Cesarean Section Surgical Site Infection Surveillance Initiative (CS-SIMPI)

Pilot

2021

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Contents

1. ABBREVIATIONS

AIIMS	All India Institute of Medical Sciences
ANM	Auxiliary Nurse Midwife
ASHA	Accredited Social Health Activist
CDC	US Centers for Disease Control and Prevention
GOI	Government of India
HAI	Healthcare Associated Infections
HICC	Hospital Infection Control Committee
HICN	Hospital Infection Control Nurse
ICMR	Indian Council of Medical Research
ID	Identification number
ICN	Infection Control Nurse
IPC	Infection Prevention and Control
LAQSHYA	Labour room Quality Improvement Initiative
LMIC	Low- and Middle-Income Countries
LSCS	Lower Segment Caesarian Section
MoHFW	Ministry of Health & Family Welfare
NHSN	National Healthcare Safety Network
OPD	Outpatient Department
PI	Primary Investigator
OT	Operation Theatre
QI	Quality Improvement
SSI	Surgical Site Infections

2. BACKGROUND

Surgical site infections (SSIs) are among the most common healthcare associated infections (HAIs) in low and middle income countries (LMIC) with an incidence over three times higher than that seen in developed nations [1]. Surgical site infections result in longer hospital stays, repeated admissions and greater healthcare costs to both patients and the healthcare system overall [2-4]. Because many surgical site infections are preventable through infection prevention strategies and good surgical practice, the increased healthcare cost and associated patient morbidity from SSIs are avoidable in most settings. A standardized approach to SSI surveillance directly connecting SSI surveillance to SSI prevention activities has been shown to be an effective intervention for reducing the risk of SSI and establishing safer surgical practice [5].

The All India Institute of Medical Sciences (AIIMS), New Delhi is spearheading a surveillance initiative for healthcare associated infections, technically coordinated by Indian Council of Medical Research (ICMR) in more than 50 hospitals across India, and supported by Centers for Disease Control and Prevention (CDC). The existing surveillance system focusses on the blood stream and urinary tract infections. This protocol has been developed to initiate surveillance for Cesarean Section SSIs as a pilot.

2.1 Objectives

The surveillance system is designed to accomplish four main objectives:

1. Provide a cost-effective methodology for the systematic collection, analysis, and presentation of actionable information on the occurrence of SSIs
2. Provide data to implement targeted infection prevention and control (IPC) activities
3. Provide a platform for measuring the impact of IPC activities
4. Provide a safer surgical context for patients

3. PURPOSE

The purpose of this protocol is to establish sustained and feasible post C-section SSI surveillance to inform the implementation and ongoing evaluation of SSI prevention interventions. This protocol is meant to be used by medical officers, infection control nurses (ICN), Hospital Infection Control Committee (HICC) and others involved in safe surgical practice. It may also be given to hospital administrators or other stakeholders to understand how SSI data is collected. This document is intended to be used by facilities conducting lower segment caesarean sections (LSCS). The protocol contains detailed information for setting up SSI surveillance and instructions that a surveillance officer or others in charge of the surveillance system should follow.

4. SURVEILLANCE SETTINGS

1. Surveillance of surgical patients will occur in inpatient and/or outpatient settings where C-sections are performed. This protocol focuses on inpatient surveillance in health facilities with a provision for post-discharge surveillance, if feasible. A primary objective of this protocol is to establish a feasible, cost effective SSI surveillance initiative, that can be done with a modest amount of resources. Good surveillance will provide valuable information on ways to improve patient outcomes, surveillance and ensure patient safety in the long run. Each facility should review the resources available for surveillance for implementation of evidence-based IPC activities. Designation of a dedicated staff nurse to lead the SSI surveillance in the healthcare facility, a ICN will be preferable.

2. Presence of an engaged healthcare facility administration and a HICC. The team should be willing to consider surveillance findings and be able to implement IPC activities to prevent surgical infection [6, 7]
3. Presence of human and material resources needed to conduct the SSI surveillance activities

Having an established IPC Program that can take action based on surveillance results would be an added advantage. Sites should preferably have a written policy of single dose of prophylactic antibiotic prior to the C-section/ or recognized alternative based on relevant locally developed antibiograms/antibiotic policy.

5. DEFINITIONS

The following key terms and definitions have been adopted from the National IPC Guidelines for Healthcare facilities, MoHFW, January 2020 and are in line with those used by the United States Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN) [8] and the World Health Organization [6, 7, 9, 10]. Due to operational feasibility the lab confirmation is not mandated in the current protocol.

5.1 Key Terms

Surveillance Period: The number of days over which surveillance data is collected, and results presented (Example: 1-month surveillance period)

Surveillance Inpatient Period: The period from the C-section procedure (Day 0) to discharge from the facility

Post-discharge Period: The period from discharge from the facility to the end of the follow-up period (Day 30)

Follow-up Period: The 30-day period in which symptoms meeting the case definition will be attributed to the surgical procedure.

Elective Procedure: A scheduled surgical procedure, usually performed with standard pre-procedure activities (also called a 'routine procedure')

Emergent Procedure: An unscheduled surgical procedure, often performed without standard pre-procedure activities

Wound Class: Grouping surgical wounds by risk of infection based on contamination and where the wound is located on the body.

Diagnosed Wound Infection: A wound determined to be infected after being assessed by a physician, surgeon or other qualified healthcare provider

5.2 SSI Case Definition

The recommended surveillance case definition for SSI represents a balance between simplicity and data value/usability and relies only on observable patient symptoms for case determination

- SSI Case Definition

  A patient within 30 days of the surgical procedure with the following observed or reported:

  - A purulent (pus) discharge in, or coming from, the wound (including evidence of an abscess)

    OR
  - Any reopening of the surgical wound

    OR
  - Evidence of fever with painful, spreading erythema surrounding the surgical site

* ***Sites, based on laboratory capacity, may also collect bacteriology culture and sensitivity results to aid with the clinical diagnosis of SSI, but this information will not be included as part of this surveillance protocol***

The case definition is for the purpose of surveillance and is not meant to serve as a clinical definition for use in diagnosis and treatment

6. SURVEILLANCE METHODS

6.1 Training

A half day virtual or in-person training for surveillance staff will be done prior to the implementation of the C-Section SSI protocol. The objective of the training is to briefly share reasons to performing the surveillance, to ensure standardized use of the protocol, and answer any doubts the participants have.

6.2 Infection Control Assessment

A baseline assessment of focused infection control practices (e.g., hand hygiene, pre-surgical prophylaxis, sterilization, disinfection, and aseptic practices, and environmental cleaning) in labour rooms, operating theaters and post-surgical wards should be performed before initiating surveillance to identify gaps in infection control policies and practices.

The information from the baseline assessment should be used to prioritize SSI prevention and activities to improve safe surgical practice. Surgical focused infection control practices should be reassessed at least annually to evaluate progress.

6.3 Surveillance Population

To reduce the resources needed for SSI surveillance and increase the comparability of findings, SSI surveillance will be limited to C-sections. The surveillance population shall include all patients undergoing the surgical procedures of interest. The surveillance population is established when the surveillance staff starts the Surgical Safety Checklist and Surveillance Form (Appendix 1) as part of good surgical safety practice and documentation during the procedure. This form will be maintained throughout the follow-up period and will be used to document case finding (section 6.4) and establish denominators (section 6.5). An example Surgical Safety Checklist and Surveillance Form is provided as Appendix 1.

6.4 Case Finding

On or around post-operative day 3, trained surgical staff and/or surveillance staff will record findings from their surgical wound assessment to determine if the surveillance case definition has been met. Assessment findings should be documented on the patient's Surgical Safety Checklist and Surveillance Form (Appendix 1).

Ideally, the first wound assessment will occur on the day when the wound dressing is changed i.e post op Day 3 (or as per the hospital's policy), to minimize patient discomfort and avoid unnecessary dressing change. While surgeon/physician diagnosis of infection is NOT itself sufficient to meet the surveillance case definition, physician assessment of the wound and consideration of any symptoms of infection are valuable and should be considered for clinical care.

A second wound assessment will be completed and documented at patient discharge. If post-discharge case finding is not being done or is lost to follow-up (e.g. patient phone number not reachable or patient moved to a different state), this discharge assessment will be the final wound assessment and serve as final determination of patient case status.

***Third Wound assessment*:** Because a substantial portion of SSI may occur after discharge from the healthcare facility where the patient had undergone the procedure, post-discharge case finding is important to consider for SSI surveillance [14]. Methods for post-discharge case finding could include:

- Telephone interview with patients
- Capture assessment data from follow-up clinic visits
- Suture removal or wound assessment if the patient returns to the facility for care or follow-up

If a surgical site infection is noted during the suture removal or during the follow up visit before 30 days, then the case forms will be closed as a case of SSI.

Post-discharge Case Finding: Telephone Interview

This protocol focuses on telephone interview by the surveillance staff (project nurse).

For post-discharge case finding, all patients should be contacted at least once (on or around day 30 post-procedure) and interviewed to determine if the case definition has been met. When patients are contacted and how they are interviewed should be kept as consistent as possible. An example script for post-discharge case finding interviews is provided as Appendix 2.

For patients that cannot be reached by phone, it is recommended that three attempts on different days be attempted to the patient or the birth companion. Following the third contact attempt the patient should be recorded as 'lost to follow-up' by clearly marking through the 'Final Check' section of the Surgical Safety Checklist and Surveillance Form (Appendix 1). While every attempt should be made to contact every patient for post-discharge case finding, some 'lost to follow-up' is expected. Patients that refuse or do not have a telephone contact number should be considered 'lost to follow-up'. There may be cases of self-referral by mothers or providers to see mothers as part of routine follow-up. This surveillance case

finding method does not take away from the usual efforts already in place for ANMs and ASHA workers to refer mothers for care, for mothers to self-refer to care, or providers to see mothers as part of routine follow-up. Any cases of infection that are referred to the ICN leading the surveillance program do not need to be called again

6.5 Collection of Denominator Data

To calculate C section SSI rates, the data on number of C- section performed should be collected. The total number of C section performed in each month at the health facility will be the denominator for calculating the SSI rate for that month.

Denominator data will be calculated based on Surgical Safety Checklist and Surveillance Forms (Appendix 1) completed during the surveillance period. **Therefore, it is important that every surgical patient having a procedure under surveillance have a Surgical Safety Checklist and Surveillance Form started and available for consideration**. A Denominator Form for recording denominator data is provided as Appendix 3.

6.6 Case Reporting

Case reporting will be done by completing the Surgical Safety Checklist and Surveillance Form. No additional documentation is needed. All forms should be near the patient care area readily available to staff recording wound assessments, but secure from loss or destruction.

Patient ID

While the Surgical Safety and Surveillance Form must include patient's name and contact information, to protect privacy - surveillance data will be managed (entered, stored, and analyzed) for analysis will not include this information. Instead, a unique facility Patient ID will be recorded (if unique IDs are used by the facility) or a surveillance specific ID assigned (when no facility assigned Patient ID is available) for data management.

It is important that any Patient ID used meet two criterial:

- Unique: No two Patient IDs in the surveillance system are the same
- Linked to the original Surgical Safety Checklist and Surveillance Form: Allows identification of the patient if needed for follow-up.

If a surveillance specific Patient ID must be assigned, the following format is suggested:

DDMMYY_XX

Where DD = Day of the month, MM = Month, YY = Year, and XX = Sequential number equating to count of procedures performed that day. For example, 301118_01 would indicate the first procedure performed on November 30, 2018.

6.7 Data Management and Analysis

Organizing the flow of surveillance data from primary sources (e.g. Surgical Safety Checklist and Surveillance Forms and wound assessment) through analysis and report dissemination is a key component of SSI surveillance. Participating sites should ensure data entry and reporting to AIIMS on a monthly basis.

Sites are encouraged to enter surveillance patient data and denominator data into their Excel file surveillance database daily.

A software will be developed, which will facilitate daily on-site data entry.

Analysis Plan

C-section SSI rates will be stratified by elective or emergent procedures. Using numerator and denominator data, incidence will be calculated for total SSI and stratified SSI as described below:

- **Total SSI rate**: SSI per 100 procedures. Divide the total number of SSI recorded by the number of procedures performed and then multiply by 100.
- **Elective SSI rate**: SSI per 100 elective procedures. Divide the number of SSI recorded for elective procedures by the number of elective procedures performed and then multiply by 100.
- **Emergent SSI rate**: SSI per 100 emergent procedures. Divide the number of SSI recorded for emergent procedures by the number of elective procedures performed and then multiply by 100.

6.8 Monitoring and Evaluation of Surveillance

Data validation is a necessary element to assure quality. Validation activities should include: 1) review of data entered into the surveillance database against the Surgical Safety Checklist and Surveillance Forms; 2) monitoring loss to follow-up rates; 3) monitoring trends in the number of procedures performed through existing surgical logs against the number of completed Surgical Safety Checklist and Surveillance Forms completed and available for entry. These can be done periodically and reports on errors and inconsistencies should be distributed to and discussed with the appropriate personnel.

6.9 Data Usage and Ownership

Facility-level data may be used to implement infection control and as quality improvement measures at individual facilities. AIIMS, New Delhi team and CDC would support data analysis and use of the data to implement targeted IPC practices.

The diagram below, Figure 1, summarizes how implementation of SSI surveillance begins a cycle that results in use of data to improve IPC practices that leads to decreased SSI rates at a facility.

Recommended surveillance data flow is diagramed as Figure 2 with solid lines indicating the movement/use of physical data forms and broken lines indicating the flow of digital information.

Figure 1. SSI Surveillance Data Use Cycle

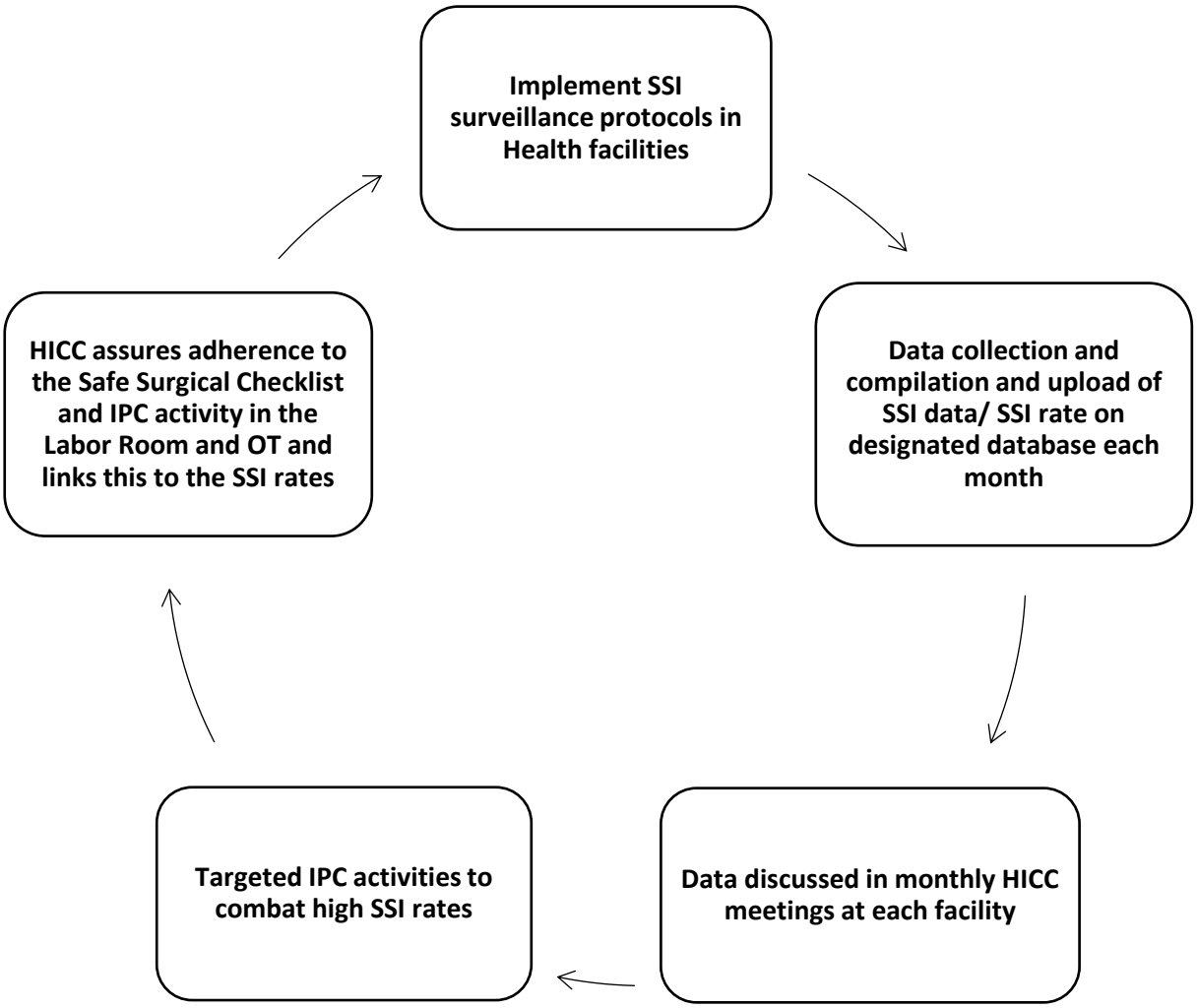
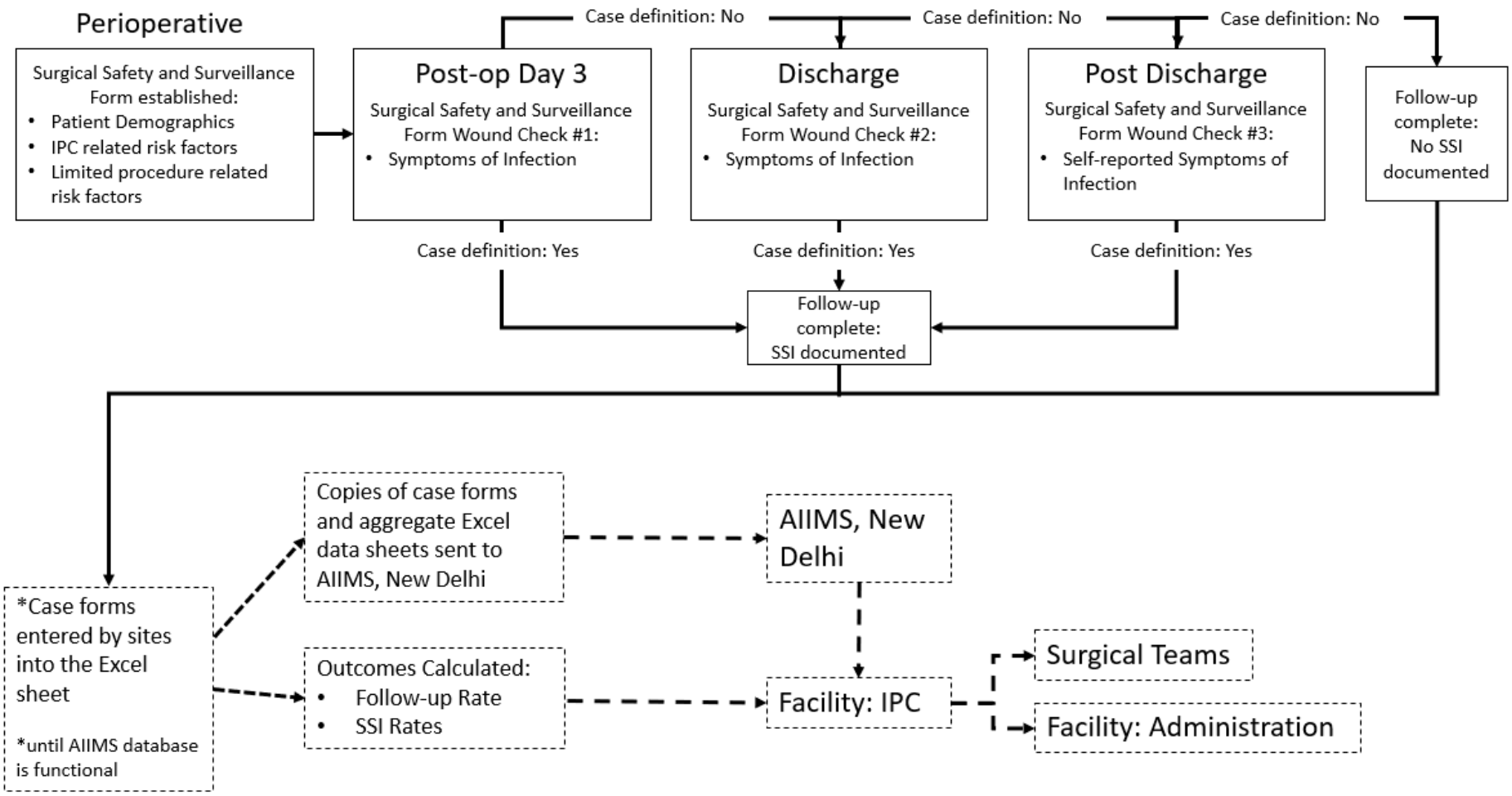


Figure 2: Recommended data flow of C-Section SSI surveillance System



Solid Lines: Physical/Form data flow
Broken lines: Digital information flow

7 ROLES AND RESPONSIBILITIES

1. Site PIs: will oversee implementation of the SSI protocol and ensure results are reported and used to improve patient outcomes.
2. Infection Control Nurse or staff nurse focal point: A designated contact person at the participating facility assigned to manage the SSI surveillance. This individual works with the surgical staff to ensure completion of the Surgical Safety Checklist and Surveillance Form, accurate recording of SSI events, and denominator data collection. Additional responsibilities might include follow-up to reconcile missing or conflicting data and disseminating surveillance reports to relevant stakeholders at the hospital.
3. Clinical units: One investigator from the obstetrics department will be designated to coordinate with the Microbiology department and infection control nurse to facilitate identification and reporting of SSIs.
4. AIIMS, New Delhi Trauma Center Team and CDC Staff : AIIMS Trauma Center Team and CDC staff will provide technical assistance to the team in charge of the surveillance system with all aspects of the surveillance initiative. This may include initial facility assessments related to infection control practices, training of facility staff, preparation of necessary materials, database management and analysis, and creation of summary reports for internal use and publication. AIIMS/CDC staff may also participate in initial facility practice/surveillance assessments and in regular monitoring, evaluation, mentoring and data validation activities to ensure completeness and accuracy of data collected. Additionally, they can provide access to subject matter expertise on SSI/HAI surveillance and prevention.

8 ETHICAL CONSIDERATION AND REVIEW

This protocol describes a public health surveillance activity, which is considered public health practice and not research, therefore individual patient consent will not be collected as a prerequisite of collecting necessary data to monitor SSI incidence. Patient consent could potentially involve all post-surgical patients housed in the facility at any given time, as patient level data (e.g. clinical evaluation, symptoms) are required to determine whether a patient is a case. Requiring this broad consent would result in a substantial burden and render the surveillance system unable to complete basic case finding functions. Every reasonable effort will be made to protect patient privacy during this surveillance. Electronic and physical security measures will be taken to ensure protection of potentially identifiable data. Electronic data will be stored in a database housed on a certified secure server and will be accessed via password protected computers/tablets.

9 REFERENCES

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10 APPENDIXES

Appendix 1: Surgical Safety Checklist and Surveillance Form

Instructions for completing this form: The surveillance staff at the healthcare facility should start using this form immediately prior to the start of each surgical procedure targeted for surveillance. While used as the principle data collection form for SSI surveillance collection, this form also serves as a surgical safety checklist. The checklist is not intended to be comprehensive. Additions and modifications to fit facility practice are encouraged; however, SSI surveillance elements should be maintained.

For detailed guidance on utilizing a surgical safety checklist, see the Implementation Manual WHO Surgical Safety Checklist (Fist Edition) available at https://www.who.int/patientsafety/safesurgery/ss_checklist/en/

In brief, a single person must be made responsible for checking the boxes on the list. This designated Checklist coordinator will often be a circulating nurse, but it can be any clinician or healthcare professional participating in the procedure. The Checklist divides the operation into three phases, each corresponding to a specific period/phase in the normal flow of a procedure:

1. Before Anesthesia
2. Before Incision
3. After Wound Closure

In each phase, the Checklist coordinator must be permitted to confirm that the team has completed its tasks before it moves forward.

Having a single person lead completion of the Surgical Safety and Surveillance form is essential for its success. In the complex setting of an operating room, steps may be overlooked. Designating a single person to confirm completion of each safety step of the Checklist can ensure that safety steps are not omitted in the rush to move forward with the next phase of the operation

The Infection Surveillance Section will be completed at set intervals during the patient's recovery (i.e., Day 3, Discharge, and Day 30 through wound assessment and patient interview/self-report.

World Health Organization

SURGICAL SAFETY CHECKLIST (FIRST EDITION)

Before induction of anaesthesia ▸▸▸▸▸▸▸▸▸ Before skin incision ▸▸▸▸▸▸▸▸▸▸▸▸▸ Before patient leaves operating room

SIGN IN

- ☐ **PATIENT HAS CONFIRMED**
  - IDENTITY
  - SITE
  - PROCEDURE
  - CONSENT
- ☐ **SITE MARKED/NOT APPLICABLE**
- ☐ **ANAESTHESIA SAFETY CHECK COMPLETED**
- ☐ **PULSE OXIMETER ON PATIENT AND FUNCTIONING**

DOES PATIENT HAVE A:

KNOWN ALLERGY?
- ☐ NO
- ☐ YES

DIFFICULT AIRWAY/ASPIRATION RISK?
- ☐ NO
- ☐ YES, AND EQUIPMENT/ASSISTANCE AVAILABLE

RISK OF >500ML BLOOD LOSS (7ML/KG IN CHILDREN)?
- ☐ NO
- ☐ YES, AND ADEQUATE INTRAVENOUS ACCESS AND FLUIDS PLANNED

TIME OUT

- ☐ **CONFIRM ALL TEAM MEMBERS HAVE INTRODUCED THEMSELVES BY NAME AND ROLE**
- ☐ **SURGEON, ANAESTHESIA PROFESSIONAL AND NURSE VERBALLY CONFIRM**
  - PATIENT
  - SITE
  - PROCEDURE

ANTICIPATED CRITICAL EVENTS

- ☐ **SURGEON REVIEWS:** WHAT ARE THE CRITICAL OR UNEXPECTED STEPS, OPERATIVE DURATION, ANTICIPATED BLOOD LOSS?
- ☐ **ANAESTHESIA TEAM REVIEWS:** ARE THERE ANY PATIENT-SPECIFIC CONCERNS?
- ☐ **NURSING TEAM REVIEWS:** HAS STERILITY (INCLUDING INDICATOR RESULTS) BEEN CONFIRMED? ARE THERE EQUIPMENT ISSUES OR ANY CONCERNS?

HAS ANTIBIOTIC PROPHYLAXIS BEEN GIVEN WITHIN THE LAST 60 MINUTES?
- ☐ YES
- ☐ NOT APPLICABLE

IS ESSENTIAL IMAGING DISPLAYED?
- ☐ YES
- ☐ NOT APPLICABLE

SIGN OUT

NURSE VERBALLY CONFIRMS WITH THE TEAM:

- ☐ **THE NAME OF THE PROCEDURE RECORDED**
- ☐ **THAT INSTRUMENT, SPONGE AND NEEDLE COUNTS ARE CORRECT** (OR NOT APPLICABLE)
- ☐ **HOW THE SPECIMEN IS LABELLED** (INCLUDING PATIENT NAME)
- ☐ **WHETHER THERE ARE ANY EQUIPMENT PROBLEMS TO BE ADDRESSED**
- ☐ **SURGEON, ANAESTHESIA PROFESSIONAL AND NURSE REVIEW THE KEY CONCERNS FOR RECOVERY AND MANAGEMENT OF THIS PATIENT**

THIS CHECKLIST IS NOT INTENDED TO BE COMPREHENSIVE. ADDITIONS AND MODIFICATIONS TO FIT LOCAL PRACTICE ARE ENCOURAGED.

NAME OF FACILITY_____ Unit Number: _____
SURGICAL SAFETY CHECKLIST& SURVEILLANCE FORM

Date: DD/MM/YYYY

Patient Name: _____ **Patient ID**: _____

Sex: □ Female □ Male **DOB**_____ **Age**: _____

Telephone: _____

Birth Companion Name: _____ **Birth Companion Telephone:**_____

Surgeon/OG Team: _____

Prior to procedure:

Surfaces and Environment cleaned: □ Yes □ No/Inadequate

Hand Hygiene Performed: □ Yes □ No/Inadequate

□ antimicrobial soap and water □ alcohol-based hand rub

Patient Skin Preparation: □ chlorhexidine □ betadine □ other

Antibiotic Prophylaxis □ Yes □ No □ NA

□ Cefazolin □ Cefuroxime □ Other _____

Procedure: □ C-Section □ Other _____ □ Elective □ Emergent

Wound Class: □ Clean □ Contaminated □ Dirty

Supply Problems:[1] □ No □ Yes: _____

[Infection Surveillance]

	First Check	**Discharge**	**Final Check**
Days after procedure	_____Days	_____Days	_____Days
Purulent Drainage / Abscess	□ Yes □ No	□ Yes □ No	□ Yes □ No
Wound Reopened	□ Yes □ No	□ Yes □ No	□ Yes □ No
Fever & Wound Redness	□ Yes □ No	□ Yes □ No	□ Yes □ No
Fever & Wound Swelling	□ Yes □ No	□ Yes □ No	□ Yes □ No
Fever & Increased Wound Pain	□ Yes □ No	□ Yes □ No	□ Yes □ No
Infection was Diagnosed:	□ Yes □ No	□ Yes □ No	□ Yes □ No

[1] Supply problems may include equipment (IV pump, lighting,) or availability of needed sterile or clean supplies.

Appendix 2: Post-Discharge Case Finding Script and Data Collection Form

Instructions for completing this form: This form should be used as both interview script and data collection form for post-discharge case finding. Steps for form use:

1. Complete Patient contact information –based on the Surgical Safety Checklist and Surveillance Form:
    - "Name of Patient"
    - "Procedure"
    - "Contact" [usually a mobile number]
    - "Date of Procedure"
    - "Follow-up Date" [30-days after the "Date of Procedure"]
2. On or within 5 days of the "Follow-up Date" the <u>first attempt</u> to contact the patient for follow-up should be made. Three attempts should be made on separate days. Record the date of each attempt in the space provided.
3. When the individual has been contacted, record the "Name of Interviewer" and complete the interview by reading each question as written. Record answers on the form.
4. Complete the "Final Check" section of the Surgical Safety Checklist and Surveillance Form based on interview responses:
    - Purulent Drainage = Yes: Question 1 (Yes) + a (Cloudy or Yellow or Green)
    - Fever & Wound Redness = Yes: Question 8 (Yes) + Question 5 (Yes)
    - Fever & Wound Swelling = Yes: Question 8 (Yes) + Question 6 (Yes)
    - Fever & Increased Wound Pain = Yes: Question 8 (Yes) + Question 7 (Yes)
5. Store completed Post-discharge form with the Surgical Safety Checklist and Surveillance Form for data entry

Post-Discharge Patient Interview Script

Hello, this is [**YOUR NAME**] from [**HEALTH FACILITY**]. My records show that you had a [**NAME OF PROCEDURE**] on [**DATE OF OPERATION]**. Is this correct?

[ ] Yes Corrected information:

[ ] No (specify)

[ ] Report that patient has died (date of death: ____ / _____ / _____)

Thanks for that, I am calling today to check that you are doing well and that your wound has healed as it should. Do you have 5 to 10 minutes to answer a few questions?

If not a good time, note a better time to call: _____

Your answers are very important to us and combined with hundreds of others will help to improve the quality care at [**HEALTH FACILITY**]. I want to assure you that all your responses will be kept confidential.

I would like to start with asking about fluid that may have come from your wound. A small amount of clear or bloody fluid from a healing wound is normal. I am interested in fluid we call **pus** that is a sign of an infection in your wound. Pus is usually thick and cloudy or milky and can sometimes have an unpleasant smell.

1. At any point did you see pus coming from your surgical wound? [[symptom_pus]]
   - ☐ Yes*
   - ☐ No [**SKIP TO QUESTION 5**]
2. What color was the pus?
   - ☐ Clear [clarify: puss is typically not clear]
   - ☐ Cloudy
   - ☐ Yellow
   - ☐ Green
   - ☐ Red/bloody [clarify: pus is not usually described as mainly bloody
3. Did the pus have a bad smell?
   - ☐ Yes
   - ☐ No
4. What was the date when you noticed the pus coming from the surgical wound? [[ssi_date]]
   - ☐ (dd/mm/yyyy) ____ / ____ / _____

I am now going to ask you about redness, swelling, and pain around your wound.

5. Did you notice redness around your wound that got worse instead of better? [[symptom_erythema]]
   - ☐ Yes*
   - ☐ No

6. Did the area around your wound ever become swollen? By swollen I mean an enlargement of the wound area or the affected part of the body causing pain or limited your movement. [[symptom_erythema]]

   ☐ Yes*

   ☐ No [clarify, if #5 = yes, confirm there was **NO swelling noted**]

7. While there was redness and/or swelling around the wound, did you have pain at the site that was worse than you expected? [[symptom_erythema]]

   ☐ Yes*

   ☐ No [clarify, if #5 and #6 = YES, confirm there was **NO pain noted**] [**SKIP TO QUESTION 9**]

8. While there was redness and/or swelling around the wound, did you have fever? By fever I mean a measured temperature above 38^0 C (oral), 37.5^0 C (axillary) or symptoms of a fever including periods of unusual sweating, shivering, headache, muscle aches, loss of appetite, or general weakness. [[symptoms_fever]]

   ☐ Yes*

   ☐ No [clarify, if #5, #6, and #7 are YES, confirm there was **NO fever or symptoms of fever**] [SKIP TO QUSTION 11]

9. What was the date when you measured or noticed your fever?

   ☐ (dd/mm/yyyy) ____ / ____ / _____

10. At any point did you seek health care for treatment of your surgical wound? [[ssi_care]

    ☐ Yes

    ☐ No

11. Did the health care provider tell you that your wound was infected? [[ssi_dx]]

    ☐ Yes

    ☐ No

    ☐ Unknown

12. Did you take antibiotics to treat the infection? [[ssi_abx]]

    ☐ Yes

    ☐ No

    ☐ Unknown

Thank you for taking the time to answer these questions. Do you have any questions for me? If you think of any questions later you can reach our team at: _____

Appendix 3: Denominator Form

Instructions for completing this form: This form should be completed for each surveillance period (usually at least monthly) by counting all the Surgical Safety Checklist and Surveillance Forms completed during the period. It is assumed that every patient has a Surgical Safety Checklist and Surveillance Form started during his or her procedure and that every form will be available for counting.

If there is any question about forms being completed and available for surveillance, the Surveillance coordinator should be contacted.

Denominator Form (C-Section) to be collected by data manager – training to be provided

First Day of Surveillance Period	Last Day of Surveillance Period	Number of **ALL** C-sections performed	Number of **Elective** C-sections performed	Number of **Emergent** C-sections Performed
DD/MM/YYYY	DD/MM/YYYY			
DD/MM/YYYY	DD/MM/YYYY			
DD/MM/YYYY	DD/MM/YYYY			
DD/MM/YYYY	DD/MM/YYYY			
DD/MM/YYYY	DD/MM/YYYY			
DD/MM/YYYY	DD/MM/YYYY			
DD/MM/YYYY	DD/MM/YYYY			
DD/MM/YYYY	DD/MM/YYYY			
DD/MM/YYYY	DD/MM/YYYY			
DD/MM/YYYY	DD/MM/YYYY			

Notes:

Denominator Form (General)

First Day of Surveillance Period	Last Day of Surveillance Period	Number of **ALL** Procedures* Performed	Number of **Elective** Procedures* performed	Number of **Emergent** Procedures* Performed
DD/MM/YYYY	DD/MM/YYYY			
DD/MM/YYYY	DD/MM/YYYY			
DD/MM/YYYY	DD/MM/YYYY			
DD/MM/YYYY	DD/MM/YYYY			
DD/MM/YYYY	DD/MM/YYYY			
DD/MM/YYYY	DD/MM/YYYY			
DD/MM/YYYY	DD/MM/YYYY			
DD/MM/YYYY	DD/MM/YYYY			
DD/MM/YYYY	DD/MM/YYYY			
DD/MM/YYYY	DD/MM/YYYY			

- Procedures = C-Section Surgical Procedures included in SSI surveillance

Notes: