nosocomial infections in the hospital and occur in 2-5% of patients undergoing surgery in the US¹. They are a considerable burden for healthcare systems resulting in reoperation, increased post-surgical pain, poor wound healing, decreased quality of life and an independent risk factor for the development of incisional hernias^{1,2}. Emergency surgery is a strong risk factor for SSI because many of the risk factors for SSI are present in these surgeries such as contaminated and dirty wounds, prolonged duration of operation, patient comorbidities and high American Society of Anesthesiologists (ASA) scores¹. Recent articles have demonstrated that specifically damage control laparotomy emergency surgeries are at high risk of SSIs^{3,4}.

Surgical site infections are classified as superficial (involving only skin and subcutaneous tissue), deep (involving fascia and muscle), and organ space (intraabdominal infection). To attempt to mitigate the risks of these infections, several interventions have been recommended including antibiotics, antibiotic wound irrigation, primary closure with wicks and incisional incisional wound vacs, and delayed primary closure and leaving skin open to heal by secondary intention in high risk wounds⁵⁻⁹.

Due to the risk of SSI in DCL, many surgeons leave the skin open to heal by secondary intention which increases the time for wound healing and results in increased burden of dressing changes¹⁰. The reported high rates of SSI in DCL include patients with organ space infections which occurs should not influence skin closure techniques⁴.

Due to this increase burden on patients with open incisional wounds, several studies have attempted to decrease this incisional infection rate by performing delayed primary closure^{7,8}, placing wicks in the wound^{5,6} and (most recently) incisional wound vac therapy. A meta-analysis from 2013 comparing primary vs delayed primary skin closure in contaminated and dirty abdominal incisions found a decrease in SSI rates from 20.5% to 13.3%. More recently, investigators have been evaluating utilizing incisional wound vac therapy to decrease SSI. While some studies have identified decreasing SSI rates or comparable infection rates of patients with incisional wound vacs to delayed primary closure¹²⁻¹⁴, other studies have found no difference in reducing SSI¹⁵. A Cochrane 2019 review comparing incisional wound vacs with standard therapy demonstrated a decreased SSI rate with incisional NPWT from 15.1% vs 9.6%¹⁴. While incisional wound vacs have shown promise in decreasing wound infection rates, they do come at a significant cost to healthcare delivery. Performing primary closure with placement of wicks between the staples has been shown by some studies as a promising method to decrease wound infection rates^{5,6}; however, other studies have not demonstrated benefit¹⁶.

While other studies have identified cost savings associated with decreasing SSIs, these studies do not apply to patients undergoing emergency general surgery. Schweizer et al evaluated costs associated with surgical site infections and found that even superficial surgical site infections were associated with 1.25 times greater cost than patients not having SSIs or 7003 dollar difference per patient¹⁷. Although approximately 10% of the patients in this study were emergency surgery cases, the patient population also included subspecialties such as ortho, vascular and neurosurgery in the analysis. Additionally, the cost of surgical site infections were assigned utilizing "activity-based costing" which uses automated data to assign costs based on the relative resources use for each patient. The costs that the study captured included health care products and staff time. Unfortunately we do not know how the wounds were managed in the emergency surgery patients or patients at high risk of infection rates in this patient population. As mentioned before, keeping all wounds open to heal by secondary intention would increase cost of health care products (wound vacs/gauzes), staff time and potential need for home health service while significantly decreasing the incidence of superficial and deep surgical site infections. On the other hand, if all wounds were closed, then only those that developed a superficial surgical site infection would incur the extra costs.

Because preoperative risk factor modification is generally not feasible in emergency general surgery, determining appropriate quality metrics are important in order to improve patient centric outcomes. While allowing all wounds to heal by secondary intention may decrease DCL superficial site infections to zero, it also increases the time for wound healing, is associated with increased pain and suboptimal cosmetic results. Scarborough et al evaluated the overall impact of specific postoperative complications in the emergency general surgery patient and found that incisional SSI had negligible impact while post op bleeding and pneumonia had the greatest overall impact on mortality and end-organ dysfunction¹⁸.

We hypothesize that patients after DCL can have their wounds primarily closed with wicks or with low rates of superficial surgical site infections.

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December 18, 2019

Principal Investigator: Katherine Pellizzeri

IRB Protocol # **Pro00094656**

Study Title: **Superficial surgical site infections after damage control laparotomy**

Items Submitted for Review: Study protocol; CITI Training; Investigator COI; Investigator Assurance Signature Form; PI CV; Data collection tool

On December 18, 2019, the Institutional Review Board (IRB)/Office of Human Research Protection of Prisma Health–Upstate reviewed the above-mentioned study. The IRB granted expedited approval for one year.

Your study will **require a study status update by *December 17, 2020*. It is the investigator’s responsibility to make sure the proper re-approval information is submitted to the IRB.** Please submit approximately 30 days prior to the study’s expiration date to ensure that the IRB has sufficient time to review this information.

The IRB has approved to waive or alter consent in accordance with 45 CFR 46.116 (e)(3). The IRB has also approved a HIPAA Authorization Waiver in accordance with 45 CFR 160 & 164.

Requirements of the Institutional Review Board are listed below:

1. Destroy research data identifiers at the earliest opportunity consistent with the research.
2. Do not reuse or disclose PHI to any entity or person outside the research team.
3. Notification/approval from the IRB is required prior to use/practice of any modified procedures, protocol, other forms, etc.
4. Notification of any adverse or other reportable event must be submitted to the IRB as documented in Prisma Health–Upstate Office of Human Research Protection Policies.
5. Continuing Review of your study for renewed approval of continuation is required. Information required for continuing reviews include but not limited to: study status, enrollment, progress reports, verified current human subjects protection training, etc.

Should you have any questions, please do not hesitate to call Office of Human Research Protection of Prisma Health–Upstate at 864-455-8997; 701 Grove Road, Greenville, SC 29605.



Eastern Association for the Surgery of Trauma
Advancing Science, Fostering Relationships, and Building Careers

**DAMAGE CONTROL LAPAROTOMY WOUND CLOSURE WITH WICKS
EAST MULTICENTER STUDY
DATA COLLECTION TOOL**

Multicenter Study: _____

Enrolling Center: _____

Enrolling Co-investigator: _____

Demographics:

Age: _____ Gender: _____ BMI: _____

Comorbidities:

Alcohol Use Disorder	YES/NO
Angina Pectoris	YES/NO
Anticoagulant Therapy	YES/NO
Bleeding Disorder	YES/NO
Cerebral Vascular Accident	YES/NO
Chronic Obstructive Pulmonary Disease	YES/NO
Chronic Renal Failure	YES/NO
Cirrhosis	YES/NO
Congestive Heart Failure	YES/NO
Current Smoker	YES/NO
Currently Receiving Chemotherapy	YES/NO
Dementia	YES/NO
Diabetes Mellitus	YES/NO
Disseminate Cancer	YES/NO
Hypertension	YES/NO
Myocardial Infarction	YES/NO
Peripheral Arterial Disease	YES/NO
Steroid Use	YES/NO

Mechanism of initial injury:

Trauma YES / NO
Blunt: YES / NO
Penetrating: YES / NO

Acute Care: YES / NO

Wound Classification (check one)

- Clean _____
- Clean Contaminated _____
- Contaminated _____
- Dirty _____

Ostomy present at time of closure YES / NO

Did Patient Undergo Antibiotic Irrigation of Wound/Abdomen at time of Closure of Skin YES / NO
If yes what antibiotics did you use and what dose? _____

Outcomes:

Complications: (check all that apply)

- _____ Superficial Surgical Site Infections
- _____ Deep Infections
- _____ Organ Space Infections
- _____ Surgical Site Occurrences
 - _____ Seromas
 - _____ Hematomas
 - _____ Skin dehiscence
 - _____ Enteric fistula
 - _____ Fascial dehiscence

Procedural Interventions (check all that apply)

- _____ None
- _____ Wound Opening
- _____ Wound Debridement
- _____ Percutaneous Drainage
- _____ Negative Pressure Therapy

Mortality (circle one): YES NO

Mortality within 7 days of skin closure? YES NO



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**EAST MULTICENTER STUDY
DATA DICTIONARY**

Damage Control Laparotomy Wound Closure With Wicks – Data Dictionary

Data Entry Points and appropriate definitions / clarifications:

Entry space	Definition / Instructions
<u>Standard Study Questions</u>	
Age	Age of patient enrolled
<u>Case Information</u>	
Gender	Gender of Patient enrolled
Height	Height of patient in inches
Weight	Weight of patient in pounds
Days until Closure	Number of days from damage control laparotomy to closure of skin
<u>Mechanism of initial Injury</u>	
Trauma	Choice if initial injury which led to patient requiring a damage control laparotomy was a result of a traumatic injury. If yes then proceed to drop down menu of type trauma.
Blunt	Single choice for best description of blunt mechanism.
Penetrating	Single choice for best description of penetrating mechanism.
Acute Care	Choice if initial injury which led to patient requiring a damage control Laparotomy was a result of an emergent non trauma related surgery.
Wound Classification-based on index case(check one)	
Clean	The wound is not infected or inflamed. It is the result of a non-penetrating, blunt trauma. The wound must be free from entry into respiratory, alimentary, or genitourinary tract.

Clean Contaminated	The respiratory, alimentary or genitourinary tract were entered under controlled conditions without evidence of infection or contamination or major break in technique (spillage from gastrointestinal tract).
Contaminated	The wound has gross (visible) spillage from the gastrointestinal tract or there is acute non-purulent inflammation present. There was a major break in sterile technique (unsterile instruments used) during the procedure.
Dirty	Wound with retained devitalized tissue (gangrene/necrosis) or an existing clinical infection (purulence) or a perforated viscera.
Ostomy Presence	Was an ostomy present at time of skin closure
Appropriate Dosage of Preop Antibiotics	Did the patient receive appropriate dosage of IV preoperative antibiotics in concordance to SCIP guidelines?
Antibiotic Irrigation Utilization	Did the patient undergo antibiotic washout of the abdomen and skin at time of skin closure? If so proceed to drop down menu of type of antibiotics
Type of antibiotics	Free entry for specific type of antibiotic initiated Generic or trade-name acceptable.

Pre-existing Conditions/Comorbidities

ALCOHOL USE DISORDER Diagnosis of alcohol use disorder documented in the patient medical record.

Additional Information

- Present prior to injury.
- Consistent with American Psychiatric Association (APA) DSM 5, 2013.
- A diagnosis of Alcohol Use Disorder must be documented in the patient's medical record.

ANGINA PECTORIS Chest pain or discomfort due to coronary heart disease. Usually causes uncomfortable pressure, fullness, squeezing or pain in the center of the chest. Patient may also feel the discomfort in the neck, jaw, shoulder, back or arm. Symptoms may be different in women than men.

Additional Information

- Present prior to injury.
- A diagnosis of Angina or Chest Pain must be documented in the patient's medical record.
- Consistent with American Heart Association (AHA), May 2015.

ANTICOAGULANT THERAPY

Documentation in the medical record of the administration of medication (anticoagulants, antiplatelet, agents, thrombin inhibitors, thrombolytic agents) that interferes with blood clotting.

ANTICOAGULANTS ANTIPLATELET AGENTS

THROMBIN INHIBITORS

THROMBOLYTIC AGENTS

Fondaparinux Tirofiban Bevalirudin Alteplase

Warfarin Dipyridamole Argatroban Reteplase

Dalteparin Anagrelide Lepirudin, Hirudin Tenecteplase

Lovenox Eptifibatide Drotrecogin alpha kabikinase

Pentasaccaride Dipyridamole Dabigatran tPA

APC Clopidogrel

Ximelagatran Cilostazol

Pentoxifylline Abciximab

Rivaroxaban Ticlopidine

Apixaban Prasugrel

Heparin Ticagrelor

Additional Information

- Present prior to injury.
- Exclude patients whose only anticoagulant therapy is chronic Aspirin.

BLEEDING DISORDER

A group of conditions that result when the blood cannot clot properly.

Additional Information

- Present prior to injury.
- A Bleeding Disorder diagnosis must be documented in the patient's medical record (e.g. Hemophilia, von Willenbrand Disease, Factor V Leiden).
- Consistent with American Society of Hematology, 2015.

CEREBRAL VASCULAR ACCIDENT (CVA)

A history prior to injury of a cerebrovascular accident (embolic, thrombotic, or hemorrhagic) with persistent residual motor sensory or cognitive dysfunction (e.g., hemiplegia, hemiparesis, aphasia, sensory deficit, impaired memory).

Additional Information

- Present prior to injury.
- A diagnosis of CVA must be documented in the patient's medical record.

CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

Lung ailment that is characterized by a persistent blockage of airflow from the lungs. It is not one single disease but an umbrella term used to describe chronic lung diseases that cause limitations in lung

airflow. The more familiar terms "chronic bronchitis" and "emphysema" are no longer used, but are now included within the COPD diagnosis and result in any one or more of the following:

- Functional disability from COPD (e.g., dyspnea, inability to perform activities of daily living [ADLs]).
- Hospitalization in the past for treatment of COPD.
- Requires chronic bronchodilator therapy with oral or inhaled agents.
- A Forced Expiratory Volume in 1 second (FEV1) of < 75% or predicted on pulmonary function testing.

Additional Information

- Present prior to injury.
- A diagnosis of COPD must be documented in the patient's medical record.
- Do not include patients whose only pulmonary disease is acute asthma.
- Do not include patients with diffuse interstitial fibrosis or sarcoidosis.
- Consistent with World Health Organization (WHO), 2015.

CHRONIC RENAL FAILURE

Chronic renal failure prior to injury that was requiring periodic peritoneal dialysis, hemodialysis, hemofiltration, or hemodiafiltration.

Additional Information

- Present prior to injury.
- A diagnosis of Chronic Renal Failure must be documented in the patient's medical record.

CIRRHOSIS

Documentation in the medical record of cirrhosis, which might also be referred to as end stage liver disease.

Additional Information

- Present prior to injury.
- If there is documentation of prior or present esophageal or gastric varices, portal hypertension, previous hepatic encephalopathy, or ascites with notation of liver disease, then cirrhosis should be considered present.
- A diagnosis of Cirrhosis, or documentation of Cirrhosis by diagnostic imaging studies or a

laparotomy/laparoscopy, must be in the patient's medical record.

CONGESTIVE HEART FAILURE (CHF)

The inability of the heart to pump a sufficient quantity of blood to meet the metabolic needs of the body or can do so only at an increased ventricular filling pressure.

Additional Information

- Present prior to injury.
- A diagnosis of CHF must be documented in the patient's medical record.
- To be included, this condition must be noted in the medical record as CHF, congestive heart failure, or pulmonary edema with onset of increasing symptoms within 30 days prior to injury.
- Common manifestations are:
 - Abnormal limitation in exercise tolerance due to dyspnea or fatigue
 - Orthopnea (dyspnea or lying supine)
 - Paroxysmal nocturnal dyspnea (awakening from sleep with dyspnea)
 - Increased jugular venous pressure
 - Pulmonary rales on physical examination
 - Cardiomegaly
 - Pulmonary vascular engorgement

CURRENT SMOKER

A patient who reports smoking cigarettes every day or some days within the last 12 months.

Additional Information

- Present prior to injury.
- Exclude patients who report smoke cigars or pipes or smokeless tobacco (chewing tobacco or snuff).

CURRENTLY RECEIVING CHEMOTHERAPY FOR CANCER

A patient who is currently receiving any chemotherapy treatment for cancer prior to injury.

Additional Information

- Present prior to injury.
- Chemotherapy may include, but is not restricted

to, oral and parenteral treatment with chemotherapeutic agents for malignancies such as colon, breast, lung, head and neck, and gastrointestinal solid tumors as well as lymphatic and hematopoietic malignancies such as lymphoma, leukemia, and multiple myeloma.

DEMENTIA

Documentation in the patient's medical record of dementia including senile or vascular dementia (e.g., Alzheimer's).

Additional Information

- Present prior to injury.
- A diagnosis of Dementia must be documented in the patient's medical record.

DIABETES MELLITUS

Diabetes mellitus that requires exogenous parenteral insulin or an oral hypoglycemic agent.

Additional Information

- Present prior to injury.
- A diagnosis of Diabetes Mellitus must be documented in the patient's medical record.

DISSEMINATED CANCER

Patients who have cancer that has spread to one or more sites in addition to the primary site AND in whom the presence of multiple metastases indicates the cancer is widespread, fulminant, or near terminal.

Additional Information

- Present prior to injury.
- Other terms describing disseminated cancer include: "diffuse", "widely metastatic", "widespread", or "carcinomatosis."
- Common sites of metastases include major organs, (e.g., brain, lung, liver, meninges, abdomen, peritoneum, pleura, bone).

HYPERTENSION

History of persistent elevated blood pressure requiring medical therapy.

Additional Information

- Present prior to injury.
- A diagnosis of Hypertension must be documented in the patient's medical record.

MYOCARDIAL INFARCTION (MI)

History of a MI in the six months prior to injury.

Additional Information

- Present prior to injury.
- A diagnosis of MI must be documented in the patient's medical record.

PERIPHERAL ARTERIAL DISEASE (PAD)

The narrowing or blockage of the vessels that carry blood from the heart to the legs. It is primarily caused by the buildup of fatty plaque in the arteries, which is called atherosclerosis. PAD can occur in any blood vessel, but it is more common in the legs than the arms.

Additional Information

- Present prior to injury.
- Consistent with Centers for Disease Control, 2014 Fact Sheet.
- A diagnosis of PAD must be documented in the patient's medical record.

STEROID USE

Patients that require the regular administration of oral or parenteral corticosteroid medications within 30 days prior to injury for a chronic medical condition.

Additional Information

- Present prior to injury.
- Examples of oral or parenteral corticosteroid medications are: prednisone and dexamethasone.
- Examples of chronic medical conditions are: COPD, asthma, rheumatologic disease, rheumatoid arthritis, and inflammatory bowel disease.
- Exclude topical corticosteroids applied to the skin, and corticosteroids administered by inhalation or rectally.

Outcomes

Complications (check all that apply)

NOTE = for calculation of all complication days, day of admission = hospital day #1

Definitions of complications included in this section:

Superficial Surgical Site Infections

Infection involving only skin and subcutaneous tissue of the incision and has at least one of the following:

- a) Purulent drainage from the superficial incision.
- b) Organism(s) identified from an aseptically-obtained specimen from the superficial incision or subcutaneous tissue by a culture or non-culture based microbiologic testing method which is performed for purposes of clinical diagnosis or

treatment (for example, not Active Surveillance Culture/Testing)

- c) Superficial incision that is deliberately opened by a surgeon, attending physician or other designee and culture or non-culture based testing of the superficial incision or subcutaneous tissue is not performed AND patient has at least one of the following signs or symptoms: localized pain or tenderness; localized swelling; erythema or heat.
- d) Diagnosis of a superficial incisional SSI by the surgeon, attending physician or other designee
- e) Cellulitis by itself or a stitch abscess does NOT meet criterion for a superficial incisional SSI.

Deep Infections

An infection that involves deep soft tissues of the incision (for example, fascial and muscle layers) AND patient has at least one of the following:

- a) Purulent drainage from the deep incision
- b) A deep incision that spontaneously dehisces, or is deliberately opened or aspirated by a surgeon, attending physician or other designee AND organisms identified from the deep soft tissues of the incision by a culture or nonculture based microbiologic testing method which is performed for purposes of clinical diagnosis or treatment AND patient has at least one of the following signs or symptoms: fever (>38 degrees Celcius), localized pain or tenderness.
- c) An abscess or other evidence of infection involving the deep incision that is detected on gross anatomical or histopathologic exam or imaging test.

Organ Space Infections

An infection that involves any part of the body deeper than the fascial/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 into the organ/space
- b) Organisms identified from fluid or tissue in the organ space by a culture or non-culture based microbiologic testing method which is performed for purposes of clinical diagnosis or treatment
- c) An abscess or other evidence of infection involving the organ/space that is detected on gross anatomical or histopathologic exam, or imaging test evidence suggestive of infection.

Surgical Site Occurrences

Wound complications not including SSI including seromas, wound dehiscence, enterocutaneous fistula, wound cellulitis, fascial disruption, skin or soft tissue ischemia, skin or soft tissue necrosis, hematoma

Seromas

pocket of clear fluid that develops under incision/wound

Hematomas	Clotted blood within tissues of wound
Skin dehiscence	Edges of the wound at sites of closure (suture or staples) pull apart
Enteric fistula	Check if applies. Defined as free communication between the skin or outside surface of an open abdomen and any portion of the enteric tract
Fascial dehiscence	Fascial disruption

Procedural Interventions

None	No procedural interventions were needed to treat wound
Wound Opening	Sutures or staples had to be removed to allow the wound to be opened
Wound Debridement	Tissue removed to treat necrosis or infection
Percutaneous Drainage	A percutaneous drain was placed to treat an infection
Negative Pressure Therapy	Negative pressure therapy was used to treat a wound due to drainage
Mortality	Drop down menu – yes or no. Did patient expire during admission?
Mortality within 7 days of closure	Drop down menu – yes or no. Did patient expire Within 7 days of skin closure?