Title

Addition of pre-wound closure povidone iodine wash versus direct wound closure effect on surgical site infections: A randomized controlled trial

NCT Number: Not Yet assigned

Date: 11th of September, 2021

Background

Surgical site infections are post-operative infections of the incision or organ or space that was included in the surgical field [1]. Incisional surgical site infections (SSIs) are a growing healthcare challenge [2]. Currently, up to 10% of surgical procedures may be complicated by an SSI [3]. Not only do SSIs lead to worse patient outcomes, but they also account for a large proportion of healthcare expenditure [4-6]. In the United Kingdom alone, SSIs are estimated to cost the National Health Service 1 billion pounds annually [7]. The problem is further compounded in low- and middle-income countries (LMICs) where the prevalence of antibiotic-resistant infections is increasing, and national healthcare budgets are strained [8]. In fact, SSIs are estimated to account for additional costs of up to $30,000 in LMICs [9].

The global crisis of drug-resistant bacteria has further highlighted the need for more effective perioperative preventive strategies to minimize healthcare-associated resistant infections [10,11]. Optimal surgical antisepsis is critical in reducing the incidence of SSIs, and therefore in reducing the use of post-operative antibiotics [12,13]. Recently, there has been a renewed interest in using povidone-iodine (PVI) intraoperative wound irrigation to achieve this goal. The choice of PVI is especially suitable for LMICs where the availability of chlorhexidine preparations may be limited by scarce resources [14].

A possible adjunctive role of pre-wound closure PVI irrigation in reducing incisional SSIs is still unclear [15,16]. A meta-analysis by López-Cano et al. analyzed data of 7,601 patients and found a reduction in overall SSI rate. However, the heterogeneity and uncertain quality of most studies limited the synthesis of conclusive evidence [17]. The possible benefits of irrigating the surface of an open incision include local antimicrobial effect, physical removal of debris and dilution of contamination. Recent guidelines have all emphasized the lack of sufficient evidence on intraoperative use of PVI [18-21].

We aim to conduct a randomized controlled trial in Ain Shams University Hospitals to compare the effect of adding PVI wash prior to skin closure to direct wound closure on reducing the rates of SSIs.

Study Objective

To assess the efficacy of povidone-iodine wash before wound closure in preventing surgical site infections.

Trial Design

Superiority, parallel group randomized controlled trial, allocation 1:1

Methods

Study Setting
Operative theatres at Ain Shams University Hospitals

Inclusion Criteria
- Adult patients (≥ 18 years old)
- Open and minimally invasive surgeries
- Emergency (any unplanned admission) and elective (planned admission) surgical procedures
- Clean, Clean-Contaminated, Contaminated, Dirty wounds [22], (See appendix 1)
- Inclusion surgery list according to Current Procedural Terminology (CPT) National Healthcare Safety Network (NHSN) operative procedure code mapping [23] , List of included surgical procedures (See appendix 2)

Exclusion Criteria
- Povidone-iodine allergy
- Surgeries for infected wounds.
- Exclusion surgery list according to Current Procedural Terminology (CPT) National Healthcare Safety Network (NHSN) operative procedure code mapping, [23] List of excluded surgical procedures, (See appendix 3)

Intervention
- 10% povidone iodine wound wash before wound closure versus direct wound closure.
- Antibiotic prophylaxis will be administered according to local protocols.
- Wound dressing type and frequency will not differ between both groups.
- Diagnosed SSIs will be managed according to local antibiograms and management guidelines.

Outcomes
- Primary: Incidence of superficial and deep surgical site infection (SSI) within 30 days postoperatively

- Secondary:
  1. Post-operative morbidity and mortality by (Clavien-Dindo classification system) [24], (See appendix 4)
  2. Length of hospital stay
  3. Readmission and Reoperations related to surgical site infection
  4. Infectious complications (Sepsis, septic shock, multiple-organ dysfunction syndrome, wound dehiscence) [25-28]
  5. Microbiology culture and sensitivity results
  6. Local adverse events for povidone-iodine application (Local irritation, poor wound healing)
  7. Cost-analysis

Participant Timeline

Recruitment will start from day (18/09/2021) till sample size is reached.

Patients will be introduced to and asked to participate in the trial when they arrive to the surgical ward or emergency department by the surgical resident. They will not be subjected to any additional steps other than the standard hospital protocols as our trial begins in the operating room where patients will be randomly allocated into 2 groups: the control group (direct wound closure) and the intervention group (PVI wound wash before closure).

After the operation, patients will be monitored and observed at the hospital by the staff until discharge and will be given a specialized follow-up card. Following discharge, follow-up will be in the form of fixed outpatient clinic visit after the first week postoperatively and continue with phone calls made at regular 1-week intervals inquiring about symptoms and signs of SSI based on a questionnaire guided by the CDC definitions [27]. If a patient displays ≥1 symptom listed in the CDC checklist (See appendix 5), he/she will be invited to follow-up in our outpatient clinic and will be identified by their card. This will allow the physician to fill out the data collection form in their files and obtain a picture for documentation purposes. Follow-up will continue for a period of 30 days.

Sample Size

Using PASSII program for sample size calculation and assuming SSI incidence of 10% in control group and 5% in intervention group, setting **power** at 80% and **α-error** at 0.05, sample size of 345 patient for each group will be needed. We plan to enroll an additional 10% of the calculated sample size for each group in anticipation of a loss to follow-up rate of 10%. The total sample size will be **760 patients**.

Assignment of Interventions

Sequence Generation

A statistician not directly involved in the study or analysis will prepare a computer-generated randomization sequence. No blocking will be used. The sequence will be provided to the trialists in the form of serially numbered opaque envelopes containing details of either the intervention or the control and a random identifier.

Enrolment and Allocation Concealment

The patients will be enrolled by the resident doctors and given a study ID number.

The allocation sequence will be made available to the OR head nurse in the form of sealed envelopes. The head nurse will provide the surgeons with closed opaque envelopes which will be opened by the nurse directly before wound closure. The head nurse will ensure that the envelopes are opened at wound closure and not before it. After the intervention/control is carried out, the random identifier will be noted down in the patient's operative data collection form. Following that, the nurse will tear the envelope and its contents.

Blinding

The patients and outcome assessors will be blinded. The details of which intervention was used will not be recorded in the regular patient records. The surgeons will be blinded till directly before wound closure, however, because of the nature of intervention, complete blinding of the surgeons would be impossible.

Data Collection Methods

Preoperative data collection will aim to collect baseline data about the recruited patients: patient identifiers, age, BMI, comorbidities including hypertension, diabetes, CKD, chronic liver disease, chronic heart failure, as well as any documented medication use and ASA score; through a standardized data collection form. All patients will be monitored by the doctors who will be responsible for filling their follow-up data till 30 days postoperatively (See appendix 6 for data collection forms).

Teams of four (surgeons or medical students) will be recruited to collect data from included surgical departments, each team collecting information over a two-week interval from all patients undergoing included surgical procedures in the department. Teams will then follow up with patients recruited in this allowed interval over the 30-day follow-up period, according to the methods described above.

We will obtain written informed consent from participants before surgery explaining the study procedures and the follow-up plans. All those who volunteer will be followed up in our clinics and provided carefree-of-cost.

Data Management

Package: R (latest available version)

Methods: Descriptive statistics will be presented as mean ± SD for quantitative data. If the data is severely skewed/not normally distributed, median and IQR will be used. N & percentile will be used for qualitative data. Relevant statistical tests will be reported when applicable.

Statistical Methods

Suitable statistical tests will be used for data analysis.

The study participants will be divided into 4 groups (Clean, Clean-contaminate, Contaminated, Dirty). Each group will be stratified and analyzed separately.
Subgroup analyses will also be performed according to the type of surgical access (open versus minimally invasive), and the presence or absence of Diabetes.
The need for additional subgroup analyses will be determined at the time of completion of data collection.
Both per-protocol and intention to treat analyses will be used and their findings will be reported.

Monitoring

The study will not employ a data monitoring committee (DMC) as the trial is conducted on an adult population with no perceived risk to either arm of the trial.

Interim analysis will be done on reaching 50% of the total sample size by an independent statistician blinded for the intervention allocation. The unblinded data will be reported to the Ain Shams Surgical Research Group. The primary purpose of this analysis would be to determine if the study should be prematurely terminated in the case of patient harm. The final decision on the matter will reside with the Ain Shams Surgical Research Group and the study's principal investigators.

In our study an adverse event will be defined as any medical occurrence in a subject with a probable causal relation to the intervention.

Adverse events will be collected after the subject has provided consent and enrolled in the study.
The known as well as novel adverse effects of the study intervention (povidone iodine) will be investigated and recorded until the period of patient follow up is completed.

Ethics and Dissemination

Ethical Approval

This protocol, the template informed consent forms (Arabic and English versions), and any subsequent modifications will be reviewed and approved by the applicable IRB [institutional review board] with respect to scientific content and compliance with applicable research and human subjects' regulations prior to starting the study.

Protocol Amendments

Any modifications to the protocol which may impact on the conduct of the study, potential benefit of the patient or may affect patient safety, including changes of study objectives, study design, patient population, sample sizes, study procedures, or significant administrative aspects will require a formal amendment to the protocol. Such amendments will be reviewed and approved by the IRB prior to implementation in accordance with local regulations.

Administrative changes of the protocol are minor corrections and/or clarifications that have no effect on the way the study is to be conducted will be agreed upon by the principal investigators and documented.

Informed Consent and Participant Rights

Surgical residents will introduce and discuss the trial to patients answering all questions and/or concerns they might have. Patients will then be able to have an informed discussion with the participating consultant. Surgical residents will then obtain written consent from patients willing to participate in the trial. Consent forms are provided for all patients involved in the trial in Arabic or English language.

The informed consent will be a tiered consent. Participants will be given the option to consent for the use of their data in current protocols or for future ancillary research unrelated to the clinical condition under study as well.

All participants will also be given a special follow up card. Any complications, if present, will be treated at the Ain Shams University Hospitals at no additional cost.

Healthcare-Information Security and Privacy

All study-related information will be stored securely at the study site. All participant information will be stored in locked file cabinets in areas with limited access. All data collection, process, and administrative forms will be identified by a coded ID [identification] number only to maintain participant confidentiality. All records that contain names or other personal identifiers, such as locator forms and informed consent forms, will be stored separately from study records identified by code number. All local databases will be secured with password-protected access systems. Forms, lists, logbooks, appointment books, and any other listings that link participant ID numbers to other identifying information will be stored in a separate, locked file in an area with limited access.

The Ain Shams Surgical Research Group will oversee the data storing process. All Principal Investigators will be given access to the cleaned data sets. All data sets will be password protected. To ensure confidentiality, data dispersed to project team members will be blinded of any identifying participant information.

Conflicts of Interest

All principal and team investigators declare no conflict of interest.

Publication Policy

The primary and secondary outcome papers of the trial are expected to be published in the relevant journals regardless of the trial results. The selection of the journal will be decided by the Ain Shams Surgical Research Group. All papers and abstracts stemming from this trial must be approved by the Ain Shams Surgical Research Group before they are submitted. The study results will be released to the participating physicians, medical students, patients and to the general medical community.

Authorship

Each participant will be recognized on any resulting publications as PubMed-citable co-authors. A corporate authorship model will be used.

The study protocol will be publicly available after submission to the clinicaltrails.gov website.

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Appendices:
(1)

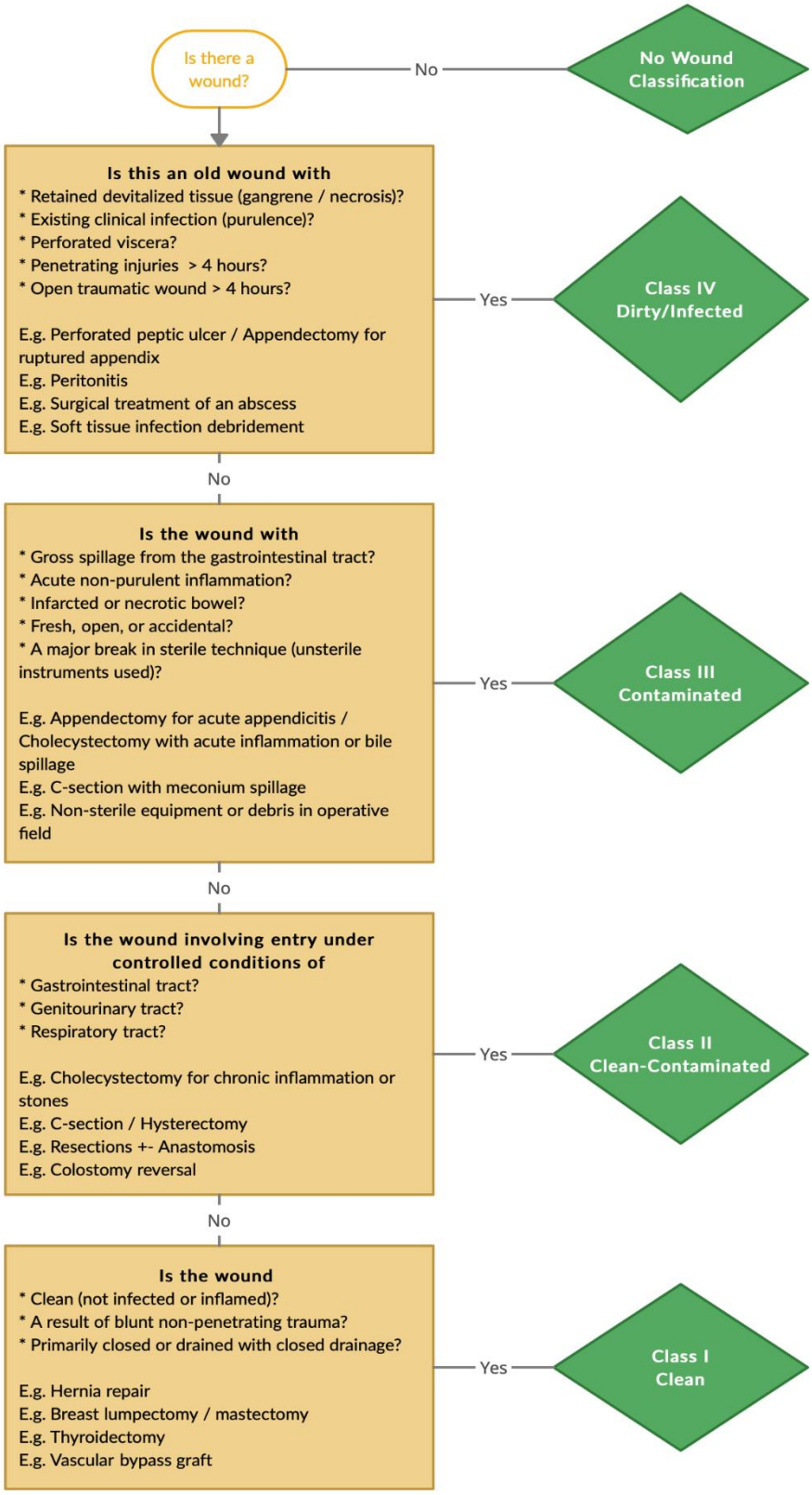
Table 1

Surgical Wound Classification Grades (I–IV) as Defined by the CDC

CDC Surgical Wound Classification Definitions
Class I/Clean: An uninfected operative wound in which no inflammation is encountered, and the respiratory, alimentary, genital, or uninfected urinary tract is not entered. In addition, clean wounds are primarily closed and, if necessary, drained with closed drainage. Operative incisional wounds that follow no penetrating (blunt) trauma should be included in this category if they meet the criteria.
Class II/Clean-Contaminated: An operative wound in which the respiratory, alimentary, genital, or urinary tracts are entered under controlled conditions and without unusual contamination. Specifically, operations involving the biliary tract, appendix, vagina, and oropharynx are included in this category, provided no evidence of infection or major break in a sterile technique is encountered.
Class III/Contaminated: Open, fresh, accidental wounds. In addition, operations with major breaks in a sterile technique (eg, open cardiac massage) or gross spillage from the gastrointestinal tract, and incisions in which acute or no purulent inflammation is encountered are included in this category.
Class IV/Dirty-Infected: Old traumatic wounds with retained devitalized tissue and those that involve existing clinical infection or perforated viscera. This definition suggests that the organisms causing postoperative infection were present in the operative field before the operation.

CDC = Centers for Disease Control and Prevention.

Algorithm for wound classification



(2) Included surgeries

1. ***Vascular surgeries***
   a) ***Abdominal aortic aneurysm repair*** (Resection of abdominal aorta with anastomosis or replacement)
   b) ***Limb amputation*** (Total or partial amputation or disarticulation of the upper or lower limbs, including digits)
   c) ***Shunt for dialysis***
   d) ***Carotid endarterectomy*** (Thromboendarterectomy, including patch graft, Reoperation, carotid, thromboendarterectomy, more than 1 month after original operation)

2. ***Hepatobiliary surgeries***
   a) ***Bile duct, liver, and pancreatic surgery*** (Excision of bile ducts or operative procedures on the biliary tract, liver, or pancreas)
   b) ***Gallbladder surgery*** (Cholecystectomy and cholecystostomy)
   c) ***Liver transplant***

3. ***Gastrointestinal surgeries***
   a) ***Appendectomy***
   b) ***Intestinal resection and anastomosis***
   c) ***Segmental colectomies*** (Incision, resection, or anastomosis of the large intestine; includes large-to-small and small-to-large bowel anastomosis)
   d) ***Bariatric procedures***
   e) ***Gastric surgery*** (Incision or excision of stomach; includes subtotal or total gastrectomy)
   f) ***Spleen surgery***
   g) ***Rectal surgery***

4. ***Exploratory laparotomy*** (abdominal operations not involving the gastrointestinal tract or biliary system; includes diaphragmatic hernia repair through abdominal approach)

5. ***Neck surgeries***
   a) Thyroid and/or parathyroid surgery
   b) Sialoadenectomy
   c) Major excision or incision of the larynx and radical neck dissection

6. ***Thoracic surgeries***
   a) Heart transplant

7. ***Neurosurgery***
   a) ***Laminectomy*** (Exploration or decompression of spinal cord through excision or incision into vertebral structures)

8. ***Urological surgeries***
   a) ***Kidney transplant***
   b) ***Kidney surgery*** (Resection or manipulation of the kidney with or without removal of related structures)
   c) ***Prostate surgery*** (Suprapubic, retropubic, radical, or perineal excision of the prostate; does not include transurethral resection of the prostate)

9. ***OB&GYN***
    a) ***Cesarean section***
    b) ***Abdominal hysterectomy***
    c) ***Ovarian surgery***
    d) ***Vaginal hysterectomy***

(3) Excluded surgeries

1. ***Anal surgeries***
2. ***Surgery for infected wounds***
    a. Debridement for necrotizing fasciitis
    b. Laparotomy for intra-abdominal abscess
3. ***Breast surgery***

Excision of lesion or tissue of breast including:

a) Radical, Modified, or Quadrant resection.
b) Lumpectomy.
c) Incisional biopsy.
d) Mammoplasty

4. ***Cardiac surgery***
    - Procedures on the heart; includes valves or septum
5. ***Coronary artery bypass graft with both chest and donor site incisions***
6. ***Coronary artery bypass graft with chest incision only***
7. ***Pacemaker surgery***
8. ***Craniotomy***
    - Excision, repair or exploration of the brain or meninges
9. ***Spinal fusion***
    - Spinal fusion or refusion - Immobilization of spinal column
10. ***Open reduction of fracture***
    - Open reduction of fracture or dislocation of long bones with our without internal or external fixation
11. ***Herniorrhaphy***
    - Repair of inguinal, femoral, umbilical, or anterior abdominal wall hernia
12. ***Hip prosthesis***
13. ***Knee prosthesis***
14. ***Peripheral vascular bypass surgery***
15. ***Ventricular shunt***

(4) Clavien-Dindo classification system:

Grades	Definition
Grade I	Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic and radiological interventions Allowed therapeutic regimens are: drugs as antiemetics, antipyretics, analgesics, diuretics and electrolytes and physiotherapy. This grade also includes wound infections opened at the bedside.
Grade II	Requiring pharmacological treatment with drugs other than such allowed for grade I complications. Blood transfusions and total parenteral nutrition are also included.
Grade III	Requiring surgical, endoscopic, or radiological intervention
- IIIa	Intervention not under general anesthesia
- IIIb	Intervention under general anesthesia
Grade IV	Life-threatening complication (including CNS complications) * requiring IC/ICU-management
- IVa	Single organ dysfunction (including dialysis)
- IVb	Multiorgan dysfunction
Grade V	Death of a patient

(5) *Outpatient clinic follow-up form:*

Surgical Site Infection (SSI)		
Superficial incisional SSI (SIP, SIS)		
Element	**Element Met**	**Date**
Must meet the following criteria:		
Date of event occurs within 30 days after any NHSN operative procedure (where day 1 = the procedure date)	☐	
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 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 (ASC/AST)).	☐	
c. Superficial incision that is deliberately opened by a surgeon, physician* or physician 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 • Heat	☐	
d. Diagnosis of a superficial incisional SSI by a physician* or physician designee.	☐	
*The term physician for the purpose of application of the NHSN SSI criteria may be interpreted to mean a surgeon, infectious disease physician, emergency physician, other physician on the case, or physician's designee (nurse practitioner or physician's assistant).		
Comments: There are two specific types of superficial incisional SSIs: 1. Superficial Incisional Primary (SIP) – a superficial incisional SSI that is identified in the primary incision in a patient that has had an operation with one or more incisions (for example, C-section incision or chest incision for CBGB) 2. Superficial Incisional Secondary (SIS) – a superficial incisional SSI that is identified in the secondary incision in a patient that has had an operation with more than one incision (for example, donor site incision for CBGB)		
Reporting Instructions for Superficial SSI: **The following do not qualify as criteria for meeting the NHSN definition of superficial SSI:** • Diagnosis/treatment of cellulitis (redness/warmth/swelling), by itself, does not meet criterion "d" for superficial incisional SSI. Conversely, an incision that is draining or that has organisms identified by culture or non-culture based testing is not considered a cellulitis. • A stitch abscess alone (minimal inflammation and discharge confined to the points of suture penetration). • For an NHSN operative procedure, a laparoscopic trocar site is considered a surgical incision and not a stab wound. • A localized stab wound or pin site infection is not considered an SSI; depending on the depth, these infections might be considered either a skin (SKIN) or soft tissue (ST) infection.		

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Surgical Site Infection (SSI)		
Deep incisional SSI (DIP, DIS)		
Element	**Element Met**	**Date**
Must meet the following criteria:		
Date of event occurs within 30 or 90 days after the NHSN operative procedure (where day 1 = the procedure date) according to the list in Table 2 (see below)	☐	
AND		
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, physician* or physician designee **AND** Organism(s) identified from the deep soft tissues of the incision 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 (ASC/AST)) or culture or non-culture based microbiologic testing method is not performed. A culture or non-culture base test from the deep soft tissues of the incision that has a negative finding does not meet this criterion. **AND** Patient has *at least one* of the following signs or symptoms: • Fever (>38°C) • 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.	☐	
*The term physician for the purpose of application of the NHSN SSI criteria may be interpreted to mean a surgeon, infectious disease physician, emergency physician, other physician on the case, or physician's designee (nurse practitioner or physician's assistant).		
Comments: There are two specific types of deep incisional SSIs: 1. Deep Incisional Primary (DIP) – a deep incisional SSI that is identified in a primary incision in a patient that has had an operation with one or more incisions (for example, C-section incision or chest incision for CBGB) 2. Deep Incisional Secondary (DIS) – a deep incisional SSI that is identified in the secondary incision in a patient that has had an operation with more than one incision (for example, donor site incision for CBGB)		

(6) Data collection form:

Data collector's details:

Name: **Study ID:**

Identification details (used locally for follow up only)

Patient Name: **study ID:** **Phone number:**

1) Baseline data

***1-1 Age**
- ☐ 18-25
- ☐ 26-34
- ☐ 35-43
- ☐ 44-52
- ☐ 53-61
- ☐ 62-70
- ☐ 71-79
- ☐ ≥80

***1-2 Gender:**
- ☐ Male
- ☐ Female

1-3 Height:
Weight
***BMI:**

***1-4 Smoking status:**
- ☐ Yes -current smoker
- ☐ No -never smoked
- ☐ No -ex-smoker, stopped ≥ 6 weeks ago
- ☐ No -stopped in the last 6 weeks

***1-5 Illicit substance use:**
- ☐ yes specify:
- ☐ no

***1-6 Comorbidities check all that apply)**
- ☐ Diabetes mellites * Hb A1c level:
- ☐ Hypertension
- ☐ Chronic Kidney Disease *Preoperative Cr:
- ☐ Chronic liver disease *Albumin: *INR:
- ☐ Chronic heart disease
- ☐ **Respiratory Comorbidities:**
  - ☐ Asthma
  - ☐ COPD
- ☐ Anemia Hb level:
- ☐ Autoimmune disease if yes specify:
- ☐ Others comorbid conditions:
- ☐ Remote infection
(Presence of infection in a site other than the site of surgery)

***1-7 ASA:**
- ☐ Grade 1
- ☐ Grade 2
- ☐ Grade 3
- ☐ Grade 4
- ☐ Grade 5

1-8 *SARS-CoV-2 Details:

1-8-1 SARS-CoV-2 infection
- ☐ No SARS-CoV-2 infection
- ☐ Yes –preop diagnosis (at **ANY** time before surgery)

1-8-2 How was the SARS-CoV-2 confirmed? *(tick all that apply)*
- ☐ SARS-CoV-2 swab (PCR) test
- ☐ CT thorax scan
- ☐ Clinical diagnosis based on history and examination

1-9 *Medications regularly used :
- ☐ Steroids
- ☐ Iron or other supplements
- ☐ Chemotherapy
- ☐ Others;(please specify)

Data collector's details

Name: **Study ID:**

Patient identification details (used locally for follow-up only)

Patient name: **Study ID:** **Phone number:**

2) Operative data (Patient's random code:……)

2-1 *Date of surgery:

2-2 *Hospital admission:
- ☐ Performed as day-case (no overnight admission)
- ☐ Performed with overnight admission
(overnight admission can include nights spent in hospital either before and/or after surgery)

2-3 *Duration of preoperative hospital stay:

2-4 *Type of surgery:
- ☐ Emergency
- ☐ Elective

2-5 *Surgical procedure:

Type of wound: *(For definitions please refer to appendix 1 in protocol)*
- ☐ Clean
- ☐ Clean-Contaminated
- ☐ Contaminated
- ☐ Dirty

2-6 *Duration of surgery (minutes):

2-7 *Surgical approach:
- ☐ Open surgery
- ☐ Minimally invasive surgery
- ☐ Minimally invasive surgery converted to open
- ☐ Hybrid surgery (e.g. laparoscopic abdomen, open chest)

2-8 *Surgical drain:
- ☐ Yes for how many days?
- ☐ No

2-9 *wound closure was done by:
- ☐ Sutures
- ☐ staples

Data collector's details

Name: **Study ID:**

Patient identification details (used locally for follow-up only)

Patient name: **Study ID:** **Phone number:**

3) Follow up

3-1 *Follow up intervals:
(Make sure you contact the patient at every interval, then checkmark the interval that the patient develops SSI)

- ☐ 0-7 days
- ☐ 8-14 days
- ☐ 15-21 days
- ☐ 22-28 days
- ☐ 28-30 days

3-5 *SSI survey Qs: *(check all that apply)*
Does the patient suffer from….

- ☐ Pain or tenderness at the surgical site
- ☐ Swelling at the surgical site
- ☐ Hotness at the surgical site
- ☐ Pus draining from the site of incision
- ☐ Fever postoperatively (degree:)
- ☐ Surgical incision has been deliberately opened by a physician for signs of infection before due time for stitch removal

*if the patient scored 1/6 or more please ask him to directly go to the surgical outpatient clinic to complete the follow up process.

*if the patient scored 0/6 please repeat the SSI survey in the mentioned intervals till the end of the 30 days follow up.

3-6-1 *Did the patient develop SSI within 30 days postoperatively?

- ☐ Yes, please specify the postoperative day:
- ☐ No

3-6-2* Was the patient readmitted to the hospital due to SSI?

- ☐ Yes (for how many days: ……)
- ☐ No

3-6-3* Did the SSI require another surgical procedure?

- ☐ Yes (specify: ……)
- ☐ No

3-2 *Follow up was done through: *(check all that applies)*

- ☐ Inpatient hospital records
- ☐ Outpatient clinic
- ☐ Over phone

3-7 *Did the patient develop any of the following due to SSI? *(check all that apply)*

- ☐ Sepsis
- ☐ Septic shock
- ☐ Multiple organ dysfunction syndrome
- ☐ Wound dehiscence
- ☐ Others (specify ……)

3-3 *After surgery the patient was discharged to:

- ☐ Surgical ward
- ☐ ICU (for how many days:…….)
- ☐ Home

3-8 *Was there any adverse effect of PVP-I application?

- ☐ Local skin reaction
- ☐ Poor wound healing
- ☐ Other: (please specify: ……..)

3-4-1 *What was the length of hospital stay after the surgical procedure?

…… days

3-4-2 *Was it extended due to wound infection related complications?

- ☐ Yes (specify: ……)
- ☐ No

3-9 *Please specify patient grade according to Clavien-Dindo classification

- ☐ Grade I
- ☐ Grade II
- ☐ Grade III
- ☐ Grade IIIa
- ☐ Grade III b
- ☐ Grade IV
- ☐ Grade IV a
- ☐ Grade IV b
- ☐ Grade V

***Reason for choosing that grade:**