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<th>Name</th>
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<td>Sue Waters</td>
<td>Programme Director</td>
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<td>Sally Roberts</td>
<td>Chair Steering Committee</td>
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<td>Rachel Hill</td>
<td>Programme Manager</td>
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## Distribution list

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<td>Arthur Morris, Rachel Hill, Christine Sieczkowski, Michelle Taylor, Sally Roberts, Trevor English, Anja Werno, Hayley Callard</td>
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SSIs can cause emotional and financial stress, serious illness, longer hospital stays, long-term disability, and can result in loss of life. The consequences for patients, as well as health services, mean that the prevention of SSIs is extremely important.

To address this, in 2012 the Commission entered into a partnership with Auckland and Canterbury District Health Boards to deliver the SSII Programme nationally.

Drawing upon the 2010 report to the Ministry of Health Recommendations for a National Surgical and Procedural Site Infection Surveillance Program, the SSII Programme in collaboration with district health boards (DHBs) throughout the country, has refined these recommendations and has implemented a consistent, evidence-based approach for collecting and reporting high quality data about hip and knee arthroplasty procedures.

Through its consultative process the SSII Programme promotes culture change and practice improvements that focus on the prevention of SSIs. This encourages performance improvement by highlighting practice that may require attention. The Programme also provides intervention guidance on how to drive improvements that result in safer patient care.

Over the next one to two years the SSII Programme will focus on SSIs following selected cardiac procedures and caesarean sections. The SSII Programme has been intentionally spread over three to five years to ensure that improvement can be achieved in a sustainable way.
ACKNOWLEDGEMENTS
The SSII Programme Implementation Manual builds upon the hard work and recommendations provided by the National Quality Improvement Programme (NQIP) in 2010. We would like to thank all contributors and authors involved in developing this manual. It is a key document for the SSII Programme.

Some of the content in this document has been drawn from information, resources and advice made available by organisations with well-established SSI improvement programmes in place. The SSII Programme team would like to acknowledge the following organisations as integral to the development of the SSII Programme’s Orthopaedic Implementation Manual:

- Health Protection Scotland
- US Centers for Disease Control and Prevention
- Welsh Healthcare Associated Infection Programme
- VICNISS Healthcare Associated Infection Surveillance System.

The initial Orthopaedic SSII Programme implementation took place in eight DHB development sites across New Zealand. It is thanks to the considerable hard work and commitment of these sites that we have been able to learn from the implementation and as a result, revise this manual.

Finally, thank you to the SSII Programme steering group and clinical advisory group for your ongoing expertise and input into this manual.
**EXECUTIVE SUMMARY**

International evidence shows that healthcare associated infections are a significant risk to patients with SSIs identified as being among the highest proportion of these. The consequences of these infections include increased morbidity and mortality as well as prolonged hospital stays and additional interventions and treatment, all of which divert resources away from other priority areas.

Surveillance can be defined as the ongoing systematic collection, analysis and interpretation of health data essential to the planning, implementation and evaluation of public health practice, closely integrated with the timely dissemination of these data to those who need to know. The final link of the surveillance chain is the application of the high quality data to infection prevention. The SSII Programme will use the Lean Six Sigma improvement methodology to improve care.

This manual provides guidance for the delivery of a national SSII programme in New Zealand. It is anticipated that it will strengthen and standardise data collection.

The implementation of this improvement project has been staged, with the initial stage involving eight development site DHBs where the process was tested and reviewed. This development stage took place between March and June 2013. As a result of the initial implementation further refinement and national implementation in remaining DHBs took place in July 2013. All DHBs are now contributing to this national programme.

DHBs will be supported by the SSII Programme team who will provide guidance and facilitate implementation of the SSII Programme by:

- Testing data collection mechanisms
- Initially focusing on selected orthopaedic procedures
- Providing a manual outlining the process of data collection
- Providing educational seminars and workshops for those initial and subsequent implementation sites
- Providing on-going support with interpretation of definitions and the online form for data entry.
A multidisciplinary approach is essential to ensure that the programme has the appropriate expertise involved in implementation. Hence, this manual is for the use of infection prevention and control specialists, clinical microbiologists and infectious disease physicians, quality teams, nurses, anaesthetists and surgeons, and all of those involved in the SSII Programme at a local level.

OBJECTIVES
The overarching objective of the SSII Programme is to improve the quality of patient safety and care. It will also provide hospitals with a robust reporting system of infection rates, which will be made available to clinicians. Such a mechanism of feedback has been shown to lead to improvements in performance (Haley, Culver, White et al, 1985). National data will also enable consistency in measurements and comparison between DHBs.

The SSII Programme seeks to achieve the following objectives:
- Deliver a consistent approach to the monitoring of orthopaedic surgery SSIs through the implementation of evidence based surveillance guidelines
- Provide accurate outcome measurement and reporting for SSIs through the implementation of a national monitoring system
- Lead quality improvement activities through the use of high quality data
- 25% reduction in SSI rates through the implementation of best practice improvement interventions
- Drive the required culture and behaviour change through reporting back to local clinical teams.
ESTABLISH
ESTABLISHING AN SSI IMPROVEMENT TEAM
The local SSII team is responsible for setting up SSII locally (e.g. at individual DHB level). It is important to liaise with other stakeholders because this programme is multidisciplinary and will not be sustainable without adequate team support. The make-up of the team will vary between DHBs but each member of the team will provide information to enable local data to be collected efficiently.

Key individuals and responsibilities
Surveillance primarily involves infection prevention and control teams and clinical staff. However, all stakeholders should be offered the opportunity to be represented. Members from the following groups should be considered:

- Infection prevention and control clinical nurse specialists/managers
- Clinical microbiologists/infectious disease physicians
- Surgeons from relevant disciplines
- Anaesthetists
- Clinical nurse specialists from relevant disciplines
- Ward and operating theatre based nurses (including coordinators of the orthopaedic registry
- Surveillance nurses (where employed for the purpose of surveillance)
- Quality managers/clinical audit staff
- Information technology staff
- Medical laboratory scientists from microbiology departments
- Clerical and administration staff
- Management representative.

Key roles
*Key role one: Local SSII project coordinator*
The local SSII project coordinator will either be a member of the infection prevention and control team or another member of staff with strong links to infection prevention and control (e.g. a member of the quality/clinical audit team). The key functions of this role are:

- To facilitate the improvement process at a local level
- To ensure continuing engagement of the clinical teams and management
- To provide overall coordination and liaison with the national SSII Programme team
- To ensure that mechanisms are in place for data collection, collation, transfer and dissemination
- To provide local support for staff involved in the improvement process
- To facilitate feedback of SSI to local stakeholders
- To carry out validation processes to verify data.
**Key role two: Data collector**
The data collector may be a member of the infection prevention and control team or an individual employed to carry out this role (e.g. a surveillance nurse). The key functions of this role are:

- To collect the data sets in accordance with the SSII Programme requirements
- To provide the data in a format suitable for uploading onto the online data collection form.

**Key role three: Data transfer coordinator**
The data transfer coordinator may be a member of administration or information technology staff who can upload data to a national SSI online database for analysis. The key functions of this role are:

- To ensure that any electronic format utilised locally complies with the SSI database specifications
- To ensure that data is correctly uploaded onto the online reporting system.

**SSII champions**
During the initial roll out of this project, DHBs will be invited to nominate at least two individuals who will act as ‘champions’ for the project in their DHB. These individuals should be from key roles one and two but may also be nominated members of the surgical or clinical team involved in orthopaedic procedures. The role of these champions can be summarised as follows:

- To understand and promote the benefits of the programme to your development site
- To lead through example by adopting the recommended SSII approaches
- To share knowledge with fellow SSII champions and contribute feedback to improve the programme
- To promote quality improvement to drive practice change.
DEFINE
Definitions of SSI
The definitions of SSI being utilised for this project are those utilised by The National Healthcare Safety Network (CDC, 2015). These are outlined below.

**Superficial**
A superficial incisional SSI must meet the following criteria:

Infection occurs within **30 days** after the operative procedure (where day 1 = the procedure day).

**AND**
Involves only skin and subcutaneous tissue of the incision.

**AND**
The patient has at least one of the following:

- a) Purulent drainage from the superficial incision.
- b) Organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision.
- c) Superficial incision that is deliberately opened by surgeon and is culture-positive or not cultured.

*and*
Patient has at least one of the following signs or symptoms: pain or tenderness, localised swelling, redness or heat. A culture negative finding does not meet this criterion.

- d) Diagnosis of superficial incisional SSI by the surgeon or attending physician.*

Do not report a stitch abscess (minimal inflammation and discharge confined to the points of suture penetration) as an infection.

Do not report a localised stab wound infection or pin site infection as an SSI.

Diagnosis of cellulitis by itself does not meet criterion ‘d’ for superficial SSI.

If the superficial incisional site infection extends into fascia and/or muscle layers, report as a deep incisional SSI only.

*Attending physician may mean surgeon, infectious disease, other physician on the case, emergency physician or physician’s designee (nurse practitioner or physician’s assistant).
Deep
A deep incisional SSI must meet the following criteria:

Infection occurs within 90 days after the operative procedure (where day 1 = the procedure day).

AND
Involves deep soft tissues of the incision (e.g. fascia and muscle layers).

AND
The 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 by a surgeon or attending physician* and is culture positive or not cultured.

   and

   the patient has at least one of the following signs or symptoms: fever (>38°C) localised pain or tenderness. A culture-negative finding does not meet this criterion.

   c) An abscess or other evidence of infection involving the deep incision that is found on direct examination, during invasive procedure or by histopathologic or imaging test.

Classify infection that involves both superficial and deep incision sites as deep incisional SSI.

Organ/space
An organ/space SSI must meet the following criteria:

Infection occurs within 90 days after the operative procedure (where day 1 = the procedure day).

AND
Infection involves any part of the body, excluding the skin incision, fascia or muscle layers that is opened or manipulated during the operative procedure.

AND
The patient has at least one of the following:

   a) Purulent drainage from a drain that is placed into the organ/space.
   b) Organisms isolated from an aseptically obtained culture of fluid or tissue in the organ/space.
   c) An abscess or other evidence of infection involving the organ/space that is found on direct examination during invasive procedure or by histopathologic examination or imaging test.

AND
Meets at least one criterion for a specific organ/space infection. For this orthopaedic SSI Programme this means osteomyelitis or joint infection.

*Attending physician may mean surgeon, infectious disease physician, other physician on the case, emergency physician or physician’s designee (nurse practitioner or physician’s assistant).

If a patient has an infection in the organ/space being operated on in the first two day period of hospitalisation and the surgical incision was closed primarily, subsequent continuation of this infection type during the remainder of the surveillance period is considered an organ/space SSI if the organ/space SSI and site specific infection criteria are met.

Rationale: risk of continuing or new infection is considered to be minimal when a surgeon elects to close a primary wound.
Occasionally an organ/space infection drains through the incision and is considered a complication of the incision. Therefore, classify as a deep incisional SSI.

Please note that organ/space infections occurring up to one year following implant surgery when the patient is an inpatient or is readmitted to hospital are out of scope for the SSII Programme.
REVIEWING POSSIBLE CASES OF SSI
Some additional guidance has been provided by the CDC (2013) which may be useful when reviewing possible SSI cases.

SSI following manipulation of the operative site
If during the post-operative period the surgical site has an invasive manipulation for diagnostic or therapeutic purposes (e.g. needle aspiration), and following this manipulation an SSI develops, the infection is not attributed to the operation.

More than one operative procedure through the same incision within 24hrs
If a patient goes to the operating theatre more than once during the same admission for another procedure of the same or different procedure category, which is performed through the same incision within 24hrs, report only one procedure form for the original procedure but combine the durations for both. If the wound class has changed, report the higher wound class. If the ASA has changed, report the higher ASA.

Patient dies in the operating room
Do not complete a data collection form as this procedure is excluded from the denominator.

Post-operative infection scenarios
The following scenarios may be useful and aid with interpretation:

- Once a patient is discharged from the index hospital if the incision opens due to a fall or for other reasons and there was no evidence of incisional infection at the time of its opening (as defined by lack of symptoms which make up the definition) then subsequent infection of the incision is not considered an SSI or an HAI for the index hospital as this implies a mechanical reason for the dehiscence rather than an infectious reason.
- Post-operative patient is still hospitalised following surgery and is asymptomatic, incision opens due to fall or other reasons, e.g. patient picking at wound, it is not an SSI.
- Post-operative patient sustains an injury to the incision area but incision does not open. Later incisional infection develops – this is considered an SSI.
- Post-operative patient has an intact incision (or status is unknown as not seen) or it is noted that the patient was incontinent and incision may have been contaminated, subsequent incisional infection is considered SSI.
- Post-operative patient has skin condition, e.g. dermatitis near intact incision and then subsequently develops incisional infection within follow up period. This is an SSI.
- Patient has remote site infection either prior to or after an operation or has a manipulation that ‘seeds’ operative site (e.g. dental work) and later develops deep incisional or organ/space infection. This is an SSI if it occurs in follow up surveillance period.
PROCESS
DATA COLLECTION
This section of the manual describes the active prospective methods of data collection that participating hospitals should use to enable them to compare their incidence of SSI with other participating hospitals.

Categories of procedure to be included
Forms for data collection are provided in both hard copy and in an online (web-based) format. Educational seminars have been provided to orientate staff to the programme. Automation of the system will gradually be introduced to enable more efficient and accurate data collection.

Summary table of categories and codes of procedures for inclusion

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<tr>
<th>Category</th>
<th>ICD10 code</th>
<th>Procedure</th>
<th>Description</th>
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<td>Hip procedures</td>
<td>49318 00</td>
<td>Total arthroplasty of hip, unilateral.</td>
<td>Total joint replacement of hip.</td>
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<td>49319 00</td>
<td>Total arthroplasty of hip, bilateral.</td>
<td>Total joint replacement of hip/s.</td>
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<td>Hip revision procedures</td>
<td>49324 00</td>
<td>Revision of total arthroplasty of hip.</td>
<td>Partial revision of total hip replacement; revision of total joint replacement of hip.</td>
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<td>49327 00</td>
<td>Revision of total arthroplasty of hip with bone graft to acetabulum.</td>
<td>As per procedure description. Includes: procurement of bone.</td>
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<td>As per procedure description. Includes: procurement of bone.</td>
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<td>Revision of total arthroplasty of hip with bone graft to acetabulum and femur.</td>
<td>As per procedure description. Includes: procurement of bone.</td>
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<td>49339 00</td>
<td>Revision of total arthroplasty of hip with anatomic specific allograft to acetabulum.</td>
<td>As per procedure description.</td>
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<td>49342 00</td>
<td>Revision of total arthroplasty of hip with anatomic specific allograft to femur.</td>
<td>As per procedure description.</td>
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<td>49345 00</td>
<td>Revision of total arthroplasty of hip with anatomic specific allograft to acetabulum and femur.</td>
<td>As per procedure description.</td>
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Identification of population for surveillance

All patients who undergo procedures funded by the DHB (even if they take place in a private setting) must be included in this surveillance. More than one source of data may need to be reviewed on a regular basis to ensure that all eligible procedures are included in the surveillance. These may include the following mechanisms (depending on what is available in each DHB):

- Patient management systems that provide details of surgical procedures and readmissions.
- Operating theatre records.
- Emergency theatre records.

Local decision support teams should be able to assist with some of this data capture including all procedures that may be funded by the DHB but which are performed in private settings.

Notes:
- The denominator for the SSII Programme is procedures NOT patients; hence, patients having bilateral procedures shall have two dataset forms completed.
- All procedures within each category are to be included.

### Category | ICD10 code | Procedure | Description
--- | --- | --- | ---
| 4951800 | Total arthroplasty of knee, unilateral. | Total joint replacement of knee, unilateral. Includes patella resurfacing; excludes revision of total arthroplasty of knee.
| 4951900 | Total arthroplasty of knee, bilateral. | Total joint replacement of knee, bilateral. Includes patella resurfacing; excludes revision of total arthroplasty of knee.
| 49521 00 | Total arthroplasty of knee with bone graft to femur, unilateral. | As per procedure description.
| 49521 01 | Total arthroplasty of knee with bone graft to femur, bilateral. | As per procedure description.
| 49521 02 | Total arthroplasty of knee with bone graft to tibia, unilateral. | As per procedure description.
| 49521 03 | Total arthroplasty of knee with bone graft to tibia, bilateral. | As per procedure description.
| 49524 00 | Total arthroplasty of knee with bone graft to femur and tibia, unilateral. | As per procedure description.
| 49524 01 | Total arthroplasty of knee with bone graft to femur and tibia, bilateral. | As per procedure description.

Knee Revision Procedures

| Category | ICD10 code | Procedure | Description
--- | --- | --- | ---
| 49527 00 | Revision of total arthroplasty of knee. | Revision of total joint replacement of knee. Includes removal of prosthesis.
| 49530 00 | Revision of total arthroplasty of knee with bone graft to femur. | As per procedure description.
| 49530 01 | Revision of total arthroplasty of knee with bone graft to tibia. | As per procedure description.
| 49533 00 | Revision of total arthroplasty of knee with bone graft to femur and tibia. | As per procedure description.
| 49554 00 | Revision of total arthroplasty of knee with anatomic specific allograft. | As per procedure description.
• If patients undergo revision surgery and a new prosthesis is inserted at the same site within 30 days of the original surgery for reasons other than infection, the surveillance form relating to the initial operation should be closed off and a new one commenced for the new episode of surgery. However, if the revision surgery is due to infection this will be recorded in the initial SSI form.

Case finding

Review of patients to identify cases of SSI must begin as close to the date of surgery as possible. To ensure comparable validity of data, those monitoring surgical site wounds must be trained in the definitions and diagnosis of SSI using the standard definitions (see page 14-16).

To identify patients in the selected population, the minimum requirement is to have an automated alert or manual check of the following:

• **Operating lists and liaison with staff in the operating theatre**
  Operating lists will provide the details/number of hip and knee replacements performed. Some data collection for other programmes is already in place (e.g. orthopaedic joint registry), so investigation of the most efficient way to collect relevant data is required.

• **Ward based reporting of inpatient (during their inpatient stay)**
  Active and systematic review of patients during their inpatient stay will be undertaken by the surveillance data collector. This should ideally involve a review of clinical case records at least once during the inpatient stay.

Liaison with wards caring for the cohort of patients should be undertaken. Wards should be asked to advise the surveillance data collector if patients in the selected category develop infection during the admission period. A notification system can be established for this if it is not already in place.

Once cases have been identified, the following checks are required:

• **Readmission surveillance**
  Readmission within 90 days of the surgical procedure. Hospital databases should be used to identify all patients (within a defined patient population) who have been readmitted within 30 and 90 days of the procedure. Input from local project IT or decision support staff may be required.

ICD 10 codings can be used to assist with this as the following codes are used to indicate infection and inflammatory reaction due to joint prosthesis or other implants:

- T81.41 Wound infection following procedure.
- T81.42 Sepsis following a procedure.
- T85.78 Infection and inflammatory reaction due to other internal prosthetic devices, implants and grafts.
- T84.5 Infection and inflammatory reaction due to internal joint prosthesis.
- T84.6 Infection and inflammatory reaction due to internal fixation device.
- T84.7 Infection and inflammatory reaction due to other internal orthopaedic prosthetic devices, implants and grafts.

Wards likely to receive patients readmitted with SSI should be identified and contacted regularly to ask about patients readmitted with SSI.
Note: It is advisable to complete the online data set for each procedure at 30 days and then amend this only if subsequent infection is reported at 90 days.

- **Microbiology request surveillance**
  All patients with a suspected infection should have appropriate clinical specimens collected for microbiology before the administration of antibiotics. The clinical team are responsible for obtaining these so communication with clinicians about the importance of obtaining samples is important.

- **Positive culture of a significant organism from the procedure site**
  Regular review of microbiology reports to identify any positive surgical site cultures from patients in the surveillance population should be undertaken. Where possible this should be by an automated process via the microbiology IT system. However, if this is not possible, review of electronic microbiology records of patients in the cohort will be necessary. Patients who have a relevant specimen (e.g. aseptically obtained culture of fluid or tissue from the incision) should then have records reviewed to determine if the culture is of significance (i.e. confirms diagnosis of SSI).

- **Subsequent review/confirmation of cases**
  If any of the above are identified, a review of the patient’s records including temperature charts should be undertaken by the surveillance data collector to confirm diagnosis of SSI using the definitions (see page 14-16).

Procedures that fulfil the National Healthcare Safety Network (NHSN) criteria for SSI in accordance with the definitions of SSI (see page 14-16) shall have the additional SSI minimum dataset completed and uploaded onto the online form by the data transfer team member.

- **Procedures performed at other hospitals**
  If the patient meets NHSN criteria for SSI but the procedure was performed at a different hospital, then the infection prevention and control staff at the hospital where the operation was originally performed should be notified. The relevant information that has been collected about the patient and procedure should be sent onto the original hospital. The original hospital is responsible for completing the numerator data and entering this into the online form.

- **Post discharge surveillance (PDS)**
  The SSII Programme will not include PDS due to the difficulty identified with standardisation of the process. While excluding PDS will underestimate the true level of SSI (as many superficial wound infections will not be included), consultation feedback indicated that this can be re-evaluated in the future (NQIP, 2010). If hospitals wish to perform PDS they may do so and use the data for local review but it will not be included in the national rates for comparison.

- **Numbers of cases for inclusion**
  The surveillance of surgical cases will be on a continuous basis to ensure ongoing analysis of incidence can take place. The inclusion of additional procedures, for example, cardiac and caesarean section cases will be determined by the Commission in the future.
DATA SET
This section defines each question in the surveillance dataset. This has been established only for orthopaedic procedures. Further refinement will be required when other procedures are included.

Demographic and surgical denominator data must be completed for all patients included in the surveillance. The infection data (numerator) is only to be completed for those patients that develop SSI that meet the case definitions described in the previous section.

Facility identification
Once a facility is registered for the SSI data entry, the number of beds, type of facility (secondary/tertiary) and medical school affiliation will be linked to the facility ID code.

<table>
<thead>
<tr>
<th>DHB ID</th>
<th>This will be the recognised abbreviation for the DHB.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital/facility ID</td>
<td>The participating DHB will designate hospital/s from which patients will be entered. The codes used for this will be pre-populated in the online form and are those which are used nationally for New Zealand hospitals.</td>
</tr>
</tbody>
</table>

Patient information denominator data
This can be obtained from the patient administration system wherever possible, the patient’s record and theatre records.

<table>
<thead>
<tr>
<th>Patient NHI</th>
<th>National Health Index number consisting of alpha/numeric format (AAA/1234).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td>Male, female, or unknown.</td>
</tr>
<tr>
<td>Date of Birth</td>
<td>DD/MM/YYYY To be manually entered using the format above.</td>
</tr>
</tbody>
</table>

Primary admission/discharge data

| Date of admission | DD/MM/YYYY. |
| Date of discharge | DD/MM/YYYY. |
| Date of death (if applicable) | DD/MM/YYYY. |

Note: Where a date is required, a calendar format will appear for ease of date entry.
**Procedure**

<table>
<thead>
<tr>
<th>Date of procedure</th>
<th>DD/MM/YYYY.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedure code/description</td>
<td>Select appropriate code/description from the list given. Note that if bilateral procedures are carried out then two forms need to be completed, one for each side.</td>
</tr>
<tr>
<td>If revision, is it due to infection?</td>
<td>Yes/No.</td>
</tr>
<tr>
<td>Location of procedure</td>
<td>Left/right.</td>
</tr>
<tr>
<td>Is this procedure an emergency?</td>
<td>Yes/No/Unknown.</td>
</tr>
<tr>
<td>Surgeon grade</td>
<td>First surgeon. Select from the following: Consultant/specialty registrar/locum consultant/locum registrar/other.</td>
</tr>
<tr>
<td>Surgeon code</td>
<td>First surgeon. Use unique surgeon code that is identifiable to the facility only. Codes will be preloaded into the online form and a record must be kept in each DHB of those used and who they related to. This information will not be required nationally.</td>
</tr>
<tr>
<td>Antibiotic cement used</td>
<td>Yes/No/Unknown.</td>
</tr>
<tr>
<td>Note: This question relates to antibiotic cement only. Other cement may be used but we only require ‘yes’ if it contains antibiotic.</td>
<td></td>
</tr>
</tbody>
</table>

**Risk score data**

The basic risk index will be automatically calculated provided the fields below are completed:

| Wound class | Select from the following:  
**Clean**: An uninfected operative wound in which no inflammation is encountered and the respiratory, alimentary, genital, or uninfected urinary tracts are not entered.  
**Clean-contaminated**: Operative wounds in which the respiratory, alimentary, genital or urinary tracts are entered under controlled conditions and without unusual contamination. **Note**: this category is not an option for orthopaedic procedures.  
**Contaminated**: Open, fresh, accidental wounds. In addition, operations with major breaks in sterile technique or gross spillage from the gastrointestinal tract and incisions in which acute, non-purulent inflammation are encountered.  
**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.  
| ASA score | 1/2/3/4/5  
This is used to determine risk score and is an important item to collect. This is found in the operation notes. |
The basic risk index calculator can be found in Appendix Two. It will be automatically calculated for reporting purposes.

**Anaesthetic**

<table>
<thead>
<tr>
<th>Type of anaesthetic</th>
<th>Select from the following:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- General</td>
<td>- Regional: epidural/spinal/not recorded</td>
</tr>
<tr>
<td>- Local</td>
<td>- Other</td>
</tr>
<tr>
<td>- Not recorded</td>
<td>Note: Combinations of these are available to select on the online form.</td>
</tr>
</tbody>
</table>

**Antibiotic prophylaxis**

**Pre-operative antibiotics**

<table>
<thead>
<tr>
<th>Was antibiotic prophylaxis given?</th>
<th>Yes/No/Unknown. If Yes, the following fields must be completed. If no, continue to intra- and post-operative antibiotic section.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of antibiotic(s)</td>
<td>Recognised (generic) name of the antibiotic agent(s) used Enter up to three antibiotics. Always record cefazolin and vancomycin if used. If cefazolin is used record this as the first antibiotic.</td>
</tr>
<tr>
<td>Antibiotic dose</td>
<td>Free text field (Give this in mg or gram, gram is set as the default entry).</td>
</tr>
<tr>
<td>Time given</td>
<td>Choose the most appropriate choice on the form:</td>
</tr>
<tr>
<td></td>
<td>- Within 1hr prior to incision</td>
</tr>
<tr>
<td></td>
<td>- More than 1hr prior to incision</td>
</tr>
<tr>
<td></td>
<td>- On induction</td>
</tr>
<tr>
<td></td>
<td>- After incision</td>
</tr>
<tr>
<td></td>
<td>- Not recorded.</td>
</tr>
</tbody>
</table>

**Intra-operative antibiotics**

| Was an additional dose of antibiotic given intra-operatively, e.g. for lengthy procedure? | Yes/No/Unknown. Initial antibiotics are regarded as “pre-operative” and their timing in relation to knife to skin is recorded. Intra-operative doses are defined as those given after initial doses. |

**Post-operative antibiotics (within first 24hours)**

<table>
<thead>
<tr>
<th>Were antibiotics given post-operatively?</th>
<th>Yes/No/Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>(If Yes) Were they given for <strong>less than</strong> 24 hours?</td>
<td>Yes/No/Unknown</td>
</tr>
<tr>
<td></td>
<td>Standard post-operative dosing is three doses of cefazolin given eight hourly for orthopaedic surgery. If three doses are charted post-operatively this is accepted as being for less than 24hours. If this is exceeded, then the response is no.</td>
</tr>
</tbody>
</table>

*Note:* Pre-operative antibiotic dose and timing are quality and safety markers for the SSII Programme. It is important that this information is accurately recorded.
Surgical skin preparation

Select from the following:
- Chlorhexidine and alcohol
- Povidone iodine and alcohol
- Aqueous povidone iodine
- Other (drop down choices will be added for other agents. Please contact the SSII Programme team to have other agents added to the drop down menu.)

Patient BMI

If height and weight are available this information may be used to calculate BMI. In some cases if BMI is more easily available than height and weight enter this. If unavailable, enter Unknown.

Readmission details

Information services should be able to search for a readmission with a SSI code. The options for readmissions with SSI of an orthopaedic joint can be found on page 22 under readmission surveillance.

Has the patient been readmitted? Yes/No.

Date of readmission DD/MM/YYYY__/__/_____

Was readmission due to SSI? Yes/No (if yes complete the numerator data section).

Has SSI criteria been met for this procedure? Yes/No (if yes complete the numerator data section).

Numerator data

Data field | Instructions for data collection
---|---
When was surgical site infection diagnosed? | Select from the following:
- During initial admission.
- During readmission up to 30 days post procedure.
- During readmission up to 90 days post procedure.
- The date of diagnosis must be entered. This will be when all criteria for SSI have been met. If date is unclear and patient has been readmitted enter the readmission date.

Type of SSI | Check the flowcharts to assist with decision making before completing this section. Choose one of the following:
- Superficial (must occur within 30 days post procedure)
- Deep incisional
- Organ/space.

Was a clinical sample taken from the wound? | Yes/No.
<table>
<thead>
<tr>
<th>Site of sample</th>
<th>Select from the following:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood</td>
<td></td>
</tr>
<tr>
<td>Tissue</td>
<td></td>
</tr>
<tr>
<td>Aspirate</td>
<td></td>
</tr>
<tr>
<td>Swab</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
</tr>
</tbody>
</table>

Up to three clinical samples can be entered on the online form.

<table>
<thead>
<tr>
<th>Clinically significant organism identified?</th>
<th>Yes/No</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Note:</strong> Careful interpretation is needed to ensure only those isolates considered to be the cause of infection are recorded. Consultation with a medical microbiologist or infectious diseases consultant is advisable.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Is the organism an MDRO?</th>
<th>Yes/No</th>
</tr>
</thead>
<tbody>
<tr>
<td>If yes, indicate which of the following:</td>
<td></td>
</tr>
<tr>
<td>- MRSA</td>
<td></td>
</tr>
<tr>
<td>- ESBL</td>
<td></td>
</tr>
<tr>
<td>- VRE</td>
<td></td>
</tr>
<tr>
<td>- Other (enter details in the notes filed in the online form)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Details of organism</th>
<th>Select from the following:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>- Acinetobacter baumanii</td>
</tr>
<tr>
<td></td>
<td>- Coagulase-negative staphylococcus</td>
</tr>
<tr>
<td></td>
<td>- Candida albicans</td>
</tr>
<tr>
<td></td>
<td>- Escherichia coli</td>
</tr>
<tr>
<td></td>
<td>- Enterococcus species</td>
</tr>
<tr>
<td></td>
<td>- Enterococcus faecalis</td>
</tr>
<tr>
<td></td>
<td>- Enterococcus faecium</td>
</tr>
<tr>
<td></td>
<td>- Enterobacter species</td>
</tr>
<tr>
<td></td>
<td>- Klebsiella oxytoca</td>
</tr>
<tr>
<td></td>
<td>- Klebsiella pneumonia</td>
</tr>
<tr>
<td></td>
<td>- Klebsiella species</td>
</tr>
<tr>
<td></td>
<td>- Propionibacterium species</td>
</tr>
<tr>
<td></td>
<td>- Proteus species</td>
</tr>
<tr>
<td></td>
<td>- Pseudomonas aeruginosa</td>
</tr>
<tr>
<td></td>
<td>- Staphylococcus aureus</td>
</tr>
<tr>
<td></td>
<td>- Streptococcus pyogenes (Group A Strep)</td>
</tr>
<tr>
<td></td>
<td>- Streptococcus agalactiae (Group B Strep)</td>
</tr>
<tr>
<td></td>
<td>- Other (add name to the notes field in the online form.)</td>
</tr>
<tr>
<td></td>
<td>- Not specified.</td>
</tr>
</tbody>
</table>

**Note:** If the SSI is due to a mixed infection, record the organisms by using the “site of sample” boxes, more than once to enter the different isolates. Record that it was a mixed infection by entering a comment in the notes field in the online form.
PROCESS FLOWCHARTS
The following flow charts highlight the process to be used when entering data using either the standard online data entry form or ICNet.

Standard online system

1. Print PDF version of paper form.
2. Manually enter data on electronic form for each new procedure. Store securely during follow up period.
3. Access individual DHB theatre information via printed operation lists or electronically (retrospectively).

- **Check patient management system and liaise with wards.** Has there been a readmission?
  - NO
  - YES: Was readmission due to SSI?
    - NO
      - YES: Review patient notes. Is criteria for SSI met?
        - NO
          - YES: Finalise data form confirming NO SSI.
            - Upload completed data to web based form.
        - YES: Finalise data form confirming SSI.
          - Upload completed data to web based form.
    - YES: Has a clinically significant organism been identified?
      - NO
        - YES: Will a new prosthesis be required?
          - NO
            - YES: Is further surgery required?
              - NO
                - YES: Finalise data form confirming NO SSI.
                  - Upload completed data to web based form.
              - YES: Finalise data form confirming SSI.
                - Upload completed data to web based form.
Electronic data capture system (e.g. ICNet NG)

- Individual demographic information automatically enters database
- Electronic Patient Record (ICNet) (Real time)
- Individual DHB theatre information automatically enters database

Basic data is stored electronically during follow up period

Patient readmission triggers alert (feed from patient management system)

Clinical samples triggers alert (feed from lab system)

Potential modules available

Clinical case review

Review patient notes. Is criteria for SSI met?

- Yes
- No

Is further surgery required?

- Yes
- No

Will a new prosthesis be required?

- Yes
- No

Finalise data form confirming

- NO SSI
- SSI

Submit electronic form
DATA COLLECTION TOOLS
Data collection tools are available in both paper and electronic (online versions). The paper based version is available in Appendix Three.

Once data has been collected manually or stored locally in each hospital, it needs to be entered into the online form. Training has been provided to participants about the online form. Ongoing advice is available via the national SSII Programme Team members. All delegated improvement staff in DHBs will be given a user code to the site. This is linked to their DHB and hospital/facility details.

Entering patient data

Once the login field has been successfully completed, the database will be accessible for entering the patient data. A new form must be created for each procedure using the ‘create new form’ button. This will open up the data fields for data entry. There are a number of mandatory fields, which must be completed before the form can be uploaded as a procedure case. Once a form has been created, it can be ‘re-opened’ at any stage to enter additional information about the case, for example, readmission or SSI details.
Once opened, a form will automatically be allocated a record number. This can be recorded on any hard copy version of the form you may hold as a cross reference. When a new form is created, your DHB will be auto-populated (linked to your login) and you will then need to select the hospital where the patient underwent the procedure. The form completion is straightforward with those fields that require data to be completed being highlighted in pink when they remain empty.

Some data fields will drop down only when certain information is entered. For example, if a revision procedure code is selected, a further question will appear below asking whether the revision has occurred as a result of infection.

![Image of form](image)

**Saving data entry**

Each time you complete some data entry it will need to be actively saved using the ‘save’ button on the top right of the screen. If you ‘close’ the form without first saving it, your data will be lost. If you have multiple data entries to complete, you can use the ‘save’ button and then go straight to ‘create new form’.

**Deleting forms**

Currently, this is only possible via an ICNet administrator. If you find that you no longer need a form that has been partially completed (e.g. patient dies before procedure completed) then you can either re-allocate the form/form number to another patient and overwrite the content, or request that an administrator deletes the form.

**Completion of data entry for each case**

When a new form is opened it will show that it is already 73% complete. This is due to the optional data fields which are contained in the form from the outset, even though there has been no data entry.

As data is entered the % completed will rise until all mandatory fields are completed. The percentage indicator at the top of the form then changes to green and indicates 100% complete. A case may be ‘completed’ on the online form for the following reasons:
- No wound infection reported up to 30 days post procedure
- No wound infection reported up to 90 days post procedure for hip and knees.*

*When a case is completed at 30 days it will remain in the system and can be re-opened should the patient be readmitted with an SSI within 90 days of the procedure date. Hence mechanisms are needed in each DHB to check for readmissions 90 days after the procedure.

**Note:** The export button is currently inactive as data will be downloaded by the programme team for analysis as required. However, it will be used in the future and you will be advised how and when to use this.

If you have any difficulties logging into the SSI data collection form or entering data please contact Michelle Taylor at Michelle.Taylor2@cdhb.health.nz. All enquiries must be logged through the SSII Programme team, please do not contact ICNet directly.
ASSURANCE
Responsibility for data validation rests with the local SSII project coordinator with the aim of:

- Ensuring patient demographics and other data for submission are correct.
- Verifying that all eligible patients are included (i.e. completeness of denominator data).
- Auditing the interpretation of variables such as infection/no infection and the classification of SSI.
- Assessing the competency of staff and the structure within the DHB to ensure that it is adequate to perform the tasks required for the SSII Programme.

The following validation methods have been based upon protocols from Scotland (Health Protection Scotland, 2011) and England (Health Protection Agency, 2008).

### Validation of data for the SSII Programme

<table>
<thead>
<tr>
<th>Stage of data collection</th>
<th>Information</th>
<th>Methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transcription from paper to online form</td>
<td>All data</td>
<td>Audit of 10% of forms.</td>
</tr>
<tr>
<td>Online form</td>
<td>NHI</td>
<td>Linked to database to check patient demographics (not currently available).</td>
</tr>
<tr>
<td>Dates</td>
<td>Dates for operation and discharge cannot be before admission date.</td>
<td></td>
</tr>
<tr>
<td>Complete data</td>
<td>Operation finish cannot be before operation start time.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Online form indicates percentage of completeness of each form.</td>
<td></td>
</tr>
<tr>
<td>Eligible patients</td>
<td>Type of surgery</td>
<td>Check the ICD10 codes for surgery and readmission/operating lists/microbiology results/pharmacy records. Verify number of cases with orthopaedic register coordinators.</td>
</tr>
<tr>
<td>SSI definition</td>
<td>SSI definition interpretation</td>
<td>Use of algorithms in manual.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Check with another member of team.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>NZ SSII Programme team check.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Case studies regularly circulated for interpretation.</td>
</tr>
<tr>
<td>SSII programme in the DHB</td>
<td>Data collection/structure/education related to the NZ SSII programme</td>
<td>External audit of all processes, structure and competency within the DHB for submission of data to the SSII Programme.</td>
</tr>
<tr>
<td>Case detection</td>
<td>Initial admission and readmission</td>
<td>Robust methods to detect SSIs. Refer to page 21 to 23.</td>
</tr>
</tbody>
</table>

VALIDITY OF DATA/QUALITY ASSURANCE

Interventions to improve healthcare outcomes rely on robust measurements and clinician confidence in the data being reported. Therefore, validation of surveillance data collected for this programme is required.
CONFIDENTIALITY
The SSII Programme follows strict confidentiality and privacy regulations.

Data collection

Data collected as part of the SSII Programme shall be obtained and held in accordance with the:

- Health Information Privacy Code 1994
- Health Act 1956
- Privacy Act 1993
- Official Information Act 1982
- Code of Disability Services Consumers’ Rights.

The information is also covered by the confidentiality/privacy policy of each DHB.

The information collected through the online form will be stored in a central database that will:

- Be held in the strictest confidence
- Be used only for the stated purpose.

The only patient identifiable data that should be sent to the SSII Programme should be the NHI.

Access to the online data collection form

A password will be required for designated data entry staff to access the online form. Collection/storage of any data stored locally will be in accordance with local policies. It is the responsibility of the local coordinator to ensure all data submitted is anonymous including the surgeon performing the operation. Codes must be used to identify surgeons at a local level.
REPORTS

The SSII Programme will generate reports both for local use as well as national data to allow comparison between DHBs. These reports enable the value of local as well as national improvement interventions to be evaluated.

DHB reports

Anonymised reports of infection rates for each DHB will be generated quarterly. Each DHB will be given their own code that will enable them to compare their performance with that of other DHBs. This data should be circulated to all stakeholders to facilitate discussions on improvement. These can then be examined locally by infection prevention and control committees and surgical colleagues.

National report

An annual report of the results of SSI surveillance will be published with analysis of the results for a whole calendar year. Included in this report will be feedback on the significance of any findings as well as the data collection process. Inferential reports will include:

- Cumulative incidence of SSI by DHB and hospital.
- SSI rates for each procedure with 95% confidence intervals.
- Statistical process control chart of SSI rate.
INTERVENE
Appropriate use of surgical antimicrobial prophylaxis

Antimicrobial prophylaxis may be beneficial in surgical procedures associated with high rates of infection such as clean-contaminated or contaminated procedures. It may also be beneficial in clean surgery where prosthetic devices are implanted, because although the infection rate is low, the consequence of infection is severe (Bratzler, 2013).

An optimal surgical antimicrobial prophylaxis regimen that helps to reduce the risk of SSI ensures that patients receive ALL of the following:

1. **Correct antimicrobial choice and dose**: first line of choice for orthopaedic surgery is a ≥ 2g dose of cefazolin.
2. **Correct antimicrobial timing**: antimicrobial prophylaxis is administered as a single dose 0 to 60 minutes before knife to skin.
3. **Correct duration**: antimicrobial is discontinued within 24 hours after surgery end time (3 additional doses at 8 hourly intervals).

Evidence supports the use of surgical antimicrobial prophylaxis for:

- Clean surgery involving the placement of a prosthesis or implant.
- Clean-contaminated surgery.
- Contaminated surgery.

Data collected by the SSII Programme is also fed into the Commission’s SSI Quality and Safety Markers (QSMs), which are reported nationally by the Commission on a quarterly basis. There are two QSMs associated with the use of surgical antimicrobial prophylaxis:

1. DHB performance is measured against selection of the correct antimicrobial choice and dose (2g of cefazolin), with a compliance target of 95%.
2. DHB performance is measured against the correct antimicrobial timing, with a compliance target of 100%.

The three components of appropriate use of antimicrobial prophylaxis are outlined on the following pages.
Correct antibiotic choice and dose

- Clindamycin (900mg) or vancomycin (1g up to 70kg and then 15mg/kg for patients weighing more than 70kg) should be reserved as alternative agents in the event of allergy to β-lactam agents.
- Clindamycin is preferred over vancomycin because of better compliance with timing when clindamycin is used.
- Vancomycin should be included with cefazolin for routine prophylaxis for patients known to be colonised with MRSA.

The recommended dose of cefazolin for ALL adults (≥ 18 years) is 2g.
- It is unclear if the dose of cefazolin for those patients weighing >120kg should be increased to 3g. A number of studies, all with differing design, have looked at this issue and provide conflicting conclusions (Forse et al., 1989, Edmiston et al., 2004, Koopman et al., 2007, Van Kralingen et al., 2011 and Ho et al., 2012).

**Rationale**

This measure assesses whether DHBs are complying with evidence based practice.

**Improvement**

An increase in the rate of compliance i.e. xx% of patients received cefazolin ≥ 2g as their first choice of antimicrobial.

**Numerator statement**

Number of procedures where a ≥ 2g dose of cefazolin was administered.

**Denominator statement**

Number of procedures.
Correct antibiotic timing

- Evidence indicates that antimicrobial prophylaxis should be given within the 60 minutes before the surgical incision (knife to skin) (Classens, 1992).
- To allow adequate time for the infusion to occur, patients who receive vancomycin should have the infusion initiated more than one hour before the surgical incision. The infusion should be completed before knife to skin.
- An additional dose of cefazolin may be necessary if the length of surgery is prolonged. It is recommended that re-dosing occur when the length of the procedure exceeds two half-lives; as this is 1.2 – 2.2 hours for cefazolin, re-dosing should occur 4 hours after the first dose was given.
- Re-dosing should also be considered if there is excessive blood loss (>1500mL) in order to ensure an adequate antimicrobial level until wound closure.
- An additional dose of cefazolin (2g) or clindamycin (900mg) should be given before the second side of a bilateral procedure to ensure the best timing for the second side. No additional dose of vancomycin is required because its half-life is adequate for both sides of a bilateral procedure.
- Combination prophylaxis, i.e. a cephalosporin with gentamicin, is not recommended because it has not been shown to reduce surgical site infection and gentamicin causes renal injury (Bell et al, 2014).

Rationale
This measure assesses whether DHBs are complying with evidence based practice.

Improvement
An increase in the rate of compliance.

Numerator statement
Number of procedures in which antimicrobial prophylaxis was initiated within one hour prior to surgical incision (two hours if receiving vancomycin).

Denominator statement
Number of procedures.

Collection guidance
This is a yes/no question. Was antimicrobial prophylaxis given within 60 minutes of knife to skin? If antimicrobial not administered or time of recording is not documented, count this case as one in which the patient was not given the antimicrobial on time, i.e. count as an error.
Correct duration

Data and clinical practice guidelines do not support antimicrobial prophylaxis continuing beyond 24 hours (Bratzler, 2013). There is also no evidence for benefits of continuing antimicrobial administration until all drains or catheters are removed.

Three doses of cefazolin (2g) administered eight hours post-operatively is accepted as discontinuation within 24 hours of surgery.

The use of antimicrobials is not without risk for patients. Exposure to antimicrobials is associated with a greater risk of subsequent colonisation with resistant organisms.

Antimicrobial use is a risk factor for *Clostridium difficile* associated disease.

<table>
<thead>
<tr>
<th>Rationale</th>
<th>This measure assesses whether DHBs are complying with evidence based practice.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improvement</td>
<td>An increase in the rate of compliance.</td>
</tr>
<tr>
<td>Numerator statement</td>
<td>Number of procedures where antimicrobial prophylaxis was discontinued within 24 hours after surgery end time.</td>
</tr>
<tr>
<td>Denominator statement</td>
<td>Number of procedures.</td>
</tr>
<tr>
<td>Collection guidance</td>
<td>This is a Yes/No question. Was prophylaxis discontinued within 24 hours of the end of surgery? Patients in whom antimicrobials are continued as treatment should be excluded from this measure.</td>
</tr>
</tbody>
</table>
Prevention of *Staphylococcus aureus* infection in those with a previous *S. aureus* infection

- ~30% of SSIs in the NZ SSII Programme are due to *S. aureus*.
- Some patients coming forward for arthroplasty may have had a previous *S. aureus* infection. This may have been after a previous arthroplasty.
- When a procedure is being undertaken in a patient with a previous *S. aureus* infection, especially an SSI, infectious disease or clinical microbiology advice should be sought on how to suppress/eradicate *S. aureus* before the procedure.

Implementing surgical antimicrobial prophylaxis

In implementing the three components for appropriate use of antimicrobial prophylaxis we suggest clinicians consider the following where appropriate/applicable to their DHB:

- Engage with the anaesthesia service to ensure that the correct antimicrobial agent, timing and dose for perioperative prophylaxis occurs.
- Use pre-printed or computerised instructions specifying post-operative antimicrobials and timely discontinuations.
- Use electronic prescribing order sets or pathways to direct to the appropriate antimicrobials and timely discontinuation.
- Change operating room drug stocks to include only recommended antimicrobial agents.
- Use visible reminders/checklists/stickers.
- Involve pharmacy, infection prevention and control, clinical microbiologists and infectious disease physicians to ensure appropriate timing, selection and duration.
- Verify administration time during a specified “time out” period (e.g. 5 minutes) so action can be taken if not administered.
- Use ward rounds and consider using pharmacist involvement to ensure antimicrobials are stopped within 24 hours of surgery.

Implementing the interventions to prevent SSI for hip and knee arthroplasty presents an important opportunity to build collaboration within the hospital setting, including the following:

- Enlisting the support of senior leadership in the hospital and surgical and anaesthesia departments.
- Identifying one or two surgeons and anaesthetists to further champion the case and influence peers to enhance the adoption of, implementation of and adherence to the above interventions.
- Exploring how to best communicate these interventions through strategies such as face-to-face communication at staff meetings, outreach to surgeons office, or telephone calls from leaders to their peers.
- Building collaborative relationships between the hospital operating room management team (OR nurses, anaesthetists and anaesthetic technicians) and surgeons to establish reliable processes and hand-overs for pre-operative assessment, planning and follow up.
Antiseptics can be defined as biocidal products that destroy or inhibit growth of microorganisms in, or on, living tissue, for example, the skin. Antiseptics can include a wide variety of formulations and preparations including hand washes, surgical scrubs, preoperative skin preparations, ointments, creams, tinctures, mouthwashes and toothpaste. Overall, they should have the following characteristics:

- A wide spectrum of activity against bacteria, fungi and viruses.
- Rapid biocidal activity.
- Little or no damage, irritation or toxicity to the tissue.
- Little or no absorption into the body.
- If possible, some persistent biocidal activity.

Preoperative skin preparation of the operative site involves use of an antiseptic agent with both rapid and long-acting antimicrobial activity. Two types of preoperative skin preparations that combine alcohol (which has an immediate and dramatic effect on skin bacteria) with long-acting antimicrobial agents appear to be more effective at preventing SSI (IHI, 2012):

- Chlorhexidine gluconate plus alcohol (at least 70%)
- Povidone-iodine plus alcohol (at least 70%).

**Appropriate use of skin antisepsis preparation**

Alcohol, chlorhexidine and povidone-iodine (iodine tinctures or iodophors) are the most commonly used antiseptic agents. An optimal surgical skin antisepsis preparation regimen that helps to reduce the risk of SSI ensures that patients receive:

An alcohol based antiseptic solution (at least 70%) containing one of the following antiseptics:

1. Chlorhexidine gluconate
   OR
2. Povidone-iodine.

Evidence supports the use of surgical skin antisepsis preparation for:

- Clean surgery involving the placement of a prosthesis or implant.
- Clean-contaminated surgery.
- Contaminated surgery.

Alcohol based chlorhexidine and povidone-iodine antiseptic solutions significantly reduce the likelihood of surgical site colonisation and maximise the rapidity, potency and duration of bactericidal activity when compared to other solutions.

Data collected for this intervention is also reported as a QSM. DHB performance is measured against their use of one of the above alcohol-based skin preparation agents. The compliance target for this QSM is 100%.
Chlorhexidine gluconate

The properties that make chlorhexidine highly effective are a strong affinity for binding to the skin, high antibacterial activity and prolonged residual effects on rebound bacterial growth. Chlorhexidine exhibits excellent activity against gram-positive and good activity against gram-negative vegetative organisms and fungi (APIC 2010).

Chlorhexidine is typically used in concentrations of 2% to 4% for hospital scrubs and hand washes, however, when the formulation includes alcohol, the concentration of chlorhexidine is usually 0.5% to 2%.

Patients that are allergic to chlorhexidine gluconate should receive povidone-iodine with alcohol (at least 70%) as an alternative.

Povidone-iodine

Iodine has been widely used as an antiseptic. Traditional solutions in water or alcohol include tincture of iodine or Lugol’s solutions. Iodophors are preparations containing iodine complexed with a solubilising agent such as a surfactant or povidone (povidone iodine (PVP)). Iodophors have allowed for greater flexibility in the use of iodine in antiseptics. Depending on the concentration of free-iodine iodophors can be used for routine and high risk applications such as surgical scrubs and preoperative skin antisepsis. They are generally associated with low toxicity and little irritation.

The concentration of iodine varies depends on the formulation used. For example, one formulation contains iodine poyacrylex (0.7% available iodine) and 74% weight to weight (w/w) isopropyl alcohol.
Implementing surgical skin antisepsis preparation

While fires in the operative theatre are extremely rare, alcohol based antiseptics are flammable and therefore the Programme recommends the following precautions be taken when using alcohol based antiseptic skin preparation solutions:

- Staff need to be educated before using a chlorhexidine gluconate-alcohol or povidone-iodine-alcohol solution on how to be safe and effective in their application of a flammable skin preparation agent.
- Avoid dripping or pooling of alcohol based antiseptic solutions on sheets, padding, positioning equipment, adhesive tape and on or under the patient.
- Ensure that the liquid has completely dried by evaporation – three minutes is usually sufficient. Areas with excess hair may take longer to dry. **Note** that drying is equally important for the biocidal activities of alcohol.
- Develop protocols that ensure and document that the applied solution is completely dry before draping the patient.
- Single-use applicators should ideally be used to apply flammable antiseptic agents.
- Cleanse the incision area for 30 seconds and then paint the rest of the extremity.
- Consider use of a tinted chlorhexidine gluconate-alcohol prep (orange, red or teal) for greater visibility.

Implementing the interventions to prevent SSI for hip and knee arthroplasty presents an important opportunity to build collaboration within the hospital setting, including the following:

- Enlisting the support of senior leadership in the hospital and surgical and anaesthesia departments.
- Identifying one or two surgeons and anaesthetists to further champion the case and influence peers to enhance the adoption of, implementation of and adherence to the above interventions.
- Exploring how to best communicate these interventions through strategies such as face-to-face communication at staff meetings, outreach to surgeons office, or telephone calls from leaders to their peers.
- Building collaborative relationships between the hospital operating room management team (OR nurses, anaesthetists and anaesthetic technicians) and surgeons to establish reliable processes and hand-overs for pre-operative assessment, planning and follow up.
CLIPPING NOT SHAVING INTERVENTION GUIDELINES

Preparation for surgery has traditionally included the routine removal of body hair from the intended surgical wound site. Hair is removed because its presence can interfere with the exposure of the incision site, the subsequent wound, suturing of the incision and the application of adhesive drapes and wound dressings (Best Practice 2007).

Studies have shown that preoperative hair removal by any means is associated with increased SSI rates (CDC 1999). Hair should not be removed unless it interferes with the operation. If removal is necessary, remove by clipping and not by shaving (Nichols 2001).

Clipping rather than shaving will improve the safety and quality of care that patients receive. Hair removal using electric clippers should occur as close to the time of the procedure as possible and should be performed outside the operating room. Hair removal with a razor causes epidermal micro-trauma and bacterial colonisation, has been associated with a higher risk of SSI and, therefore, should not be used (Ng, Alexander & Kerr, et al 2013).

**Appropriate use of clipping**

According to international guidelines (WHO 2009, Canadian Patient Safety Institute 2011, NICE 2008) hair should not be removed from the operation site unless it interferes with the surgical procedure. If hair removal is required, the evidence supports the use of clippers for all sites. Clipping should occur as close to the time of surgery as possible.

This measure assesses whether DHBs are complying with evidence based practice.

**Rationale**

An increase in the rate of compliance, i.e. xx% of patients having hair removed received clipping of body hair preoperatively.

**Improvement**

Number of procedures where preoperative clipping of body hair was performed.

**Numerator statement**

Number of procedures where hair is removed.

**Denominator statement**
Inappropriate hair removal

Much of the focus of SSI prevention research in relation to hair removal has been on removal practices in hospitals by surgical and nursing teams. Studies have shown that preoperative hair removal the night before an operation is associated with a significantly higher risk of SSI than hair removal immediately before the operation. This is due to skin micro-trauma and bacterial colonisation (Ng et al 2013).

Engaging patients in their care with education about appropriate hair removal is important and could be included as a quality initiative in preoperative patient literature (AORN 2013).

Implementing clipping of hair preoperatively

- Patients should be educated not to shave in the vicinity of the surgical site before their surgery. This message could be incorporated into the preoperative patient information (AORN 2013).
- Update policies and procedures. If hair removal is necessary, clippers should be used to prepare the surgical site preoperatively.
- Use either a single use electric or battery-powered clipper. Clippers should be disinfected as per manufacturer’s instructions.
- To limit bacterial contamination of the surgical site, clipping should occur less than two hours before surgery.
- Hair removal should occur outside the operating theatre or procedure room, but inside the operating department. Clipping the hair outside of the operating room minimises the dispersal of loose hair and therefore the potential for contamination of the sterile field and/or the surgical wound.
- Remove razors from surgical wards and operating rooms to prevent their use in hair removal.
- DHBs should consider providing information for patients not to remove hair before their admission and certainly not before admission for an elective caesarean section.
IMPROVE
The Model for Improvement is a simple yet powerful tool for accelerating improvement that has been used successfully by hundreds of healthcare organisations internationally (Institute for Healthcare Improvement, 2012).

The model has two parts:

1. Three fundamental questions that guide improvement teams to:
   - Set clear aims
   - Establish measures that will inform if changes are leading to improvement
   - Identify changes that are likely to lead to improvement.
2. The Plan Do Study Act (PDSA) cycle is used for small scale tests of change in the real work setting.

The Model for Improvement is shown below and explained in more detail on the following pages.
Set clear aims (goals and objectives)

Improvement requires setting aims. An organisation will not improve without a clear and firm intention to do so. The aim should be time specific and measurable. Setting an aim can assist teams to focus on what they hope to achieve by implementing SSI prevention strategies.

Build a team

It is crucial to have the active support of senior clinicians and leaders in this work. For any surgical care improvement programme to be successful, leadership must make patient safety and quality of care a strategic priority. Once leadership has publicly given recognition and support to the programme, the improvement team can be quite small.

The team should be responsible for:
- Conducting small scale tests of ideas for improvement.
- Tracking performance on a set of measures designed to help them see if the changes they are making are leading to improvement.
- Regularly report their findings back to leadership.

Establish measures

Measurement is a critical part of testing and implementing changes; it tells a team whether the changes they are making are actually leading to improvement. Measurement for improvement starts with collecting baseline data to provide your team with a picture of where you are starting from.

Given the complexity of reducing the outcome measure of SSI, we offer the following tips and suggestions:
- SSI rates need to be monitored on a long-term basis for trend. A normal variation may be noted in SSI rates even though antimicrobial prophylaxis compliance increases consistently.
- Improvement in SSI rates should be seen as a long term goal. These events are uncommon, occurring in less than 5% of all procedures and improvement will not be seen in the short term.
- Consistently applied best practice for every surgical procedure will influence SSI rates.
- There are many other variables, beyond the guidelines presented, which may affect SSI rates. For example; patient specific factors such as diabetes, obesity, surgeon experience, and technique and duration of procedure.
- Work closely with your infection prevention and control team, clinical microbiologists, infectious disease physicians, surgeons, anaesthetists, operating room nursing staff, pharmacists and information support services to capture the process and outcome measure.

Select changes

The ability to develop, test and implement changes is essential for any individual, group or organisation that wants to continuously improve.

After generating ideas, run PDSA cycles to test a change or group of changes on a small scale to see if they result in improvement. If they do, expand the tests and gradually incorporate larger and larger samples until you are confident that the changes should be adopted more widely.
PDSA cycle

**Plan** – Identify one clinician willing to test a method of ensuring one of the above antibiotic prophylactic interventions is being carried out correctly e.g. ensuring antimicrobials are discontinued within 24 hours of surgery.

**Do** – Undertake the review after a usual operating session the previous day.

**Study** – At an appropriate point in the day talk to the nurse/doctor/pharmacist involved about how ‘user friendly’ the process was.

- Did it fit into the normal pattern of patient follow up or review?
- Was there anything they would like to see added? How long did it take? Did it pick up any ‘glitches’?
- Was it too dependent on someone remembering to do it? How could we make the process better next time?

**Act** – Make refinements based on the discussion. If the refinements take time to implement, arrange to do this but agree how you could carry on the testing by making refinements as you go along, testing again each time until you can do this successfully for the whole day.

**Other guidance**

A number of countries including Wales, Canada and the U.S (National Healthcare Service, Wales 2010, Safer Healthcare Now, Canada 2011, Surgical Care Improvement Programme (SCIP) US 2006) and jurisdictions within countries (SQuIRe Western Australia, 2009) provide guidance on reducing SSI rates. The Joint Commission’s Implementation Guide (2013) also provides an overview of evidence-based best practices for preventing SSI.
REFER
REFERENCES
The following is a list of research and literature that has been used to develop this Implementation Manual.

www.apic.org/EliminationGuides


References:


Surgical Care Improvement Programme, The Joint Commission, USA July 2006. www.jointcommission.org/surgical_care_improvement_project

The Joint Commission, (2013). Implementation Guide for NPSG.07.05.01 on Surgical Site Infections: The SSI Change Project.


APPENDICES
APPENDIX ONE: FLOW CHARTS TO ASSIST DECISION MAKING

The following flow charts are based on NHSN definitions but have been adapted from the Welsh Healthcare Associated Infection SSI Surveillance Diagnostic Tool (Version 1, 2007).

Possible surgical site infection

Possible Surgical Site Infection

YES

Infection occurred within 30 days or 90 days after a procedure

NO

Do NOT report as a SSI

YES

Infection related to the operative procedure

NO

Do NOT report as a SSI

POSSIBLE SUPERFICIAL INCISIONAL SURGICAL SITE INFECTION

YES

Go to Superficial Incisional Surgical Site Infection Sheet

POSSIBLE DEEP INCISIONAL SURGICAL SITE INFECTION

YES

Go to Deep Incisional Surgical Site Infection Sheet

POSSIBLE ORGAN/SPACE SURGICAL SITE INFECTION

YES

Go to Organ/Space Surgical Site Infection Sheet
Possible superficial incisional surgical site infection (occurs within 30 days after the procedure)

- Infection involves only skin and subcutaneous tissue of incision
  - NO
  - YES

Infection involves skin or subcutaneous tissue and deep soft tissues of the incision or involves the organ/space
- YES
- NO

Check Deep Incisional or Organ/Space sheet

Culture of fluid or tissue aseptically obtained from superficial incision
- YES
- NO

Culture positive
- YES
- NO

Culture negative
- YES
- NO

Superficial incision deliberately opened by surgeon
- YES
- NO

Purulent drainage from superficial incision
- YES
- NO

Diagnosis of superficial incisional SSI by surgeon or attending physician
- YES
- NO

Do NOT report as a Superficial Incisional SSI

*BEWARE that colonised wounds can yield positive results.
Colonisation = proliferation of micro-organisms without host response.
If unsure, consult Medical Microbiologist/Infectious Disease Consultant
Possible deep incisional surgical site infection
(occurs within 90 days after the procedure)

Infection involves only deep soft tissues (e.g. fascia and muscle layers) of the incision
OR
Infection involves both skin or subcutaneous tissue and deep soft tissues of the incision

Check Superficial Incisional or Organ/Space sheet

YES

Culture of fluid or tissue aseptically obtained from deep incision

YES

Culture negative

YES

Culture positive

NO

Deep incision spontaneously dehisces or deliberately opened by surgeon

YES

Culture positive

Purulent drainage from the deep incision, but not from organ/space of surgical site

At least one of the following signs or symptoms of infection are present:
- Fever (>38°C)
- Localised swelling
- Redness
- Heat

NO

YES

NO

ABSCESS OR OTHER EVIDENCE OF INFECTION INVOLVING THE DEEP INCISION IS FOUND ON DIRECT EXAMINATION, DURING INVASIVE PROCEDURE, OR BY HISTOPATHOLOGICAL EXAMINATION, OR IMAGING TEST

YES

NO

Do NOT report as a Deep Incisional SSI

DEEP INCISIONAL SURGICAL SITE INFECTION
Possible organ/space surgical site infection
(occurs up to 90 days after the procedure)

Infection involves any part of the body, deeper than fascia or muscle layers, that is opened or manipulated during the operative procedure

YES

NO

Infection draining through incision (generally does not involves re-operation)

YES

NO

Purulent drainage from a drain that is placed into organ/space

NO

Organisms isolated from as aseptically obtained culture of fluid or tissue in organ/space

NO

An abscess or other evidence of infection involving the organ/space that is found on direct examination, during invasive procedure, or by histopathological examination or imaging test

NO

Meets the criterion for specific organ/space infection i.e. osteomyelitis or joint infection

NO

Do NOT report as an organ/space SSI

YES

ORGAN/SPACE SURGICAL SITE INFECTION
This will be calculated as follows providing that the following fields on the dataset are completed:

<table>
<thead>
<tr>
<th>Field</th>
<th>Score = 0 if:</th>
<th>Score = 1 if:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Wound class</strong></td>
<td>1 or 2 (clean/clean-contaminated).</td>
<td>3 or 4 (contaminated or dirty/infected).</td>
</tr>
<tr>
<td><strong>ASA classification</strong></td>
<td>1 or 2.</td>
<td>3, 4 or 5.</td>
</tr>
<tr>
<td><strong>Duration of operation</strong></td>
<td>&lt;1 hr (LSCS). &lt;2hrs (arthroplasty).</td>
<td>&gt;1 hr (LSCS). &gt;2hrs (arthroplasty).</td>
</tr>
<tr>
<td><strong>Basic Risk Index</strong></td>
<td>Sum of scores.</td>
<td></td>
</tr>
</tbody>
</table>

DHB data collectors do not need to calculate the basic risk index. This will be calculated during data analysis and used to risk stratify procedures in the report.
<table>
<thead>
<tr>
<th><strong>PATIENT INFORMATION</strong> <em>(denominator data)</em></th>
<th><strong>Form no:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>NHI:</td>
<td>Insert patient sticker here if available. However, the only mandatory information required for data entry is specified in the adjacent table.</td>
</tr>
<tr>
<td>Gender</td>
<td>M/F/unknown</td>
</tr>
<tr>
<td>Date of birth</td>
<td>_ _ / _ _ / _ _ _ _</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>PRIMARY ADMISSION/DISCHARGE</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of admission</td>
<td>_ _ / _ _ / _ _ _ _</td>
</tr>
<tr>
<td>Date of discharge</td>
<td>_ _ / _ _ / _ _ _ _</td>
</tr>
<tr>
<td>Date of death (if applicable)</td>
<td>_ _ / _ _ / _ _ _ _</td>
</tr>
<tr>
<td>Not yet discharged (tick)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>PROCEDURE</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of procedure</td>
<td>_ _ / _ _ / _ _ _ _</td>
</tr>
<tr>
<td>Procedure description</td>
<td></td>
</tr>
<tr>
<td>Procedure code (if any)</td>
<td></td>
</tr>
<tr>
<td>If revision, is it due to infection?</td>
<td>Yes/no</td>
</tr>
<tr>
<td>Procedure location</td>
<td>Left/right</td>
</tr>
<tr>
<td>One form for each side required if bilateral procedures</td>
<td></td>
</tr>
<tr>
<td>Is procedure an emergency?</td>
<td>Yes/no/unknown</td>
</tr>
<tr>
<td>Surgeon grade</td>
<td></td>
</tr>
<tr>
<td>Surgeon code</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>RISK SCORE</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Wound class</td>
<td>Clean/contaminated/dirty</td>
</tr>
<tr>
<td>Knife to skin time</td>
<td>_ _ / _ _ 24hr clock</td>
</tr>
<tr>
<td>Wound closure time</td>
<td>_ _ / _ _ 24hr clock</td>
</tr>
<tr>
<td>ASA score</td>
<td>1 2 3 4 5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>ANAESTHETIC</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of anaesthetic</td>
<td>☐ GA ☐ Regional: ☐ Epidural ☐ spinal ☐ Combined spin/epi ☐ Local/other</td>
</tr>
<tr>
<td>Antibiotic cement used?</td>
<td>Yes/no/unknown</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>ANTIBIOTICS</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-operative antibiotics</td>
<td>Was antibiotic prophylaxis given?</td>
</tr>
<tr>
<td>Antibiotic name</td>
<td>Dose</td>
</tr>
<tr>
<td>Time: _ _ _ _ or</td>
<td>On induction</td>
</tr>
<tr>
<td>☐ Within 1hr prior to incision</td>
<td>☐ After incision</td>
</tr>
<tr>
<td>☐ More than 1hr prior to incision</td>
<td>☐ Not recorded</td>
</tr>
<tr>
<td>Intra-operative antibiotics</td>
<td>Was an additional dose of antibiotic given intra-operatively?</td>
</tr>
<tr>
<td>Post-operative antibiotics</td>
<td>Were antibiotics given post-operatively?</td>
</tr>
<tr>
<td>If yes, were they given for ≤24hrs</td>
<td></td>
</tr>
</tbody>
</table>
**Skin preparation type used**  Unknown  ☐
- Chlorhexidine and alcohol  ☐
- Aqueous povidone iodine  ☐
- Povidone iodine and alcohol  ☐
- Other (Contact SSII Programme team to get added)  ☐

**Patient BMI:** Please write “unknown” in the spaces below if height, weight, or BMI unknown

<table>
<thead>
<tr>
<th>Height</th>
<th>Weight</th>
<th>BMI</th>
</tr>
</thead>
</table>

**READMISSION**

<table>
<thead>
<tr>
<th>Has patient been readmitted?</th>
<th>Yes/no</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of readmission</td>
<td>_ _ /_ _ /_ _ _ _</td>
</tr>
<tr>
<td>Was readmission due to SSI?</td>
<td>Yes/no (if yes complete the numerator data section)</td>
</tr>
<tr>
<td>Has SSI criteria been met for this procedure?</td>
<td>Yes/no (if yes complete the numerator data section)</td>
</tr>
</tbody>
</table>

**SSI DETAILS (NUMERATOR DATA)**

<table>
<thead>
<tr>
<th>SSI Diagnosis</th>
<th>Yes/no</th>
</tr>
</thead>
<tbody>
<tr>
<td>When was SSI diagnosed?</td>
<td>☐ During initial admission  ☐ During readmission up to 30 days post procedure  ☐ During readmission up to 90 days post procedure</td>
</tr>
<tr>
<td>Date of diagnosis</td>
<td>_ _ /_ _ /_ _ _ _</td>
</tr>
<tr>
<td>Type of SSI (check decision making flow charts)</td>
<td>☐ Superficial (must occur within 30 days post procedure)  ☐ Deep  ☐ Organ/space</td>
</tr>
</tbody>
</table>

**MICROBIOLOGY**

<table>
<thead>
<tr>
<th>Clinical Sample taken?</th>
<th>Yes/no</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site of sample</td>
<td>☐ Blood  ☐ Tissue  ☐ Aspirate  ☐ Wound swab  ☐ Other</td>
</tr>
<tr>
<td>Clinically significant organism identified?</td>
<td>Yes/no</td>
</tr>
<tr>
<td>Is the organism an MDRO?</td>
<td>Yes/no</td>
</tr>
<tr>
<td>If yes, which of the following:</td>
<td>☐ MRSA  ☐ VRE  ☐ ESBL  ☐ Other</td>
</tr>
<tr>
<td>Details of the organism. Select from the following:</td>
<td></td>
</tr>
</tbody>
</table>

- **Acinetobacter baumanii**
- **Coagulase-negative staphylococcus**
- **Candida albicans**
- **Escherichia coli**
- **Enterococcus faecalis**
- **Enterococcus faecium**
- **Enterobacter species**
- **Klebsiella oxytoca**
- **Klebsiella pneumoniae**
- **Klebsiella pneumoniae**
- **Pseudomonas aeruginosa**
- **Proteus species**
- **Staphylococcus aureus**
- **Streptococcus pyogenes (Group A Strep)**
- **Streptococcus agalactiae (Group B Strep)**
- **Other (add name to the notes field in the online form.)**

**SUMMARY INFORMATION FOR QUICK REFERENCE**

<table>
<thead>
<tr>
<th>Date/month for review at 30 days</th>
<th>Date/month for review at 90 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Review completed at 30 days</td>
<td>Yes/no</td>
</tr>
<tr>
<td>Review completed at 90 days</td>
<td>Yes/no</td>
</tr>
<tr>
<td>SSI detected</td>
<td>Yes/no</td>
</tr>
<tr>
<td>Type:</td>
<td>Superficial/deep/organ/space</td>
</tr>
<tr>
<td>When:</td>
<td>Inpatient readmission</td>
</tr>
<tr>
<td>☐ ≤30 days ☐ ≤90 days</td>
<td></td>
</tr>
</tbody>
</table>

Data entered into SSI database (ICNet)?  Y/N  Date: ____________
## APPENDIX FOUR: REVIEW OF THE EVIDENCE FOR CHOICE OF SURGICAL SKIN ANTISEPSIS AGENT

<table>
<thead>
<tr>
<th>Authors/Journal</th>
<th>Title of Publication</th>
<th>Date</th>
<th>Description</th>
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<td>Carroll K, Dowsey M, Choong P, Peel T</td>
<td>Clin Microbiol Infect. 2013; doi: 10.1111/1469-0691.12209.</td>
<td>2013</td>
<td>Retrospective cohort study of 964 patients undergoing primary or revision hip/knee procedures over an 18 month period. Multiple risk factors examined including skin antisepsis. Outcome measure: incidence and severity of superficial SSI.</td>
<td>Multivariable logistic regression analysis. Patients who received skin prep with 0.5% chlorhexidine and alcohol were at higher risk of superficial infection than those who received 1% iodine and alcohol, p=0.012.</td>
<td>Authors acknowledge findings may reflect surgeon preference and experience and that skin prep requires more evaluation/RCT.</td>
<td>Limitations- single centre, retrospective, superficial SSI with 30 day follow up only.</td>
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<tr>
<td>Tschudin-Sutter et al.</td>
<td>Ann Surg 2012 ; 255 (3):565-569</td>
<td>2012</td>
<td>Prospective study looking at skin microbial counts taken after skin disinfection with povidone-iodine-alcohol in 1005 patients. Counts compared with SSI rates.</td>
<td>3.6% of skin cultures revealed significant colonization and 41 (4%) SSI were detected. Residual bacteria before incision was unrelated to SSI even after adjusting for confounding variables.</td>
<td>Povidone-iodine-alcohol is an effective skin antisepsis agent.</td>
<td>Supports findings of Swenson et al, ICHE 2009.</td>
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<td>Darouiche R et al.</td>
<td>NEJM 2010; 362: 18-26.</td>
<td>2010</td>
<td>Prospective RCT involving 849 subjects over 4 year period in 6 hospitals in US. Clean-contaminated surgery.</td>
<td>Overall rate of SSI was significantly lower in the chlorhexidine-alcohol group than in the povidone-iodine group.</td>
<td>Authors recommend use of 2% chlorhexidine gluconate with alcohol over aqueous povidone-iodine.</td>
<td>Comparison of chlorhexidine gluconate and alcohol versus aqueous povidone-iodine. Needed additional comparator arm with povidone-iodine and alcohol.</td>
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<td>Ostrander R et al.</td>
<td>Efficacy of surgical preparation solutions in foot and ankle surgery.</td>
<td>2005</td>
<td>Prospective study comparing elimination of bacteria from sites disinfected using 3 different products. Cultures were undertaken on 125 consecutive patients undergoing surgery on the foot/ankle. 3 randomly selected preps were used: 0.7% iodine/alcohol; 3% chloroxylenol and 2% chlorhexidine/70% alcohol.</td>
<td>Limited study by numbers. Too small a study to link to fully evaluate SSI rates. Did not measure levels of microorganisms on the foot prior to skin preparation.</td>
<td>Suggestion that chloroprep (chlorhexidine and alcohol) was more effective at reducing counts of skin organisms pre-operatively.</td>
<td>Under powered as sample size too small.</td>
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<tr>
<td>Swenson et al.</td>
<td>Effects of preoperative skin preparation on post operative wound infection rates: a prospective study of 3 skin preparation protocols</td>
<td>2009</td>
<td>18 month study comparing 3 different skin preparations on SSI rates. Povidone iodine/alcohol; chlorhexidine/alcohol and iodine povacrylex in alcohol.</td>
<td>Use of each agent for 6 months each on all general surgery cases. SSI tracked for 30 days post operatively.</td>
<td>No difference in primary outcomes between traditional povidone/iodine/alcohol and iodine povacrlex in alcohol. SSI 3% higher with 2% chlorhexidine gluconate and alcohol.</td>
<td>Study involved general surgery patients so a mix of clean/clean-contaminated and contaminated cases. Study not randomised.</td>
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<td>Adams et al.</td>
<td>Evaluation of a 2% chlorhexidine gluconate in 70% isopropyl alcohol skin disinfectant.</td>
<td>2005</td>
<td>In vitro study comparing 6 commonly used skin disinfectants against S. epidermidis. The disinfectants tested were: 1. 2%chlorhexidine/70% alcohol 2. 70% alcohol 3. aqueous 10% povidone iodine 4. 0.5% aqueous chlorhexidine gluconate 5. 2% aqueous chlorhexidine gluconate 6. 0.5% chlorhexidine gluconate in 70% alcohol.</td>
<td>All disinfectants achieved a log 10 reduction factor of 5 in suspension ± protein. However, when challenged with biofilm, effectiveness was reduced reflecting inhibition of in the presence of organic matter. Most effective agent tested against S. epidermidis were 2% chlorhexidine gluconate in 70% alcohol and 10% aqueous povidone iodine.</td>
<td>Suggests that 2% chlorhexidine gluconate in 70% alcohol may offer advantages over other chlorhexidine gluconate products. No alcohol and povidone iodine comparator.</td>
<td>Need in vivo studies to assess effectiveness of this product in the clinical situation.</td>
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<td>Dumville JC, McFarlane E, Edwards P, Lipp A, Holmes A.</td>
<td>Cochrane Database of Systematic Reviews 2013; 3.</td>
<td>2013</td>
<td>Review of RCTs on preoperative skin preparation. Multiple different formulations used.</td>
<td>13 studies included Only clean surgery included.</td>
<td>Majority under powered to show a difference A single study from 1982 showed 0.5% chlorhexidine in methylated spirits reduced SSI compared to alcohol containing iodine paint.</td>
<td>Limited information provided. More research is required.</td>
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<td>Maiwald M and Chan E.</td>
<td>PLOS ONE 2012; 7: e44277 doi:10.1371/journal.pone.0044277.</td>
<td>2012</td>
<td>Systematic literature review of clinical trials and systematic reviews investigating compounds for blood culture collection, vascular access and surgical skin preparation.</td>
<td>Perceived efficacy of chlorhexidine gluconate often based on the efficacy of chlorhexidine gluconate and alcohol. Rapid effect of alcohol effect skin antisepsis is often overlooked and comparative studies compare alcohol containing preparations with non-alcohol containing.</td>
<td>Alcohol is a key component of any skin preparation. Surgery requires both immediate skin activity (alcohol) plus persistent activity (chlorhexidine gluconate or povidone iodine) hence the combination of both.</td>
<td>Skin antiseptics should contain alcohol of at least 70% for rapid action and another skin antiseptic e.g. chlorhexidine or povidone iodine for more persistent effect.</td>
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<td>Alexander J et al.</td>
<td>Annals of Surgery 2011; 253: 1082-1093.</td>
<td>2011</td>
<td>Updated recommendations for control of surgical site infections.</td>
<td>Findings from literature review inconclusive. Suggest alcohol chlorhexidine gluconate skin count is lower than iodophor/alcohol. Both better than aqueous povidone iodine.</td>
<td>Use an alcohol containing skin preparation containing chlorhexidine gluconate although alcohol/iodophors are also acceptable.</td>
<td>Use alcohol containing skin preparation with an additional antiseptic property i.e. chlorhexidine or iodophor.</td>
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<td>Lee et al.</td>
<td>Infect Control Hosp Epidemiol 2010; 31: 1219-1229.</td>
<td>2010</td>
<td>Literature review and meta analysis. 18 articles underwent review of full text. Included 9 RCTs.</td>
<td>Moderate quality of evidence to use chlorhexidine over iodine for skin antisepsis to prevent SSI. Moderate quality evidence that use of chlorhexidine is associated with fewer skin cultures</td>
<td>5 of the trials included compared chlorhexidine/iodine with povidone iodine aqueous (hence not comparable) see Darouche et al.</td>
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<td>preoperative skin antisepsis to prevent surgical site infection.</td>
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## APPENDIX FIVE: CLIPPING VERSUS SHAVING EVIDENCE REVIEW

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<td>Seropian R, Reynolds BM.</td>
<td>Wound infections after preoperative depilatory versus razor preparation.</td>
<td>1971</td>
<td>Study period June 1968- Feb 1969. Odd number cases received a standard razor preparation, even numbered cases received the depilatory preparation.</td>
<td>406 cases. The infection rate after razor preparation was 5.6% and after the depilatory 0.6%. The results of this study by sex, age, race, wound class and urgency of surgery, show no significant difference. The incidence of wound infection did vary with the interval between razor preparation and surgery. The infection rate being 3.1% after razor preparation just before surgery and 7.1 % after preparation during the 24 hrs before surgery.</td>
<td>Depilatory preparation does not contribute to the risk of wound infection, but razor preparation has a definite adverse effect. The microscopic injury that regularly accompanies razor use is a sufficient explanation without the need to implicate visible injury.</td>
<td>Limitation: no mention of the duration of patient follow up.</td>
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<td>Cruse PJE, Foord R.</td>
<td>A five year prospective study of 23,649 surgical wounds.</td>
<td>1973</td>
<td>A prospective study of 23,649 surgical wounds. All wounds were examined by one person for 28 days after the operation. Initiated for 4 reasons 1. To obtain accurate monthly infection figures 2. To determine factors that influence infection rate 3. To obtain statistical background and 4. To improve infection rate and bed utilisation.</td>
<td>Patients who were shaved- infection rate of 2.3%. Patients who had no shave but pubic hair clipping the infection rate was 1.7%. In patients who had no shave or clipping the infection rate was 0.9%.</td>
<td>Authors felt that a reduction in shaving contributed to a steady decline in clean-wound infection rate.</td>
<td>This study looked at multiple factors for reducing wound infection of which shaving was one. Others included shorter pre-op stay, skin prep, contamination prevented during op, careful surgical technique.</td>
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| Kjonniksen I, Anderson BM, Sondenaa VG, Segadal L. | Preoperative hair removal- a systematic literature review.                             | 2002 | This article describes a systematic literature review on whether, how and when to perform preoperative hair removal. Studies were divided into groups:  
  - Shaving compared to no hair removal.  
  - Shaving compared to clipping.  
  - Shaving compared to depilation.  
  - Timing of preoperative hair.  
  - Removal with razor, clippers and wet and dry shaving. | There was no strong evidence that hair removal results in a higher frequency of SSIs than no hair removal.  
Several of the randomized and observational studies showed that either wet or dry shaving the evening before the procedure resulted in a significantly higher infection rate than depilation or electric clipping.  
No convincing differences in the incidence of postoperative SSIs between electric clipping, depilation or no hair removal. | Hair removal with clippers should be performed as close as possible to the time of the procedure. | The authors’ recommended future research be directed towards randomized trials of clipping or depilation versus no hair removal. |
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<td>Tanner J, Woodings D, Moncaster K. The Cochrane Collaboration. Cochrane Reviews 2006. Issue 3. <a href="http://www.cochrane.org/reviews/en/ab004122.html">www.cochrane.org/reviews/en/ab004122.html</a></td>
<td>Preoperative hair removal to reduce surgical site infection.</td>
<td>2006</td>
<td>The preparation of people for surgery has traditionally included the routine removal of body hair from the intended surgical wound site. However, there are studies which claim that pre-operative hair removal is deleterious to patients by causing surgical site infections and therefore should not be carried out. The primary objective to this review was to determine if routine pre-operative hair removal results in fewer SSIs than not removing hair. Randomised controlled trials comparing hair removal with no hair removal, different methods of hair removal, hair removal conducted at different times before surgery and hair removal carried out in different settings.</td>
<td>Eleven RCTs were included in this review. Three trials involving 625 people compared hair removal using either cream or razors with no hair removal- no statistically significant difference in SSI rate. Three trials involving 3193 people compared shaving with clipping and found that there were statistically significantly more SSIs when people were shaved rather than clipped (RR 2.02, 95% CI 1.21 to 3.36). One trial compared shaving on the day of surgery with shaving the day before and one trial compared clipping on the day of surgery with clipping the day before. Neither trial found to be of statistical significance. No trials were identified which compared clipping with no hair removal. No trials were found comparing clipping to a depilatory cream.</td>
<td>There was no difference in SSIs among patients who have had their hair removed and those who had not. If it is necessary to remove hair, then clipping and depilatory creams result in fewer SSIs than shaving using a razor. No difference observed in SSIs when patients are shaved or clipped one day before surgery or on the day of surgery.</td>
<td>Other studies show higher rates of infection when hair removal is undertaken the day before surgery.</td>
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<td>Best Practice 2007; 11: 1-4.</td>
<td>Pre-operative hair removal to reduce surgical site infection.</td>
<td>2007</td>
<td>Reviewed the Cochrane systematic review from 2006.</td>
<td>No statistically significant difference between shaving and no hair removal. Clippers vs. no hair removal-no studies were found. Three percent (46/1627) of people who were shaved prior to surgery developed SSI compared to two percent (21/1566) of people who were clipped prior to surgery.</td>
<td>This is a statistically significant finding. Trials involved similar types of surgery and showed more people are more likely to develop SSI when they are shaved rather than clipped prior to surgery.</td>
<td>There is insufficient evidence to say whether hair removal increases or reduces SSI. However, if it is necessary to remove hair, clipping or using depilatory cream causes fewer SSI than shaving.</td>
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<td>Ng W, Alexander D, Kerr B, Ho MF, Amato M, Latz K.</td>
<td>A hairy tale: successful patient education strategies to reduce pre-hospital hair removal by patients undergoing elective caesarean section.</td>
<td>2013</td>
<td>This study was conducted in a 430 bed community teaching hospital in Toronto. They undertake approx. 6000 births per annum of which 1700 are caesarean section. Expectant mothers were given the message not to remove the hair from their lower abdomen /pubic area during the last month of pregnancy. The message was reinforced by healthcare providers and posters etc.</td>
<td>SSIs following caesarean section were studied prospectively. The rate of self-hair removal decreased significantly from 41% (2008) to 27% (2011). Concurrently, a 51% reduction in the SSI rate was observed.</td>
<td>The multifaceted strategy proved successful in reducing pre-hospital hair removal overall and in particular, shaving. The study suggested that a trend over time to lower-risk methods of hair removal, e.g. clipping, depilatory creams. Limitation: Other simultaneous SSI prevention interventions, which are alluded to but not described, are also likely to have contributed to the reduction in SSI rate.</td>
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<td>NICE Clinical Guideline October 2008 <a href="http://www.guideline.gov/content.aspx?id=13416">www.guideline.gov/content.aspx?id=13416</a></td>
<td>Surgical site infection – Prevention &amp; treatment of surgical site infection.</td>
<td>Oct 2008</td>
<td>Systematically developed statements which assist clinicians in making decisions about specific treatment. Has been developed with the aim of providing guidance on the patient’s journey throughout the pre, intra and the post-op phases of surgery.</td>
<td>Three RCT’s (n=3193 participants) compared effects of shaving with those of clipping, incidence of SSI: 2.8 % (46/1627) after shaving developed SSI compared with 1.3% (21/1566) after clipping. (RR 2.02, 95%CI 1.21 -3.36). Seven trials (n=1213 participants) effects of shaving with those of</td>
<td>There is evidence that shaving using a razor is associated with more SSIs than any other method of hair removal. If hair has to be removed, use electric clippers with a single use head on the day of</td>
<td>Despite shaving using razors being one of the less costly options for hair removal, once the costs of treating SSI were included in the analysis, this option became the most expensive. The use of clippers for preoperative hair removal was found to be the</td>
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<td>depilatory creams. Incidence</td>
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