Protocol for surgical site infection surveillance with a focus on settings with limited resources



Protocol for surgical site infection surveillance with a focus on settings with limited resources ISBN 978-92-4-156554-7

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Designed by CommonSense, Greece
Printed by the WHO Document Production Services, Geneva, Switzerland

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Acknowledgments

The World Health Organization (WHO) would like to express its sincere appreciation and gratitude to all those who have supported and contributed to the development of this protocol.

This protocol was initially developed in the context of the Surgical Unit-based Safety Programme implementation in African hospitals (http://www.who.int/infection-prevention/countries/surgical/en/) and revised thereafter. Therefore, WHO would like to thank all those who used the protocol and provided feedback on its feasibility and usefulness in the context of a strategy to improve infection prevention measures and to reduce the risk of surgical site infections. In particular, we acknowledge the efforts of Peter Nthumba, Jack Barasa, Carol Mwangi, Joseph Nyagah, and Serah Nyaga (Kijabe Hospital, Kijabe, Kenya), Gabriel Okumu, Robert Mugarura, Agness Katwesigye (Kisiizi Hospital, Kisiizi, Uganda), Alexander Elobu, Josephat Jombwe, Dorah Nakamwa (Mulago Hospital, Kampala, Uganda), and Mayaba Maimbo, Joseph Musowoya, Margaret Kasepa and Chitundu Mbao (Ndola Central Hospital, Ndloa, Zambia).

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Financial support

Agency for Healthcare Research and Quality, United States of America.

Acronyms

ABHR alcohol-based handrub

ASA American Society of Anesthesiologists

CDC-NHSN Centers for Disease Control and Prevention – National Healthcare Safety Network

GNI gross national income

HAI health care-associated infection
IPC infection prevention and control
LMIC low- and middle-income countries

NNIS National Nosocomial Infection Surveillance

SSI surgical site infection

SUSP Surgical Unit-based Safety Programme

USA United States of America
WHO World Health Organization

Glossary of terms

Alcohol-based handrub refers to an alcohol-based preparation designed for application to the hands to inactivate microorganisms and/or temporarily suppress their growth. Such preparations may contain one or more types of alcohol, other active ingredients with excipients and humectants.

The American Society of Anesthesiologists (ASA) score is a classification system used to measure a patient's pre-operative physical condition. Together with other parameters it is used to evaluate the patient's risk of acquiring infection. Class I: A normally healthy patient. Class II: A patient with mild systemic disease. Class III: A patient with severe systemic disease that is not incapacitating. Class IV: A patient with an incapacitating systemic disease that is a constant threat to life. Class V: A moribund patient who is not expected to survive for 24 hours with or without the operation.

Health care-associated infection, also referred to as "nosocomial" or "hospital" infection, is an infection occurring in a patient during the process of care in a hospital or other health care facility, which was not present or incubating at the time of admission. Health care-associated infections can also appear after discharge. They represent the most frequent adverse event during care.

Low- and middle-income countries: WHO Member States are grouped into four income groups (low, lower-middle, upper-middle, and high) based on the World Bank list of analytical income classification of economies for the 2014 fiscal year, calculated using the World Bank Atlas method. For the 2016 fiscal year, low-income economies are defined as those with a gross national income (GNI) per capita of US\$ 1045 or less in 2014; middle-income economies are those with a GNI per capita of more than US\$ 1045, but less than US\$ 12 736; (lower middle-income and upper-middleincome economies are separated at a GNI per capita of US\$ 4125) high-income economies are those with a GNI per capita of US\$ 12 736 or more.

Multimodal strategy consists of several elements or components (three or more, usually five) implemented in an integrated way with the aim of improving an outcome and changing behaviour. It includes tools, such as bundles and checklists, developed by multidisciplinary teams that take into account local conditions. The five most common components include: (i) system change (that is, availability of the appropriate infrastructure and supplies to enable infection prevention and control good practices); (ii) education and training of health care workers and key players (for example, managers); (iii) monitoring infrastructures, practices, processes, outcomes, and providing data feedback; (iv) reminders in the workplace/communications; and (v) culture change with the establishment or strengthening of a safety climate.

Surgical hand preparation refers to an antiseptic handwash or antiseptic handrub performed preoperatively by the surgical team to eliminate transient flora and reduce resident skin flora. Such antiseptics often have persistent antimicrobial activity.

Surgical procedure or operation refers to an operation where at least one incision (including a laparoscopic approach) is made through the skin or mucous membrane, or reoperation via an incision that was left open during a prior operative procedure and takes place in an operating room.

Surgical site infection refers to an infection that occurs after surgery in the part of the body where the surgery took place. Surgical site infections can sometimes be superficial infections involving the skin only. Other surgical site infections are more serious and can involve tissues under the skin, organs, or implanted material. (Source: United States Centers for Disease Control and Prevention. https://www.cdc.gov/HAI/ssi/ssi.html, accessed 21 February 2018.)

Surgical site infection is also defined as an infection that occurs within 30 days after the operation and involves the skin and subcutaneous tissue of the incision (superficial incisional) and/or the deep soft tissue (for example, fascia, muscle) of the incision (deep incisional) and/or any part of the anatomy (for example, organs and spaces) other than the incision that was opened or manipulated during an operation (organ/space). (Source: European Centre for Disease Prevention and Control. http://ecdc.europa.eu/en/publications/Publications/120215_TED_SSI_protocol.pdf, accessed 21 February 2018.)

Surveillance is defined as the ongoing, systematic collection, analysis, interpretation and evaluation of health data closely integrated with the timely dissemination of these data to those who need it.

Surgical wound refers to a wound created when an incision is made with a scalpel or other sharp cutting device and then closed in the operating room by suture, staple, adhesive tape, or glue and resulting in close approximation to the skin edges.

1. Introduction

This protocol for surgical site infection (SSI) surveillance is designed to support the implementation of the World Health Organization (WHO) Global guidelines on the prevention of SSI (1) and their implementation strategy.

The need to focus on SSI surveillance and prevention is primarily due to the following evidence (1-3).

- SSI is the most frequent type of health care-associated infection (HAI) on admission. SSI is the most frequent type of HAI in low- and middle-income countries (LMICs). Approximately one in 10 people who have surgery in LMICs acquire a SSI.
- In Africa, up to 20% of caesarean section procedures lead to a wound infection.
- SSI is also reported as the second most common HAI in Europe and the United States of America (USA). In Europe, SSI affects more than 500 000 people per year, costing €19 million; in the USA. SSI contributes to patients spending more than 400 000 extra days in hospital, costing US\$ 10 billion a year.
- In the USA, 39-51% SSI pathogens are resistant to standard prophylactic antibiotics.
- Surgical sepsis accounts for approximately 30% of all patients with sepsis.

Implementation of SSI prevention measures, especially using multimodal strategies, is effective to reduce the occurrence and the burden of infection (4-6). For example, a 17% decrease in SSI related to 10 selected procedures was reported between 2008 and 2013 in the USA (7) following improvement programmes. In African hospitals, a 60% SSI risk reduction was observed following the implementation of a WHO multimodal strategy in the context of the WHO Surgical Unit-based Safety Programme (SUSP) including SSI surveillance (8).

HAI surveillance and timely feedback of results, including SSI surveillance, are strongly recommended by WHO as part of the core components of effective infection prevention and control (IPC) programmes (4). Every health facility should be committed to this in order to provide quality, safe health care and to ensure that surveillance is not undertaken in isolation, but is instead connected to other evidence-informed activities.

Conducting high-quality SSI surveillance is crucial to detect the magnitude of the problem and to assess the impact of any prevention/improvement intervention.

This document provides a practical, reproducible and low-resource SSI surveillance methodology.

2. Purpose of this document and target audience

This protocol provides an approach to SSI surveillance that has been developed by WHO according to research-based evidence and previous experience in resource-poor settings, in particular those with limited laboratory capacity, although it can be used by any country. It was tested in the WHO SUSP programme in five African hospitals (8) and subsequently revised based on lessons learned and in the light of the 2016 WHO recommendations for SSI prevention.

There are many possible ways to conduct SSI surveillance, but variations in the methods and definitions used (that is, inconsistent application) reduce the reliability and comparability of results. This protocol is based on the widely accepted US Centers for Disease Control and Prevention – National Healthcare Safety Network (CDC-NHSN) definitions for SSI (Annex 1) (9), as acknowledged in the WHO Global guidelines on the prevention of SSI.

The protocol is intended for use by health professionals in charge of training and/or supervising and/or undertaking SSI surveillance. It should be supported by IPC teams and will be of interest also to local senior managers, including national organizations and governments, in understanding how SSI data collection should be undertaken and the organizational and resource implications.

The objectives of SSI surveillance are as follows (1):

- to systematically collect data on the occurrence of SSI in the facility and post-discharge in a defined population;
- to analyze the incidence of SSI and help identify at-risk populations/procedures;
- to assess the need for and plan implementation of SSI strategies and prevention measures;
- to examine and monitor the impact of prevention measures for controlling the incidence of SSI;
- to feedback results to surgical/IPC staff and decision-makers to to lever support for the appropriate allocation of resources and efforts;
- to compare the incidence of SSI over time and with those of other hospitals, if appropriate and feasible.

Therefore, this protocol should be used to introduce and support the conduct of SSI surveillance possibly on a routine basis or regularly (for a defined period of time, for example, six months or longer) for risk assessment and management during service delivery and to collect data to present information on patients.

It is important that surveillance protocols are accompanied by practical data collection forms, training materials and information sheets to aid application. An electronic database is considered as the gold standard in the collation and reporting of surveillance data to ensure real-time feedback and action. Tools to support these activities can be found at http://www.who.int/infection-prevention/tools/surgical/en/. However, it is accepted that some aspects of the methods and tools to be used may still need further adaptation according to local circumstances.

3. Surgical site infection surveillance overview

Surveillance is defined as "the ongoing, systematic collection, analysis, interpretation and evaluation of health data closely integrated with the timely dissemination of these data to those who need it" (9). Its objectives were defined above.

Minimum requirements for ensuring the quality of surveillance are (1):

- A written plan that states the goals, objectives and elements of the surveillance process.
- · Constant rigour of the intensity of surveillance (for example, a regular and consistent application of methods).
- Use of consistent elements of surveillance (for example, definitions, analysis/calculation methods).
- Adequate, dedicated human resources (professionals trained to undertake HAI surveillance, and ideally, in epidemiology),
- Informatics support and systems, including competencies for data management and analysis.
- Methods for data validation to ensure that data are accurate and reliable.

A careful and well-planned surveillance approach applying these elements can ensure usable surveillance data and an effective use of resources.

According to the WHO Guidelines on core components of infection prevention and control programmes at the national and acute health care facility level (4), the key principles for effective HAI surveillance are:

- Staff conducting surveillance should receive education on surveillance methods and basic concepts in epidemiology, microbiology and communicable diseases.
- · Methods for detecting infections should be active. Therefore, prospective surveillance is recommended rather than retrospective.
- Quality microbiology and laboratory capacity has a critical role to enable reliable HAI surveillance.
- Hospital-based infection surveillance systems should be linked to integrated public health infection surveillance systems.
- Feedback on results should be performed and reports disseminated in a timely manner to those at the managerial or administration level (decision-makers) and the unit/ward level (frontline health care workers). Dissemination should also include committees responsible for safety and quality as data on HAI are a quality marker.

As SSI surveillance allows for the ongoing collection, collation and feedback of SSI rates, it should be a fundamental aspect of any effective IPC programme, in particular when SSI are identified as a target for improvement.

In surgical care, the collection of SSI surveillance information can serve to motivate surgical teams to improve their services and minimize any risk to their patients. Most surgeons are very interested to know the results of SSI surveillance for their own patients, as long as they have confidence in the methods being used. Thus, it is important that surgeons understand the principles of the surveillance process.

Some barriers can be encountered when starting or conducting SSI surveillance.

Barriers are:

- Time and resource intensive (for example, increased workload).
- Organizational 'constipators' people who act as barriers and are reluctant to change.
- Difficulty building the trust of staff who might feel they are being 'watched'.
- Absence of a patient safety culture that will support surveillance and improvement in the health care facility.
- Objection to the need for dedicated surveillance resources.
- Lack of capacity for data collection and local interpretation to allow for feedback.
- Acceptance that the surveillance data are valid and reliable.
- Theatre discipline difficult to change.

However, there are a number of facilitating factors that can help progress surveillance and improvement plans at the local level.

Facilitating factors are:

- Influential and motivated individuals (surgeon, anaesthetist, nursing champions, data collector and manager) and involving a wide range of stakeholders.
- Sense of local ownership of the SSI data that can be raised among staff.
- Concrete leadership support.
- Boundary spanners individuals within a system that adopt the role of linking 'networks' (usually internal networks to external sources).
- Peer-to-peer and inter-institution learning.
- Clear action planning to ensure timely feedback.
- Consistent and regular application of surveillance methods.
- A method for data validation, particularly if data are used for benchmarking.

The epidemiological approaches for SSI surveillance are described throughout this document.

4. Definitions and risk factors for surgical site infection surveillance

Criteria for defining a SSI

One crucial aspect of SSI surveillance is that the same case definitions are used across all sites and time periods. Inconsistent application of definitions can lead to poor data and the ineffective use of resources. In this protocol, SSI is defined according to the CDC-NHSN (9), although some adaptions or prioritization are indicated below. The SSI definitions are based on factors such as site of infection and type of incision (superficial, deep, organ/space), presence of purulent (pus) discharge coming from the wound, signs or symptoms of infection, or physician diagnosis in a specific surveillance population, and specimen microbiological results, if possible (9). Specific details on the definitions are provided in Annex I.

The date when the SSI event occurs is crucial for the diagnosis and duration of surveillance. SSI is defined as occurring within 30 days after the operative procedure (where day 1 = the procedure date) for superficial SSI, or up to 90 days for deep or organ/space SSI, also depending on the surgical procedure.

It is important that staff dedicated to data collection are trained in understanding and identifying the clinical and laboratory presentations described and that reliability exercises are undertaken to reassure the health facility management of the validity of the reported results.

Risk factors

There are different types of risk, that is, at the level of the patient, procedure, hospital setting or surgical team practice. It is important to collect data on these risk factors in order to analyze SSI outcomes by subgroup, to identify high-risk patients, and to control for differences in the patient level risk. This will allow to better understand the true risk of SSI at the facility. Important data to be collected for all patients included in SSI surveillance are at least: age; sex; type of surgical procedure; whether elective or emergency surgery; the American Society of Anesthesiologists (ASA) score; timing and choice of antimicrobial prophylaxis; duration of the operation; and wound contamination class (detailed information is provided in the section 'The WHO approach to surgical site infection surveillance').

Understanding and using the ASA score of physical condition

The ASA score is a classification system used to measure a patient's pre-operative physical condition (10) and serves as one of several indicators that influence the risk of SSI development. For example, a higher ASA score can be associated with a greater SSI incidence. In particular, an ASA score of three or greater has been associated with a statistically significant increase in the incidence of SSI over those with a score less than three (11). This score is usually reported in surgical patient records to help understand surgical outcomes, which include the risk of acquiring an infection (combined with other factors described here).

ASA score

Class I: A normally healthy patient.

Class II: A patient with mild systemic disease.

Class III: A patient with severe systemic disease that is not incapacitating.

Class IV: A patient with an incapacitating systemic disease that is a constant threat to life.

Class V: A moribund patient who is not expected to survive for 24 hours with or without

operation.

Understanding and using surgical wound classification

The surgical wound classification was developed to help clinicians describe the degree of bacterial contamination of various surgical wounds. It helps gauge the risk of potential complications such as SSI among surgical procedures.

The CDC identifies four surgical wound classification categories (9), that are:

- 1. Clean: An uninfected operative wound in which no inflammation is encountered and the respiratory, alimentary, genital, or uninfected urinary tracts are not entered. In addition, clean wounds are primarily closed and, if necessary, drained with closed drainage. Operative incisional wounds that follow non-penetrating (blunt) trauma should be included in this category if they meet the criteria.
- 2. Clean-contaminated: Operative wounds 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 technique is encountered.
- 3. **Contaminated**: Open, fresh, accidental wounds. In addition, operations with major breaks in sterile technique (for example, open cardiac massage) or gross spillage from the gastrointestinal tract, and incisions in which acute, non-purulent inflammation is encountered including necrotic tissue without evidence of purulent drainage (for example, dry gangrene) are included in this category.
- 4. **Dirty or infected**: Includes old traumatic wounds with retained devitalized tissue and those that involve existing clinical infection or perforated viscera. This definition suggests that the organisms causing post-operative infection were present in the operative field before the operation.

5. The WHO approach to surgical site infection surveillance, with a focus on settings with limited resources

Based on the standardized surveillance overview and recommendations described above, WHO developed an adapted approach that has been used in settings with limited resources to conduct surveillance in the context of interventions to reduce SSI. Key points that have been the object of adaptation are listed below.

- **SSI definitions**: Given the lack of quality microbiology laboratory support, definitions based on clinical signs and symptoms should be prioritized.
- Additional indicators: In addition to data considered essential for SSI diagnosis, other process
 and practice indicators are included in data collection to document compliance with important
 measures to prevent SSI.
- Surveillance team: In order to integrate surveillance within routine practice, data related to SSI and process and practice indicators for surveillance should be recorded primarily by trained surgical staff using dedicated forms, which should become part of the patient records. This activity should be supported and supervised by IPC staff, but ideally should not be led by them. Following specific training delivered by the IPC team or others with adequate competencies, surgical staff should consider collecting these data routinely in the context of risk assessment and prevention, in collaboration with the IPC team.
- Post-discharge surveillance: For feasibility reasons, this protocol is based on post-discharge surveillance up to 30 days only; therefore one-year follow up for infections after implant surgery is not included. Some deep incisional and organ/space SSI may also be missed when using this protocol because they may require 90 days of follow-up. Post-discharge surveillance is often challenging, particularly in developing countries where patients may live in remote areas and transport is inexistent or inefficient. To mitigate these obstacles, the WHO approach includes the possibility of a telephone follow-up with patients when face-to-face consultations are really unfeasible. It also includes health workers following up the patient in health posts or clinics after hospital discharge. A key element of this approach is patient education, based on pre-discharge instructions to recognize signs of infection and to take pictures of the wound if any suspicion emerges. Careful collection of the contact details of the patient or his/her family/neighbours is crucial. Labelling of patient records to highlight that the patient is under surveillance and indicating the contact details of staff in charge of this task is also crucial.

5.1 Setting up a surveillance team

Assembling a team of individuals who are motivated to conduct SSI surveillance and disseminate the findings within a health facility is key to success. The size and composition of this team will depend on the interest and availability of local clinical staff, but important disciplines that should be represented in the 'core' team include:

- surgical staff, ideally including a surgeon with local seniority;
- theatre staff, possibly anaesthetists and/or theatre nurses;
- · IPC staff.

Many other disciplines may also be relevant to contribute to the surveillance team, including pharmacists, ward-based nursing staff, staff routinely in charge of wound dressing, and staff with

experience of data management. Involvement of senior executive staff is important to give support to the process – SSI occurrence rates are often viewed as an important indicator of institutional care quality.

5.2 Establishment of support systems

Well-functioning surveillance should be supported by a written plan that states goals and objectives, and other supporting elements including informatics services, computer support and evaluation and reporting methods.

5.3 Enrolment into surveillance

- 5.3.1 Who to enrol. The first step is to clearly define a target surveillance population. Prioritizing a particular population, such as a specific type of surgery, can be more resource-efficient and still provides useful information about risk of infection. Common surgery types surveyed are: abdominal hysterectomy; breast surgery; caesarean section; cardiac surgery; coronary artery bypass grafting; cranial surgery; hip arthroplasty; knee arthroplasty; colorectal surgery; reduction of long bone fracture; repair of neck of femur; and vascular surgery. In low-resource settings, prioritized types of surgeries could include caesarean section and/or open fracture reductions. In SSI surveillance, it is intended that all eligible patients of a defined target population are routinely enrolled into the surveillance work. Thus, once a particular patient group (including surgery type) or time period of surveillance is defined, every effort should be made to ensure that all relevant patients are identified and enrolled into the surveillance. There are no defined numbers of patients that are needed for a surveillance process, though in our experience, a single surveillance officer (for example, an appropriately trained nurse) supported by relevant members of the wider surgical department can typically enrol and follow-up between 50 and 100 patients per month.
- **5.3.2 Exclusion criteria from SSI surveillance.** These should be determined by individual hospitals. This might include patients who are unable to communicate independently or who might be difficult to contact for some other reason.
- 5.3.3 Surveillance duration. Continuous surveillance providing the rate of the occurrence of new SSI cases in specific types of surgical patients or surgical operations over time (that is, incidence) is the preferred approach to SSI surveillance, but it is often unfeasible in settings with limited resources. Period surveillance or conducting surveillance for a limited period of time (such as three to six months) can be more feasible, although it is unable to detect changes or outbreaks over longer periods of time. Detecting SSI using prevalence methods is less reliable given the high proportion of SSIs that manifest after discharge.
- 5.3.4 Information sheets and assent. Regardless of whether or not a patient is involved in a local SSI surveillance process, there will be no differences in the treatment and care they receive. Therefore, a surveillance study is not a clinical research study and should not require written consent to participate. However, as patients under surveillance using the approach proposed here are likely to be actively involved in post-discharge follow-up and to receive follow-up telephone calls from SSI surveillance staff, they should understand what the surveillance process will involve and acknowledge that this is acceptable. In practice, this typically requires 'assent' rather than 'consent' for participation, but local advice should be sought. A hospital should develop a local information sheet or card about the SSI surveillance and translate it into local languages as necessary. This might include instructions to recognize signs of infection and to take pictures of the wound if any suspicion emerges, as well as the contact details of the surveillance team. However, once again, this depends on local choices about the surveillance process.

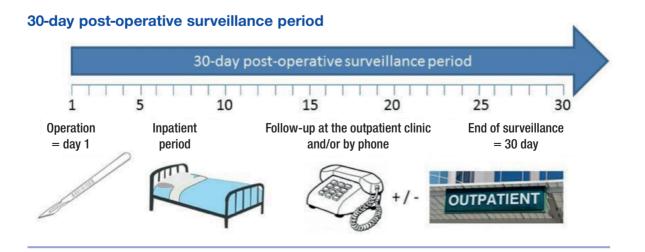
5.4 Peri-operative data collection

In SSI surveillance, there are two major time periods for collecting information about the patients having operations (that is, case finding). The first is around the time of the operation itself (that is, inpatient) and the second is the 30-day period after the operation has finished (that is, post-discharge). For this first section, see Annex 2 (SSI peri-operative data collection form).

- 5.4.1 Each patient will require one form per operation. If a patient goes back to theatre for a new (unrelated) operation, then a new form should be started. If this is within 30 days of the previous surgery, then the surveillance from the previous surgery should be discontinued. If more than 30 days have passed, then this should be considered as a distinct surgical episode. These forms can all be kept together in an A4 ring binder for example, categorized by name and/or date, as is most convenient. Technically, if a patient has two anatomically distinct procedures during the same operation (for example, bilateral inguinal hernia repair), it may be logistically easier to complete two forms as these represent two separate operations from a surveillance perspective.
- 5.4.2 Completion of data form. The peri-operative form should be completed before and during surgery, ideally by trained surgical staff. This will provide the most accurate data and allow the 'prompting' of surgeons/anaesthetists to record all the appropriate information in the patient notes. Ideally, the surveillance form should accompany the patient record at this time, including intra-operatively. If surgery takes place overnight when surveillance staff are not in the hospital, following this up should be the first task in the morning by those with this responsibility. See Annex 3 for details on the information to be entered in this form.
- 5.4.3 Data entry. Once the form has been completed, this information should be entered in the surveillance database as soon as possible tick 'yes/no' on the paper copy once this is done. The hard copy of the form should be kept for reference and audits. Notes on data entry are in the Epilnfo database manual found on the WHO web pages.
- 5.4.4 Local confidentiality. Patients should always be assured of anonymity regarding collection of data. Depending on the agreed plans at the local level, surgeons should also be assured of anonymity in overall reporting surgeon-specific reporting can be coded. Data collection forms and electronic systems should be secure and reporting should not contain any patient identifiers.

5.5 Post-operative data collection

After the surgical operation has taken place, the second phase of data collection begins, which will normally last for the 30-day period after the operation. See Annexes 4 and 5 (SSI post-operative data collection form and detailed information to complete it).



- **5.5.1** Each operation will require one post-operative form.
- **5.5.2** If acceptable at the local level, information should be given to the patient and clear instruction/training delivered to allow the patient to actively report any signs and symptoms of infection.
- 5.5.3 Across the whole 30-day period, a total of three reviews of the patient is recommended. Ideally, these would be spaced out so that these occur at roughly the end of week 1, week 2 and week 4. For patients with prolonged follow-up (implanted material), a separate filing system will be needed to keep the records 'active' for the full one-year period, if feasible (this type of surveillance is not part of this protocol). If following up over one year, we recommend a total of five follow-up interactions (weeks 1, 2 and 4; 6 months; 12 months).
- 5.5.4 Making telephone calls. Calls to patients should be made by a trained staff member involved in the surveillance work. These telephone calls represent a form of clinical interaction and should have an appropriate degree of politeness, sensitivity and confidentiality. At discharge, the patient should be told that they will receive follow-up calls about their operation wound.

5.6 Data entry

Once the form has been completed, this information should be entered in the surveillance database as soon as possible – tick 'yes/no' on the paper copy once this is done. The hard copy of the form should be kept for reference and audits. Notes on data entry are in the Epilnfo database manual found on the WHO web pages.

5.7 Other important considerations for successful SSI surveillance

5.7.1 Achieving good follow-up from both inpatient and post-discharge periods. A key feature of the CDC-NHSN definition of SSI is the fixed time-period of 30 days of follow-up for all patients, which would normally include both inpatient and outpatient periods. Surveillance data must have sufficient coverage of the patient throughout the 30-day post-operative observation period, including time after discharge from the hospital – otherwise SSI cases will be missed. Therefore, it is important that the patient should be advised at the time of discharge to return for post-operative visits in clinic according to normal practice.

Additionally, in patients who have received an implant during their surgical procedure (a non-human-derived object, material or tissue, such as prosthetic orthopaedic material), infections may not become apparent until one year after the procedure. For this reason, many surveillance networks recommend one-year post-discharge surveillance (1) (this type of surveillance is not part of this protocol).

One particular difficulty for SSI surveillance in LMICs is that patients are often unwilling or unable to return to hospital for multiple post-operative visits, particularly if the patient has no pressing symptoms. Also, should a problem occur following an operation, patients may then receive care from a health care provider different to the institution that performed the operation, meaning that the original surgeon may not be made aware of any potential surgical complications.

For these reasons, this protocol integrates the normal post-operative follow-up by the surgical team with an additional approach that attempts to overcome the difficulties of tracking post-surgical patients in LMICs. This approach recommends the use of **mobile telephone calls from SSI surveillance staff to patients** to facilitate the follow-up after discharge from the hospital. Other information, such as ward reviews of the patient prior to discharge or outpatient clinic attendance, can also be entered into the surveillance database. This flexible

format tries to accommodate as many different sources of information as available. The use of telephone calls for purposes of SSI detection has been reported in several recent studies conducted in Kenya (12, 13) and Sudan (14), showing good results in terms of reliability and improving surveillance feasibility.

5.7.2 Avoiding reporting bias from incomplete follow-up. From an epidemiologist's point-of-view, low levels of follow-up of patients under surveillance are a concern. First, some SSI cases may be missed, leading to an underestimation of the true risk. Second, there may be systematic differences in patients with complete follow-up data and those with incomplete data, which can lead to fundamental problems with surveillance results.

For example, we can imagine a situation where SSI surveillance is completed for every patient that has been operated on by surgeon X (who treats his patients very well and encourages them to return to his hospital if they have any problems), but is rarely completed for patients by surgeon Y (who is very busy and discourages his patients from returning to his hospital). In this situation, we might falsely conclude that surgeon X has a higher SSI risk than surgeon Y, because none of the SSI cases from surgeon Y are detected because they do not re-present to the hospital. This is a form of error called bias, specifically here a detection bias. Many different forms of bias exist – good surveillance attempts to minimize all of these. In practice, achieving complete follow-up on >90% of patients under surveillance is a good way to minimize the potential for this kind of bias.

- 5.7.3 Stratifying by patient characteristics. As every surgeon knows, every operation is different and some patients have a much higher risk of post-operative complications than others. This can relate to the patients themselves (for example, being diabetic), the type of surgery or the surgical technique. In surveillance, it is therefore important to compare similar operations in similar patients as far as possible. As noted in the section 'Definitions and risk factors for surgical site infection surveillance', the system known as the National Nosocomial Infection Surveillance (NNIS) risk index developed by the CDC-NHSN uses three simple indicators to classify patients into different risk groups. As described previously, these are:
 - surgical wound class (contaminated, dirty/infected=1 point; clean, clean-contaminated=0 points):
 - ASA score (3,4 or 5 = 1 point; 1 or 2 = 0 points);
 - duration of operation (operation longer than 1 hour = 1 point; shorter than 1 hour = 0 points).

Combining these gives a total score of between 0 and 3 points for each patient. Patients are then compared to patients with the same score. Separating patients into these different risk groups in this way is known as <u>risk stratification</u>. This is a way of dealing with a type of error called confounding, where a link appears to exist between a particular exposure and a disease, when actually there is some other difference or factor (a <u>confounder</u>) between the groups that is the 'true' cause of this false association.

The important principle is that this stratification puts patients into groups that have broadly similar characteristics, thus allowing reasonable comparisons within or between types of operation. In the WHO-led SUSP programme combining data from four hospitals in African countries, this index was found to perform well in stratifying the risk of SSI (8).

If the collection of data to enable the calculation of this risk index is considered unfeasible by local teams, a simple option is to stratify at least according to elective and emergency surgery, which can provide some risk consideration.

5.7.4 Balancing patient numbers and resources available. In surveillance, as in all assessments, a larger number of subjects provide more accurate results. However, conducting high-quality SSI surveillance is a resource-intensive process and in many hospitals it may not be feasible

to conduct SSI surveillance for all surgical patients all of the time. The question regarding which types of operations to enrol into surveillance, and when, should be a decision reached by local health care institutions. For example, some hospitals may decide to only conduct surveillance for particular types of surgery (for example, caesarean sections or prosthetic joint surgery) or for certain time periods (for example, only for three months each year). In some circumstances, it may be helpful to institute SSI surveillance to investigate the reasons for particularly high reported levels of SSI occurrence, although in general we recommend a planned rather than a reactive implementation of surveillance.

- 5.7.5 Considerations for using a telephone for SSI surveillance in LMICs. As this protocol recommends using mobile telephone calls to contact patients after discharge, some practical issues should be noted.
 - It is almost certainly worth procuring a dedicated 'SSI surveillance telephone', rather than
 using individual private numbers. A cheap mobile handset is probably best as this can be
 passed between different staff members easily and is less likely to disappear. Do whatever
 works best in your hospital.
 - Some basic training of staff who are going to make telephone calls is sensible. Practicing
 with a 'dummy' patient may sound strange, but it can be helpful to practice for unexpected
 situations. As with any patient interaction, it is important to check identity first, then proceed
 to information collection and close with offering the patient an opportunity to ask questions.
 - Telephone charges vary from place-to-place and between companies. For financial purposes, it is probably best to set up a monthly contract with an itemised billing list, which can be independently scrutinized (for example, by a hospital accountant) for unusual or repeated calls this reduces the temptation for staff to have long personal calls on the 'surveillance phone'. A logbook of calls (for example, one page for calls needed/done each day) can be helpful to cross-check against a telephone bill and can help with planning calls.
 - It can be helpful to publicize the surveillance telephone number, such as by putting posters
 in the relevant hospital wards and clinics and/or by giving the number to patients. This
 encourages patients and/or staff to contact the surveillance staff if they suspect that an SSI
 has developed. However, this can be problematic if patients see this as a 'short cut' to avoid
 clinic queues local judgements are needed.
 - Finding a suitable place to make surveillance telephone calls is important the same level of confidentiality should be used for a telephone call as for a face-to-face consultation. The theatre tearoom is not suitable!
 - Regular review and feedback for staff making telephone calls is important also just as you
 would discuss patients seen in clinic or on a ward round, staff making telephone phone calls
 must be 'debriefed' also. This should include a review of any notes being made from calls
 and follow-up on any problematic calls.

6. Analysis of surveillance data

The major output of SSI surveillance is two key numbers – a denominator (number of patients who have had surgery and completed their follow-up period) and a numerator (number of patients who developed SSI from the denominator). These are normally used together to calculate incidence as follows:

incidence =
$$\frac{\text{numerator}}{\text{denominator}} = \frac{\text{# of SSI cases detected during the surveillance period}}{\text{# of total surgical patients during the surveillance period}} \times 100$$

Alternatively, the number of surgical procedures performed in a specific setting during the surveillance period can be used as a denominator. This allows to take into account cases undergoing more than one surgical operation.

Incidence can also be calculated by subgroups, such as type of procedure, type of patient, time and hospital setting, using other data collected in the surveillance programme. Risk ratios and their confidence intervals can be used to compare incidence between subgroups (for example, incidence in one subgroup divided by the incidence in another subgroup). More information on basic epidemiology and analysis concepts can be found in the WHO publication on Basic epidemiology (http://apps.who.int/iris/handle/10665/43541) or the CDC Principles of epidemiology in public health practice (https://www.cdc.gov/ophss/csels/dsepd/ss1978/index.html). Furthermore, in order to adjust for patient-level differences in risk, it is recommended to present risk-adjusted SSI incidence in addition to crude estimates. This can be done using the most commonly used method of risk adjustment to predict the occurrence of an SSI in a given patient, that is, the NNIS risk index already described above, based on the ASA score, the wound classification and the duration of the surgical procedure.

7. Interpretation and feedback of surveillance data

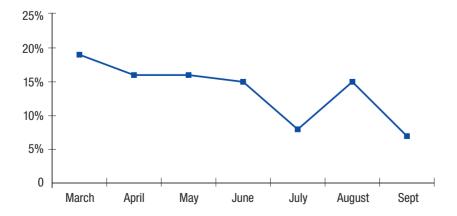
One very important aspect of surveillance that is often overlooked in the effort to collect good data and enter it accurately into a database is to give (as per the definition of surveillance) 'timely dissemination of these data to those who need to know'. Different people will have different levels of interest in the surveillance results and some of the data will require extensive analysis. The database system used for holding the surveillance data will allow to perform simple analysis and standard reports. To some extent, it is up to each site performing surveillance to establish who wants/needs to know what information and how this should be disseminated.

Data results should be interpreted carefully to identify at-risk populations and procedures and assess the impact of prevention measures. However, such interpretation should also carefully consider other factors that may influence surveillance results. It may be noted that a 'surveillance effect' may arise where simply the act of participating in a surveillance programme leads to increased compliance with SSI prevention recommendations among the surgical teams surveyed (15). Conversely, as shown in various research studies, intensive surveillance may lead to the detection of higher SSI rates than under standard surveillance conditions (1).

Below are some suggestions on how to ensure an effective feedback of surveillance data.

 Large handwritten wallcharts can be used in surgical departments or theatres to display raw numbers of cases and basic details on the infection risk. This can be a very simple format, just to show numbers of cases or numbers/trends of SSI detected in surveillance.

Surveillance project: 2013	Mar	Apr	May	June	July	Aug	Sept	Oct	Nov
Number of operations	63	55	38	48	51	60	54	44	
Superficial SSI	7	2	3	6	4	7	2		
Deep SSI	4	4	1	1	0	1	2		
Organ/space SSI	1	3	2	0	0	1	0		
Total SSI	12	9	6	7	4	9	4		
Overall SSI risk	19%	16%	16%	15%	8%	15%	7%		



This kind of chart only needs to be updated monthly, and the number of SSI cases lags a month behind the number of operations due to the 30-day surveillance. Note: as this is only showing the number of cases from one hospital, there can be large month-to-month fluctuations due to random variation.

- Morbidity and mortality meetings (or equivalent). Some hospitals/departments will have these meetings regularly. It can be straightforward to bring monthly SSI data to these meetings, ideally with some case notes of patients who have developed a SSI. This approach will also be very useful while using a 'learning from defects' tool and in the meetings dedicated to its use. Larger meetings or seminars to discuss changes in practices across a department can be organized separately with key staff.
- Direct discussion with individual surgeons. There is often a sense that someone is 'to blame' for the occurrence of an SSI - this should never be the case. HAIs are a fact of life in health care facilities all around the world - the best way to address them is by open discussion with the clinical team involved so that lessons can be learned where possible. Letting a surgeon know when a case they have operated on has developed an SSI is helping them to improve their own practice.

Whatever approach is taken, SSI will not be prevented unless surveillance data are used to improve practices and outcomes.

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Annex 1.

United States Centers for Disease Control and Prevention – National Healthcare Safety Network surgical site infection definition criteria

Superficial incisional SSI*

Date of event for infection occurs within 30 days after surgical procedure (where day 1=procedure date)

AND

involves only skin and subcutaneous tissue of the incision

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 purpose of clinical diagnosis or treatment.
- c. Superficial incision that is deliberately opened by a surgeon or attending physician or other designee and culture or non-culture based testing is not performed.

Patient has at least one of the following signs or symptoms: pain or tenderness: localized swelling; erythema; or heat.

d. Diagnosis of a superficial incisional SSI by the surgeon or attending physician or other designee.

Deep incisional SSI

Date of event for infection occurs within 30 days or 90 days after the surgical procedure (where day 1=procedure date)

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 or attending physician or other designee and organism is identified by a culture or non-culture based microbiologic testing method which is performed for purpose of clinical diagnosis or treatment or culture or non-culture based microbiological method is not performed patient has at least one of the following symptoms: fever (>38°C); localized pain or tenderness. A culture or non-culture based test that has a negative finding does not meet this criterion.
- 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 SSI**

Date of event for infection occurs within 30 days or 90 days after the surgical procedure (where day 1=procedure date) according to the list that can be found at

https://www.cdc.gov/nhsn/pdfs/pscmanual/9pscssicurrent.pdf

AND

infection 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 the drain that is placed into the organ/space (for example, closed suction drainage system, open drain, T-tube drain, CT guided drainage)
- b. Organism identified from an aseptically-obtained fluid or tissue in the organ/space by a culture or non-culture based microbiologic testing method which is performed for purpose 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.

AND

meets at least <u>one</u> criterion for a specific organ / space infection site listed at https://www.cdc.gov/nhsn/PDFs/pscManual/17pscNosInfDef_current.pdf

Note: The content of this table refers to the "Surgical Site Infection (SSI) Event. Atlanta (GA): Centers for Disease Control and Prevention, National Healthcare Safety Network; 2018 (https://www.cdc.gov/nhsn/pdfs/pscmanual/9pscssicurrent.pdf)" with some minor adaptations.

- *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).
- A localized stab wound or pin site infection- Such an infection might be considered either a skin or soft tissue infection, depending on its depth, but not an SSI.
- An infected burn wound is not an SSI.
- ** For more details on organ/space infection sites, detailed information can be found on the back page of the post-operative data collection form and at https://www.cdc.gov/nhsn/pdfs/pscmanual/17pscnosinfdef_current.pdf.

Annex 2. WHO peri-operative data collection form

Surgical site infection surveillance peri-operative data collection form

	Pa	atient name	Age/	sis#b	//	InPatient number	Date of admis	sion	le de la constant de	
ID	Pr	imary diagnosis	Sex		,, □ M	Surveillance number	//			
H									World Health	
		urgical procedure		ter []			Organization			
1										
				Grade						
		ASA class						We	i ght kg	
		☐ 1. Normal healthy person☐ 2. Mild systemic disease (e.g. hype	, well	controlled	d diabetes)		Hei	ghtcm		
2										
	□ 3. Severe systemic disease not incapacitating (e.g. moderate COPD, diabetes, malignancy) □ 4. Incapacitating systemic disease that is a constant threat to life (e.g. pre-eclampsia, heavy bleeding) □ 5. Moribund patient, not expected to survive with or without operation (e.g. major trauma)								ding)	
	dex \	Surgical wound class								
3	ž n	Clean □ = Ste Clean-contaminated □ = CC				ent bacteria e.g. neurosur		erec	tomy	
	NNIS Risk Index	Contaminated □ = UN	ICONTRO	OLLEI	D entry to	tissue with bacteria e.g. a	acute gas	stroin	testinal perforation	
	No.					soil in wound) or infectior	already	estal	olished	
	CDC	[: 1 24h clock	Urgency							
4		Franklings (alsin alastuus)	_	, ,		e done immediately to sa ne within 24-48h	,	0	najor bleed) epair of fracture)	
		[:] 24h clock	□ Semi-	electi	ve – must	be done within days-wee	ks (e	e.g. tı	umour removal)	
		Duration =hrsmins	□ Electiv	/e – r	no time co	nstraints	(€	e.g. c	osmetic procedure)	
		PRE/I	PERI-OPI	ERAT		CESS MEASURES				
		tient preparation	Data	, ,		Surgical skin preparation (under sterile conditions) ☐ Chlorhex-alc ☐ Iodine+alc ☐ Chlorhex-aq ☐ Iodine-aq				
		e-op bath/shower (full body [Y/N] itimicrobial soap used [Y/N] Plain s				Appropriate skin preparation technique [Y / N]				
		air removal (HR): 🗆 Razor 🗆 Clipper	-		-	Allowed to fully dry [Y / N]				
	HF	R Date 🗆 Home 🗆 Wa	rd 🗆 Ti	heatr	_	Surgical hand preparation				
		ırgical antibiotic prophylaxis				☐ Alcohol-based hand rub ☐ Antimicrobial soap+water				
		No prophylaxis required equired but not given due to: ☐ Unava	ilablo			☐ Plain soap+water				
		Other				Time spent on procedure		mins		
	Antibiotic given:							e: [Y/N]		
_		Co-amoxiclav ☐ Cefazolin ☐ Cloxac Ciprofloxacin ☐ Gentamicin ☐ Metro	nycin	Theatre traffic Headcount at start of ope	eration		total			
5		Other antibiotic Dose	GIIIGIIIII	Number of entries during operation						
	Tin	ne given [:] 24h clock Time re-dos	4h clock	Door openings during operation total						
	Po	stoperative antibiotics		Drain / implant						
		ere antibiotics ceased at completion of	' N]	Location						
		not, what antibiotics were prescribed?	, ,	Drain inserted? [Y/N]						
		ug Dose		If YES, type of drain: Open Closed						
	Doses / day Duration (days) Reason given					Antibiotic given in presence of drain but no infection? [Y/N]				
		Post-op prophylaxis Drain / impla		Implant used? [Y/N]						
		Treating suspected / known infection	☐ Othe	er						
6	Ot	her measure(s) – decided at local le	vel							
Dat	Date form completed/									

Key explanations to complete the peri-operative form

Box 1

Surgical procedure - refers to an operation where at least one incision (including a laparoscopic approach) is made through the skin or mucous membrane, or reoperation via an incision that was left open during a prior operative procedure AND takes place in an operating theatre – select the exact surgical procedure from the list below.

Abdominal aortic aneurysm repair Limb amputation

Appendix surgery

Appendix surger:

Shunt for dialysis

Bile duct, liver or pancreas surgery

Breast surgery

Cardiac surgery

Carotid endarterectomy

Coronary artery bypass surgery –

donor+graft sites

Coronary artery bypass surgery -

chest only

Gallbladder surgery

Colon surgery

Craniotomy

Caesarean section

Spinal fusion

Open reduction of fracture

Gastric surgery

Herniorrhaphy

Hip prosthesis

Heart transplant

Abdominal hysterectomy

Knee prosthesis

Kidney transplant

Laminectomy

Liver transplant

Neck surgery

Kidney surgery

Ovarian surgery

Pacemaker surgery

Prostate surgery

Peripheral vascular bypass surgery

Rectal surgery

Refusion of spine

Small bowel surgery

Spleen surgery

Thoracic surgery

Thyroid and/or parathyroid surgery

Vaginal hysterectomy

Ventricular shunt

Abdominal surgery

Grade of surgeon - senior (surgeon with more than 10 years of experience in total); junior (surgeon with less than 10 years of experience); trainee (junior doctor who is in training in the surgical specialty); 'other grade' of surgeon (as defined locally).

Box 3

Surgical wound class -

- 1. Clean refers to an uninfected operative wound in which no inflammation is encountered and the respiratory, alimentary, genital or uninfected urinary tracts are not entered. In addition, clean wounds are primarily closed and, if necessary, drained with closed drainage.

 Operative incisional wounds that follow non-penetrating (blunt) trauma should be included in this category if they meet the criteria.
- 2. Clean-contaminated refers to operative wounds 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 technique is encountered.
- 3. Contaminated refers to open, fresh, accidental wounds. In addition, operations with major breaks in sterile technique (for example, open cardiac massage) or gross spillage from the gastrointestinal tract, and incisions in which acute, non-purulent inflammation is encountered, including necrotic tissue without evidence of purulent drainage (for example, dry gangrene), are included in this category.
- 4. Dirty or infected includes 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.

Box 5

Patient pre-operative bath/shower – patient shower or bath should be performed with either antimicrobial soap or plan soap, ideally 1-2 hours before the operation or at least the night before.

Appropriate surgical hand preparation (scrubbing) - an antiseptic (antimicrobial soap and water) handwash or antiseptic handrub (alcohol-based handrub product classified as high quality), performed immediately preoperatively to eliminate transient flora and reduce resident skin flora (such antiseptics often have persistent antimicrobial activity). The technique should be the WHO recommended steps, including drying. Length of time is according to the manufacturers' instructions, typically 2-5 minutes for soap and water; for alcohol-based handrub follow manufacturers' instructions (http://www.who.int/gpsc/5may/hhsurgicalA3.pdf?ua=1).

Appropriate surgical skin preparation (under sterile conditions) – use of sterile gauze/ sponge and instruments, with movements from clean to dirty areas, that is, from the centre of the incision site outwards, maintaining aseptic technique and covering a broad area of the patient's skin, to be performed immediately before draping and incision. No areas touched that are not part of the preparation area.

Allow to fully dry before incision.

Annex 3. Additional detailed information on completing the WHO peri-operative data collection form

The identity (**ID**) **box** on the form contains key information that should be completed when the patient enters surveillance, that is, on the day of the operation or earlier if the date of surgery is known in advance

- Complete the patient's name, date of birth or age, sex, and date of hospital admission.
- Complete the **primary diagnosis and inpatient number**, which should come from the patient's notes.
- The **surveillance number** will be assigned by the surveillance database when these data are entered into a computer and should be recorded on this sheet at a later stage so that reference can be made between paper forms and the database (if used).

Box 1. Information about the surgical procedure and lead surgeon name should be collected by someone observing/working in the operating theatre – this could be a surgeon, an anaesthetist or a theatre nurse. A standard list exists for the surgical procedure (see data collection form explanation; codes for the related type of surgery are included in the Epilnfo database). The grade of the surgeon should also be completed and refers to their level/years of experience and should generally be categorized as follows senior (a surgeon with more than 10 years of experience); junior (less than 10 years of experience); trainee (junior doctor who is in training in the surgical speciality); or 'other grade' of surgeon. Complete date of surgery and the operating theatre number as allocated in the hospital.

Boxes 2, 3, 4. Information in these boxes is used to derive the National Nosocomial Infection Surveillance (NNIS) risk index (surgical wound class, American Society of Anaesthesiologists (ASA) score and duration of the operation, and the urgency of the operation).

- Box 2: Recording the ASA score. Most anaesthetists working in low— and middle— income countries (LMICs) will be aware of the ASA score, but not all will routinely record it for their patients. This measure is a useful 'snapshot' indicator of general health at the time of the operation, which can be helpful for separating out high-risk patients for SSI. For the purposes of surveillance, it is important that anaesthetists record the ASA score for all patients who could potentially be enrolled in surveillance. Specific training sessions for relevant staff may help with this or some other means, such as reminders from senior staff or posters in the operating theatre. The height and weight of the patient can be recorded using standard scales and measuring devices. Weight to the nearest kilogram and height to the nearest 5 cm are acceptable.
- Box 3: Surgical wound class. Similar to the ASA score, most surgeons know of the surgical wound class but may not always record it. Again, regular reminders and senior support are helpful in ensuring that these are reliably recorded. Junior surgical staff may need training on how to use this scoring system.
- Box 4: Timing, duration and urgency of operation. The time and date of the start and end of surgery (and also the timing of antibiotic prophylaxis) are all important in surveillance – these are used to calculate the operation length, as well as the relative timing of prophylaxis to the start of surgery.
 - These should be recorded in the 24-hour clock format (for example, 7:15pm = 19:15).

- It may help with the consistency of these recordings if there are clocks sited in visible locations around the operating theatres, rather than personal timepieces; consider assigning someone to replace the clock batteries.
- The duration of the operation (in minutes) should be recorded and is defined as the duration from skin incision to skin closure.
- The urgency of the operation should be determined by the surgeon.
- In the case of re-intervention within 72 hours after the primary procedure, the duration of the re-intervention is added to the duration of the primary surgical procedure.

A note on scoring consistency: surgeons (and anaesthetists) do not always agree with one another – sometimes this is due to a lack of experience, sometimes divergent opinions, and sometimes a mistake. In order to achieve consistency in the use of the surgical wound class and ASA classifications, it is worth regularly reviewing the scores assigned to check for 'odd' scores (for example, elective lipoma removal in a healthy adult with a surgical wound class of dirty/infected and an ASA score of 5).

Box 5: Pre/peri-operative process measures. These are questions concerning the quality of processes in the operating theatre related to the risk of SSI. Most of these process measures link directly with recommendations in the WHO *Global guidelines for the prevention of surgical site infection.*

- This information should be collected prior to and during the operation, probably by a non-sterile theatre staff member.
- Patient preparation Pre-operative bath/shower (at home or in hospital).
 It is good practice for patients to have a full body bath or shower prior to surgery a plain or antimicrobial soap may be used for this purpose. If this information cannot be collected and recorded prior to surgery, it should be established if the patient had a pre-operative shower or bath to complete this field peri-operatively. All attempts should be made to record the date of bath/shower.
- Patient preparation hair and surgical site skin.
 - It is recommended that for inpatients undergoing any surgical procedure, hair should not be removed or, if absolutely necessary, it should be removed only with a clipper. Shaving is strongly discouraged at all times, whether pre-operatively or in the operating room.
 - Whether or not hair removal was performed should be recorded. If it was undertaken, date, time and different possible locations of where hair removal was performed should be recorded (for example, 'home', 'ward' and 'theatre') and the type of hair removal.
 - Observation of the technique and product used for surgical site skin preparation by a skilled health worker should be undertaken within the operating theatre and recorded in the form.
 - Features of inadequate preparation might include: insufficient or excessive amounts of skin preparation product; inadequate time or extent of area prepared; re-contamination of a cleansed area after completion of skin preparation; not enough time allowed to let the skin preparation antiseptic solution dry.
 - Record the type of solution used (alcohol-based antiseptic solutions based on chlorhexidine gluconate are recommended for surgical site skin preparation in patients undergoing surgical procedures), the technique used (see guidance on appropriate technique in the explanations section of the data collection form), and whether the solution was left to fully dry.
 - Note antimicrobial sealants should not be used after surgical site skin preparation for SSI prevention.

Surgeon's surgical hand preparation.

 Record if performed by scrubbing with either a suitable antimicrobial soap and water or using a suitable, quality assured (waterless) alcohol-based handrub (ABHR) before donning sterile gloves.

- Record the **time spent** on the surgical hand preparation procedure. This should be determined according to the manufacturer's instructions, usually between two and five minutes for soap and water, for alcohol-based handrub follow manufacturer's instructions. An experienced, independent observer should time the procedure and determine whether or not the technique meets the relevant quality criteria by observing the steps undertaken. These are outlined by WHO and can be found at http://www.who.int/infection-prevention/tools/surgical/remindersadvocacy/en/. It would be useful to have a copy of this poster available in the surgical scrub area.
- Features of inadequate hand preparation technique would likely include: inadequate coverage of hands and forearms; inadequate time spent on cleaning (specific to product being used); hands not dried properly or insufficient time given to allow ABHR to dry; touching non-sterile items between hand cleaning and donning sterile gloves.

Theatre traffic.

Although not an evidence-based WHO recommendation, it was felt to be achievable to measure certain aspects and practices relevant to the risk of SSI in hospitals in LMICs that are potentially modifiable and support the overall patient safety culture within the health care setting.

- A non-sterile member of staff in theatres should perform a headcount at the start of the operation (not including patient) and count the number of entries during the operation. Door openings occurring during the operation should also be recorded. Space is provided on the form for a 'tally' (that is, IIII II) to record this as the operation progresses and to then record the total

Surgical antibiotic prophylaxis.

Use of pre-operative antibiotic prophylaxis and post-operative prescriptions of antibiotics should have been recorded in the patient's drug chart.

- This information should be copied across to the surveillance form.
- Surgical antibiotic prophylaxis should be administered before surgical incision when it is indicated; if not administered record 'no prophylaxis required'. If required but not given record the reason not given.
- If administered, tick which antibiotic given and dose (mg).
- Recording the exact time antibiotic given. Additionally, record time re-dosed if this occurs. This is a relevant quality marker in SSI prevention and it is recommended that antibiotic prophylaxis be administered within 120 minutes before the incision, considering the half-life of the antibiotic.
- Antibiotics that were already in use before surgery to treat a pre-existing infection do not count as prophylaxis.
- Surgical antibiotic prophylaxis should not be prolonged after completion of the operation recording information on whether this occurs or not is important for understanding both the impact on the treatment of SSI if this occurs and in support of the antimicrobial resistance agenda.
- Record if antibiotics ceased at completion of surgery and if not, which drug, dose, dose / day and duration (days) was prescribed and reason given.

Drain/implant.

- -The use of implanted material should all be recorded in the operation notes copy information from here to the surveillance form.
- Record the body **location** the drain/implant refers to. Record if **drain inserted** and **type of** drain (open or closed drains; closed drains are formed by tubes draining into a bag or bottle; open drains including corrugated rubber or plastic sheets, drain fluid on to a gauze pad or into a stoma bag) and if antibiotic given in presence of drain but no infection. Record if **implant used** and **type** (metal (ortho), skin graft, mesh, other).
- If patients have an implanted non-human derived prosthetic material of some kind, the

post-operative surveillance period should extend to one year (explanation provided under information on completing the post-operative form).

Box 6: this box can be used to record compliance with other IPC measures that may be considered relevant at the local level, by adapting this form.

Importantly, finally enter the **date form completed**, if it has been entered into the **computer database** and the person completing the form has **signed** the paper copy for filing.

Annex 4. WHO post-operative data collection form

			Age/ Date of birth/.	InPatient number	Addres	s (town/village)	
Т	Telephone number	r 1	Whose tele	phone number	Checked?		
	Telephone number 2			phone number	Checked?	World Health Organization	
colum discha hree antibio mport	on from the day of arge, outpatient (reviews are reco otics are prescri tant notes in the	of surgery onwards, ind (OP) review, telephone ommended in the 30-d bed/being taken, comp last column (see footno	cluding: surgical p call, readmission, lay follow-up peri plete health work te 1).	orded in Box 2. Each patien procedure, wound dressing in return to the operating theat od. For each "Event", pleasers' initials, and record any cont	removed, itre, surv se record surgical	/changed, (eacl eillance discont I the date, tick site infection (S	ecorded in the "Ever h) inpatient (IP) revie inued (reason). <u>At lea</u> the "Antibx" column SI) symptoms or oth
D	ay Date	e Event	Antibx	SSI symptoms and other	notes1		Health worker initial
	1	Surgical proced	ure				
2	2-3						
4	l-5						
6	6-7						
8-	-10						
11	-14						
15	5-17						
18	3-21						
	2-25						
	5-29						
Day	y 30			End of SSI surveillance (sta	andard)		
зох :			occu to Box o to	determine the SSI case defi	intion an	a conount with t	
_	ent re-admitted	ion? ⊔ Yes ⊔ No I for Surgical Site Infe	•	case definition tick boxes No (note reason)	,		
Patie		I for Surgical Site Infe	ection? Yes		······		
Patie Date Date OR OR AND OR	e of re-admissic Superficial SSI e.g. cellulitis Purulent drainag superficial incisio Organism identifi Superficial incisi e-opened Infection sympto	I for Surgical Site Inferon for Surgical Site Inferon for Surgical Site Inferon for Surgical Site Inferon (skin/subcutaneous) July (pus) from fine (if culture done)* The control on deliberately coms ¹	ection?	□ No (note reason)	/	rgan/space SS eeper than fasc g. endometritis pace) urulent drainag gan or space (iain) rgan or space i und on imaging	SI** cia/muscle s (organ), peritonitis e (pus) from sterile from an inserted infection/abscess g/examination ied from fluid/tissue
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Database entry [Y/N]

Date form completed/.....

Key explanations to complete the post-operative form

Whose phone number = patient (mobile or home), or family member, or neighbour, or friend

Checked = phone number called to check before patient leaves hospital

** List of specific organ/space infection sites

Code	Site	Code	Site
BONE	Osteomyelitis	MED	Mediastinitis
BRST	Breast abscess or mastitis	MEN	Meningitis or venticulitis
CARD	Myocarditis or pericarditis	ORAL	Oral cavity (mouth, tongue, or gums)
DISC	Disc space	OREP	Other infections of the male or female reproductive tract
EAR	Ear, mastoid	PJI	Periprosthetic joint infection
EMET	Endometritis	SA	Spinal abscess without menigitis
ENDO	Endocarditis	SINU	Sinusitis
GIT	Gastrointestinal tract	UR	Upper respiratory tract
IAB	Intraabdominal, not specified	USI	Urinary System infection
IC	Intracranial, brain abscess or dura	VASC	Arterial or venous infection
JNT	Joint or Bursa	VCUF	Vaginal cuff
LUNG	Other infections of the lower respiratory tract		

To understand specific criteria for defining these infections please refer to CDC/NHSN Surveillance Definitions for Specific Types of Infections https://www.cdc.gov/nhsn/PDFs/pscManual/17pscNosInfDef_current.pdf

Annex 5. Additional detailed information oncompleting the WHO post-operative data collection form

Box 1 of the post-operative form contains key information that should be completed when the patient enters surveillance, that is, on the day of the operation. **Name, age / date of birth and inpatient number** can be copied across from the peri-operative side of the form. **Address** should be recorded on the form, at least town, village or district.

Recording patient telephone numbers. Although not all patients will have their own telephone, our experience is that most individuals in most low— and middle— income countries (LMICs) will have a close relative through whom they can be contacted by telephone. Always try to record two different contact telephone numbers and, if possible, check that the numbers are working before the patient leaves hospital by ticking 'checked'. If it is not the patient's telephone number that is recorded and/or the patient is unable to communicate over the telephone (for example, child or elderly), record whose telephone number is recorded and you can also take the contact details of the relation or other person who can act as a proxy. If a patient cannot provide any telephone numbers, then they can still be entered into surveillance, but it should be noted in the database that no telephone number was available and hence no telephone calls to the patient are possible.

Box 2. Follow-up calendar table – recording post-operative patient information. This is the most important element of the post-operative form – it reminds us that the whole 30-day surveillance period is important after an operation, not just the first few days. Information can be added to this form over time and when it has been completed, the relevant data are entered into the surveillance database. For patients with prolonged follow-up (implanted material), a separate filing system will be needed to keep the records 'active' for the full one-year period.

- Start with Box 2 on the day of the operation by filling in the **date** and the words **surgical procedure** and also the **date of admission for the primary surgical procedure**.
- Then calculate what date will be 30 days later when the **surveillance ends** and enter this **date** in the date column a calendar helps with this. Additionally, calculate and write down the **dates for the planned contacts with the patient** in the date column (clinic appointments/ follow-up telephone calls) this reminds staff when these will be needed and suggestions are given on the form.
- Events to record. Essentially, all important events for the patient that relate to SSI should be recorded in this box and examples are described in the information on the form. The first event will most likely be a change of the patient's surgical dressing on post-operative day 2 or 3. This can be recorded (for example, wound dressing removed) and then additional notes added in the last column.
- At any time, while still in hospital or after discharge and during follow up surveillance, antibiotics (written as **Antibx** on the data collection form) are prescribed or being taken (for any reason) this should be recorded.
- If all is going well, the patient will probably be discharged home at some point between three and seven days after the operation, sometimes even sooner. Record the date that the patient actually left hospital against the **hospital discharge date** text (that is, the day on which the patient did not sleep overnight in the hospital, rather than the date that the patient was medically fit-for-discharge there may be some unexpected delay in departure). Aim to review

the patient's operation wound on the day they leave hospital or the day before and information can be recorded in the notes (last column).

- If acceptable at the local level, information should be given to the patient and clear instruction/training delivered to allow the patient to actively report any signs and symptoms of infection as described on the form this might need some explanation and a written reminder.
- Outpatient clinic visits should be arranged for the patient in the way that would normally be done in the hospital, giving clear instructions on time and place to attend. The staff in charge of surveillance should make every possible effort to get in touch with health workers following up the patient in health posts or clinics after hospital discharge. Ideally, surveillance staff should organize to attend all the patient's follow-up visits within the 30-day follow-up period. Relevant information and observations made should be recorded in the form following review of the patient's operation wound. Labelling of patient records to highlight that the patient is under surveillance and indicating the contact details of staff in charge of this task is also helpful to avoid patient loss at follow-up.
- Follow-up telephone calls should be performed as described below. Across the whole 30-day period, a total of three reviews of the patient is recommended. Ideally, these would be spaced out so that these occur at roughly the end of week 1, week 2 and week 4.
- After each 'event' recorded, the staff member making the entry should put their **initials** in the box in the right-hand column to confirm who has collected this information.
- Information on making telephone calls. Calls to patients should be made by a trained staff
 member involved in the surveillance work. These telephone calls represent a form of clinical
 interaction and should have an appropriate degree of politeness, sensitivity and confidentiality.
 At discharge, the patient should be told that they will receive follow-up calls about their
 operation wound. The format of the call should be broadly as follows:
 - Introductions and confirmation of patient identity. For example, "Hello, I am nurse xxx from xxx hospital. Please can I confirm, is this Mr xxx? Were you recently in our hospital for an operation? What kind of operation was this please?". It is important to confirm the correct identity, especially if contacting via a telephone of a relative.
 - General ('open') enquiry about post-operative recovery. For example, "Please tell me how are you getting on since your operation...". Make any notes as necessary (for example, "no problems reported" or "patient reports feeling weak and tired, but wound healing well.").

Box 3. Specific symptom enquiry - should be completed whenever any wound complications occur. These questions on any wound complications should be asked in every telephone call to determine if the patient has symptoms suggestive of SSI. This information is included on the data collection form underneath table 2 and includes the following:

- (1) Drainage of fluid from wound: pus versus clear fluid / bloody / other
- (2) Pain or tenderness (more pain than would normally be expected from this kind of surgery)
- (3) Localized swelling (more than would normally be expected from this kind of surgery) or wound breakdown (wound edges separated)
- (4) Redness/heat of skin (abnormal redness and or heat for the kind of surgery that is also accompanied by pain)
- (5) Generally unwell especially fever>38°C and any other symptoms (this might include an offensive smell from the wound).

Note: For each of the specific enquiries, it is helpful to record negative findings on the form in Box 2 to confirm that the relevant questions have been asked.

• Finishing the telephone call. When the relevant information has been collected, it is important to also give the patient an opportunity to ask questions. If there are reported problems associated with the wound, the patient should be encouraged to attend hospital for a direct visualization of the wound by the surveillance staff or a clinician.

See Annex 6 for a script that can be used by staff as a stand-alone resource when phoning a patient.

- **Diagnosing SSI.** If an SSI is suspected, either based on directly seeing the patient or a telephone conversation, every effort should be made to get a clinician from the original surgical team to see the patient themselves to arrange appropriate investigations and determine if an infection is present. Patients should be encouraged to return to hospital if at all possible when they have a wound problem. If it is not possible for re-attendance to be arranged, then the surveillance team should make their best estimate of the situation and this should always be followed up by discussion with a clinician.
- Classification of SSI. As far as possible, classification and definitions of SSI in this work aim to
 follow the schema provided by the CDC-NHSN. A summary of the criteria is provided in the
 surveillance form the appropriate type of infection (superficial, deep and organ/space
 infection) and the relevant diagnostic criteria should be ticked.

BOX 3 Surgical Site Infection? ☐ Yes ☐ No (Determine with case definition tick boxes below) Patient re-admitted for Surgical Site Infection? ☐ Yes □ No (note reason) Date of re-admission for Surgical Site Infection:/..... Discharge date:/...... ☐ Superficial SSI (skin/subcutaneous) ✓ Deep SSI (fascia/muscle) □ Organ/space SSI** e.g. cellulitis e.g. deep abscess Deeper than fascia/muscle ☐ Purulent drainage (pus) from ☐ Purulent drainage (pus) from deep e.g. endometritis (organ), peritonitis superficial incision incision (space) OR ☐ Purulent drainage (pus) from sterile ☐ Organism identified (if culture done)* ✓ Deep incision dehiscence or organ or space (from an inserted deliberately opened by surgeon OR drain) ☐ Superficial incision deliberately Organism identified (if culture done)* re-opened ☐ Organ or space infection/abscess AND AND Infection symptoms¹ found on imaging/examination □ Infection symptoms¹ OR OR ☐ Organism identified from fluid/tissue ☐ Surgeon/attending physician ☐ Deep infection/abscess found from organ/ space* diagnosis on imaging/examination Other surgical complications ▼ Non-infectious local wound complications including bleeding and abnormal skin reactions ☐ Patient death: Date/........... Cause of death (as far as known) Specimen taken Organism(s) identifed Antibiotic resistance/sensitivities Microbiology culture results* Date 12/05/2015 type..... S. aureus R to ovacillin, S to co-trimoxazole

Treatment of SSI. Any SSI identified via surveillance should be managed in the normal way as per local policies and procedures. This includes sampling for microorganisms and treatment – this information should be recorded in Box 3 as **microbiological culture results**.

Multiple SSI after one operation. It is rare to need to record multiple SSI after one operation, The CDC definitions advise to categorize dual 'superficial + deep' infections as 'deep' and organ/space infections draining through the incision as 'deep'. It is unusual for multiple SSIs of the same type to occur in one patient within a 30-day period – normally this will represent incomplete treatment of the first infection. If an infection is initially judged to be one type of infection and later felt to be an anatomically deeper type of infection (that is, progression of infection), it should be recorded as the deeper of the different types. Finally, one operation may result in multiple incisional sites (for

example, donor and graft sites), which may develop separate complications. In this situation, the most severe occurrence of SSI at any of the operation sites should be considered as the outcome. Two separate operations performed under the same anaesthetic should be recorded separately, as described earlier.

Non-infectious diagnoses. Non-infectious local wound complications following surgery can also be recorded on the surveillance form, although these do not require formal classification

Patient death should also be recorded is this occurs.

Importantly, finally enter the **date form completed**, if it has been entered into the **computer database** and the person completing the form has **signed** the paper copy for filing.

Annex 6. Example of a script for post-discharge telephone follow-up

Introduction: "Hello, I am nurse xxx from xxx hospital. Please can I confirm, is this Mr/Mrs/Miss xxx? Were you recently in our hospital (name hospital) for an operation?"

Clarification of the operation: "What kind of operation was this please?"

Note: It is important to confirm the correct identity, especially if contacting via a telephone of a relative.

General ('open') inquiry about post-operative recovery: "Please tell me how are you getting on since your operation."

Note: make any notes as necessary. For example: "No problems reported" or "Patient reports feeling weak and tired, but wound healing well; patient is concerned about his/her wound..."

Specific symptom enquiry: "Can you tell me if you are experiencing any of the following at the operation wound site?

- Pain or tenderness
 (try to establish if any feedback on pain is more than would normally be expected from this kind of surgery).
- Localized swelling
 (try to establish if any feedback on swelling is more than would normally be expected from this kind of surgery).
- Erythema/redness
 (try to establish if it is abnormal redness for the kind of surgery and if it is also accompanied by pain).
- Heat
 (try to establish if any feedback is more than would normally be expected from this kind of surgery)
- Breakdown (dehiscence) of the wound
 (ask if wound edges are separated; this would be a symptom generally associated with the
 others described).
- Pus (purulent discharge)
 (ask if there is opaque fluid of any colour coming from the surgical wound. Serous fluid, that is, clear fluid, is not pus, but may sometimes be difficult to distinguish, especially if only seen on dressings. Yellow or green-coloured staining on bandages or clothes suggests pus).
- Other symptoms
 (ask for other feedback; for example, this might include an offensive smell from the wound or the patient having fever (> 38°C)."

(Note: For each of the specific enquiries, it is helpful to record negative findings on the form in Box 2 to confirm that the relevant questions have been asked.)

Finishing the telephone call: "Do you have any final questions you would like to ask or other information you would like to give me while we are talking..... Thank you very much for your time" (confirm when the next follow-up telephone call will take place if relevant).

(Note: If there are reported problems associated with the wound, the patient should be encouraged to attend hospital for a direct visualization of the wound by the surveillance staff or a clinician – give direction instructions on this if the situation arises.)



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