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Appendix

HSG Cerebral Palsy Complications Manual*

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SIRS = systemic inflammatory response syndrome, SSI = surgical site infection, VAC = vacuum-assisted closure, PO = per os, NG = nasogastric, TPN = total parenteral nutrition, IV = intravenous, CRP = C-reactive protein, CSF = cerebrospinal fluid, SIADH = syndrome of inappropriate antidiuretic hormone secretion, SSEP/MEP = somatosensory evoked potential/motor evoked potential, PT = physical therapy, NSAIDS = nonsteroidal anti-inflammatory drugs, I & D = irrigation and debridement, OR = operating room, and ICU = intensive care unit.

HSG
HARMS STUDY GROUP
Pioneering Research in Spinal Deformities

HSG Cerebral Palsy Complications Manual

Welcome to the Manual!

In the slides that follow, you'll be shown how to enter complications into the database, and you will be given an overview of the complications we collect. We will include definitions, time frames, and treatments for complications.

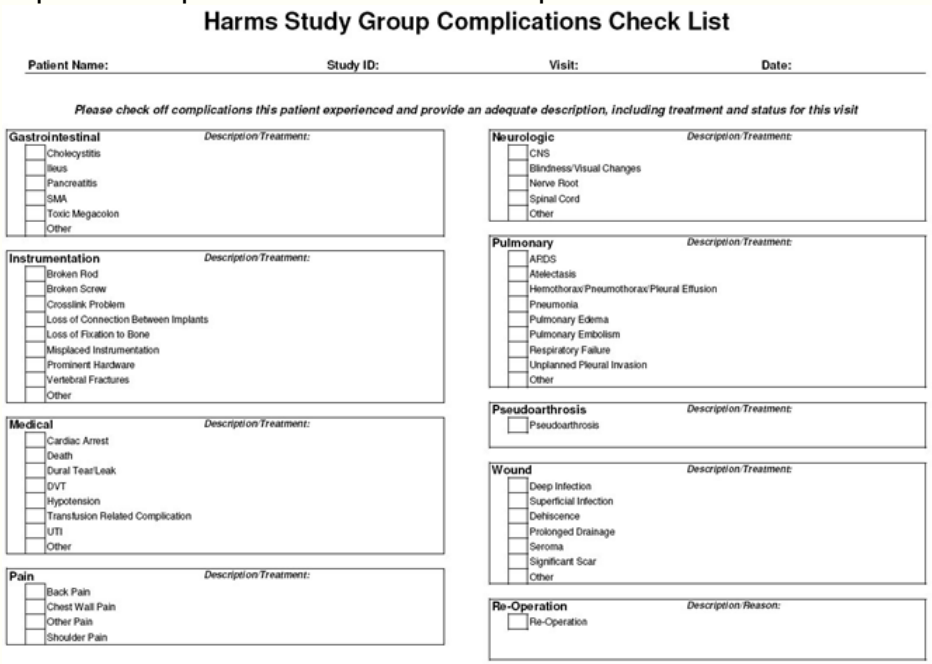
The guidelines included here are as comprehensible as possible at this time, but if you find that you have unanswered questions, please reach out to the Database Manager or QA Manager who will act as a liaison between coordinators and the complication committee.

Database Manager: mpetcharaporn@ssshsg.org

QA Manager: abartley@ssshsg.org

Complication Data Collection Overview

An HSG Complications Check List has been created with the intent to improve the efficiency and accuracy of our complications data collection. **The Complications Check List should be completed by the surgeon at all post-op time points**. Intra- and peri-operative complications may be captured on the day of discharge or at the 1st erect visit. Any and all post-op complications would be collected at all visits ranging from First Erect (FE) to 25Y. **Please check patient charts at all visits!** Pictured below is the HSG Complications Check List, which lists all complications HSG is interested in capturing and provides space to describe the complication and treatment.



Harms Study Group Complications Check List

Patient Name: **Study ID:** **Visit:** **Date:**

Please check off complications this patient experienced and provide an adequate description, including treatment and status for this visit

Gastrointestinal *Description/Treatment:*
- ☐ Cholecystitis
- ☐ Ileus
- ☐ Pancreatitis
- ☐ SMA
- ☐ Toxic Megacolon
- ☐ Other

Instrumentation *Description/Treatment:*
- ☐ Broken Rod
- ☐ Broken Screw
- ☐ Crosslink Problem
- ☐ Loss of Connection Between Implants
- ☐ Loss of Fixation to Bone
- ☐ Misplaced Instrumentation
- ☐ Prominent Hardware
- ☐ Vertebral Fractures
- ☐ Other

Medical *Description/Treatment:*
- ☐ Cardiac Arrest
- ☐ Death
- ☐ Dural Tear/Leak
- ☐ DVT
- ☐ Hypotension
- ☐ Transfusion Related Complication
- ☐ UTI
- ☐ Other

Pain *Description/Treatment:*
- ☐ Back Pain
- ☐ Chest Wall Pain
- ☐ Other Pain
- ☐ Shoulder Pain

Neurologic *Description/Treatment:*
- ☐ CNS
- ☐ Blindness/Visual Changes
- ☐ Nerve Root
- ☐ Spinal Cord
- ☐ Other

Pulmonary *Description/Treatment:*
- ☐ ARDS
- ☐ Atelectasis
- ☐ Hemothorax/Pneumothorax/Pleural Effusion
- ☐ Pneumonia
- ☐ Pulmonary Edema
- ☐ Pulmonary Embolism
- ☐ Respiratory Failure
- ☐ Unplanned Pleural Invasion
- ☐ Other

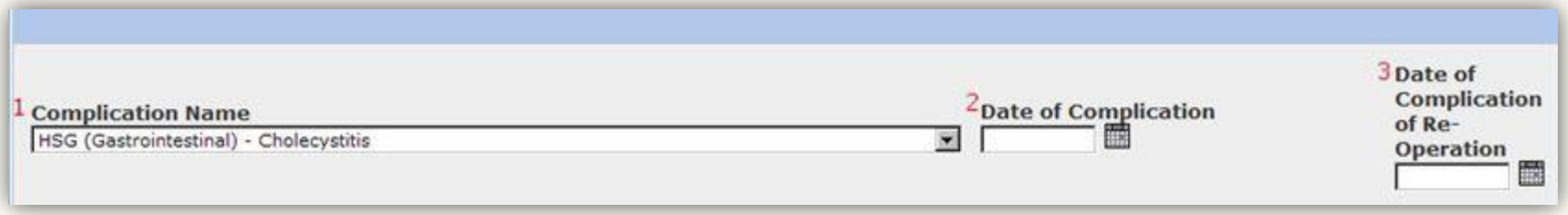
Pseudoarthrosis *Description/Treatment:*
- ☐ Pseudoarthrosis

Wound *Description/Treatment:*
- ☐ Deep Infection
- ☐ Superficial Infection
- ☐ Dehiscence
- ☐ Prolonged Drainage
- ☐ Seroma
- ☐ Significant Scar
- ☐ Other

Re-Operation *Description/Reason:*
- ☐ Re-Operation

The main goal of this check list is to reduce the amount of time spent reviewing charts for complications. **However, if this form is not completed by the surgeon, the coordinator is responsible for gathering complications data from patient charts.** In this instance, the manual will provide information on which complications to gather information on, including definitions, average time frames of occurrence, and possible treatments.

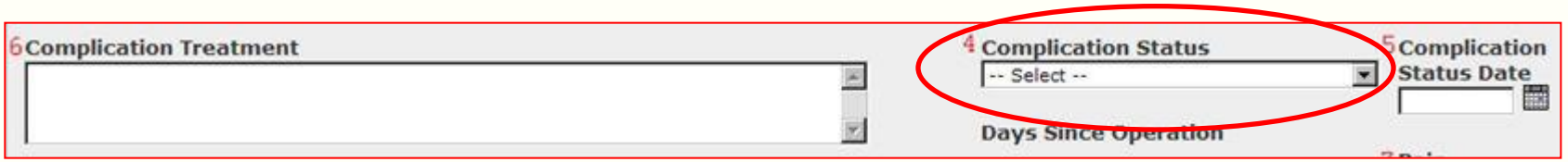
Complications Data Entry



1. **Complication Name**: Please choose an option from the pull-down menu that best fits the patient's complication as described in this manual. The “Other” section is reserved for rare complications and those that are not listed in the manual. Please do not choose “Other” without consulting this manual for the examples given or contacting HSG’s central administrative staff to clarify that this is the right selection.

2. **Date of Complication**: Use the date the complication was reported by the patient. This date should correspond to either the peri-operative or subsequent follow-up visits. Do *not* use the date the complication was entered into the database as the date of complication.

3. **Date of Complication Re-Operation**: This information is required if an additional surgery was performed as a result of a complication related to the patient's spine surgery i.e., a deep infection. **Do not enter the date of any surgeries not related to a complication from the index surgery**. For example, if a patient had a femur fracture surgery after the initial spine fusion, do not enter this data as it is unrelated to the index surgery. If the surgery qualifies as a revision surgery, please also create a new surgery (Rev 1, Rev 2, etc.) under the surgeries tab for that patient and enter the surgical data.



4. **Complication Status**: It is imperative to update the complication status with any changes during the course of follow-up. *If there is no change in the status on subsequent follow-up visits, the complication status will remain the same, but you must update the status date with the most recent visit date and continue to do so until the complication is resolved*. Please choose the correct status as described below:

   • **Reported**: Choose this option if a complication was reported, the patient was not prescribed a treatment, and the complication is not being monitored by the surgeon.

   • **Monitoring**: Choose this option if the complication was reported and is being monitored by the surgeon and has not yet been resolved. Usually this option is chosen if the surgeon would like to see the patient back to follow-up on a specific complication for signs of resolution on its own.

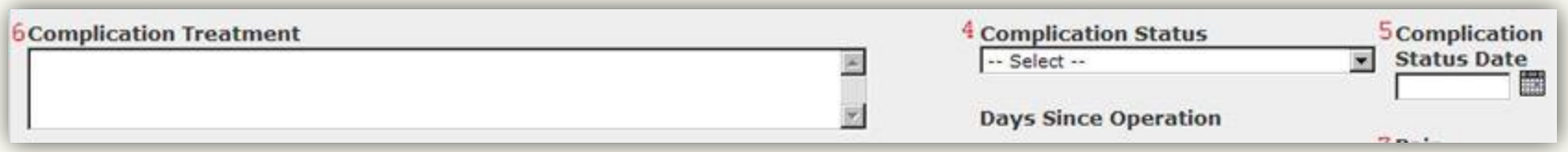
   • **Treatment Prescribed**: Choose this option if a treatment has been prescribed for the complication but the complication has not yet been resolved.

   • **Complication Resolved**: Choose this option if the complication has resolved.

   • **Complication Resolved (Pain Continues)**: Choose this option if the complication has been resolved but the patient still experiences pain. This status should never be used for “pain” complications.

   • **Chronic Condition**: Choose this option if the complication does not resolve and the condition is chronic. This option is best suited for long-term, persistent complications that do not fully resolve over several visits.

   • **Patient Died from this Complication** – Choose this option if the patient died as a result of a complication relating to spine surgery or as a result of the surgery itself.

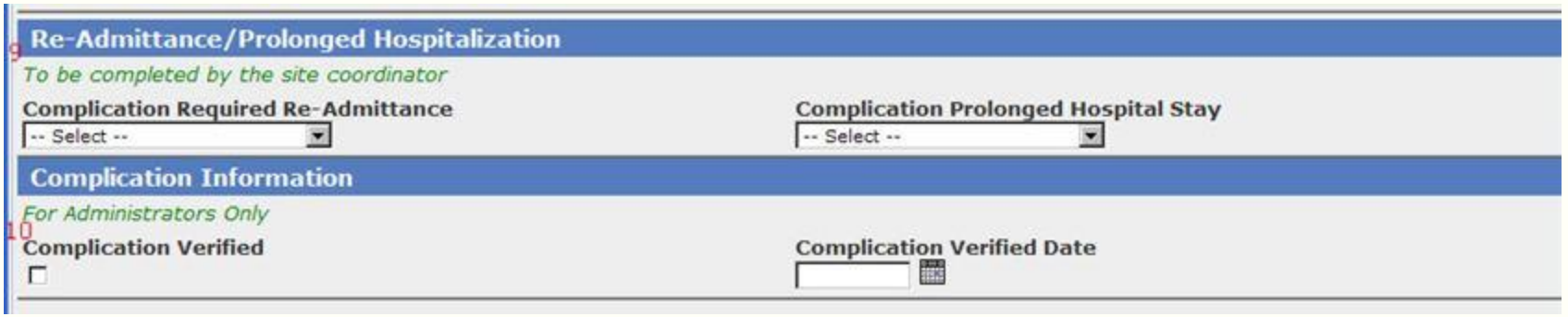


5. Complication Status Date: This is required information. When a status is entered you are prompted to enter a status date. If it is a new complication, enter the date the complication was reported, not the date it is input into the database. If you are updating the complication, changing the status, or confirming that the status is the same, please enter the patient's most recent visit date or the most recent date the clinic staff was informed of the updated status (e.g., phone call from family). If the complication is resolved, enter the date of resolution.

6. Complication Treatment: This section should always be completed & should contain only treatment information. If no treatment has been prescribed, please enter the date followed by "No Treatment." If multiple treatments are prescribed, please list the date followed by full treatment information.

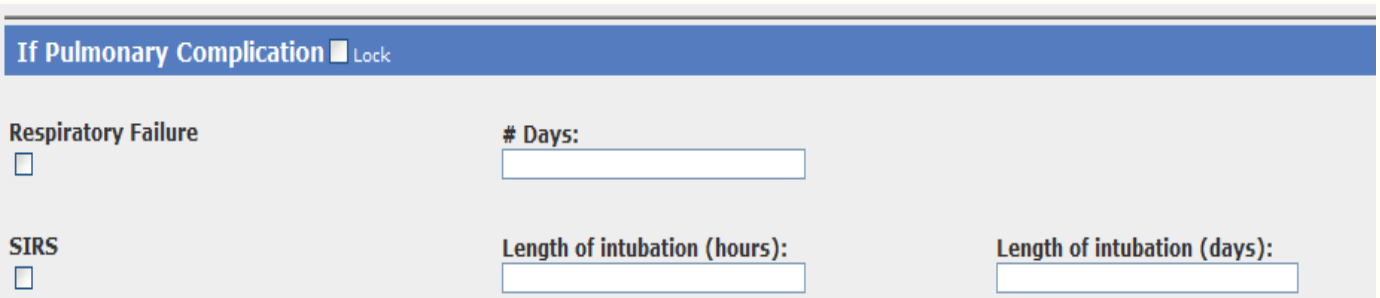
7. Pain Reported at Time of Complication: Check this box if the patient reports pain with the complication.

8. Notes: Please use this section to add necessary information, to further describe the complication, and to include updates during future visits. Always include dates when adding notes!

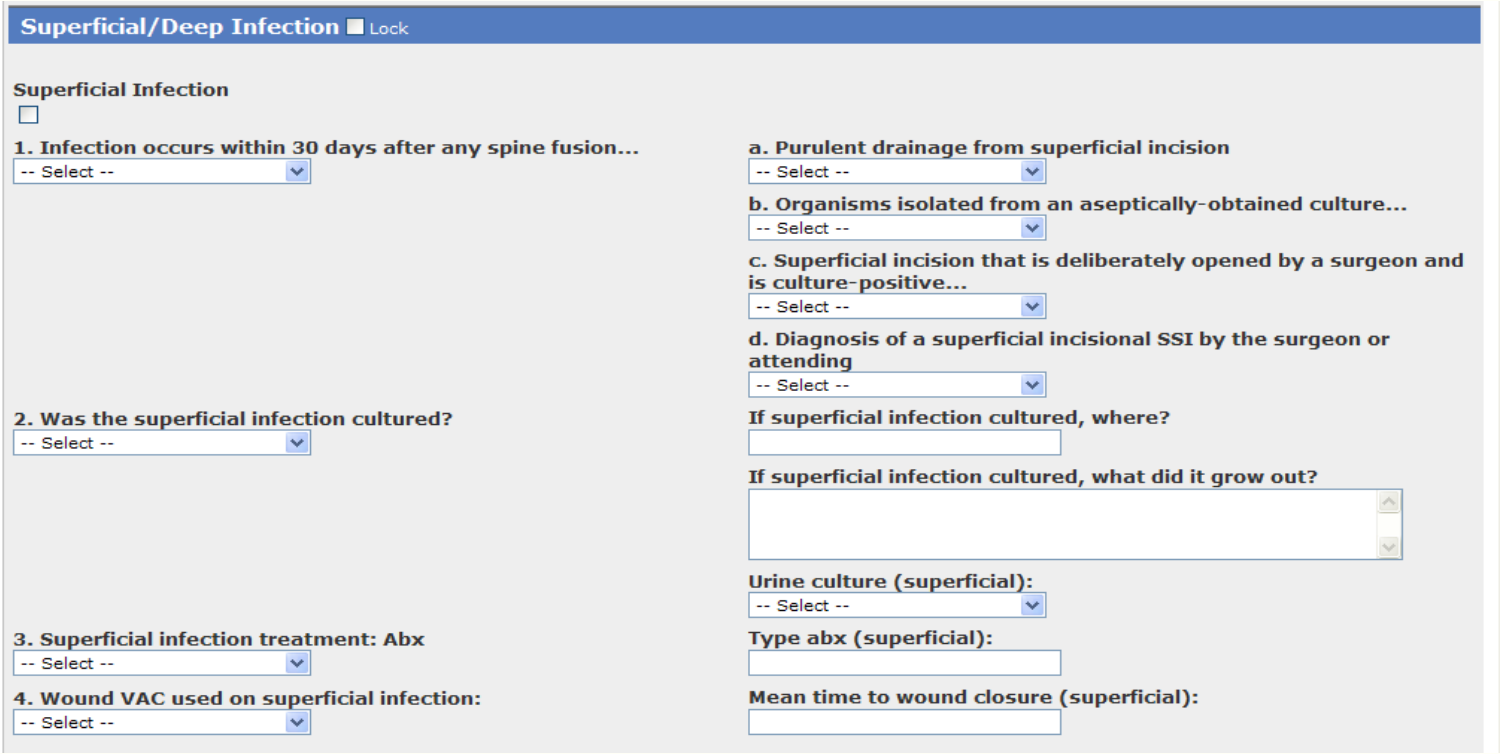


9. **Re-admittance/Prolonged Hospitalization**: This section is to be completed by the site coordinator. The coordinator must specify whether a complication prolonged hospitalization or required admittance to the hospital. The drop-down menu for these fields lists Yes, No, or Unknown. If the complication required either re-admittance or a prolonged hospital stay, select "Yes" from the drop-down menu for the appropriate field. If the complication did NOT require re-admittance or a prolonged stay in the hospital, choose "No." **If you are unsure, ask your surgeon**. If this information cannot be determined, please select "Unknown" from the drop-down menu. Be sure to complete both fields. Do not leave them blank.

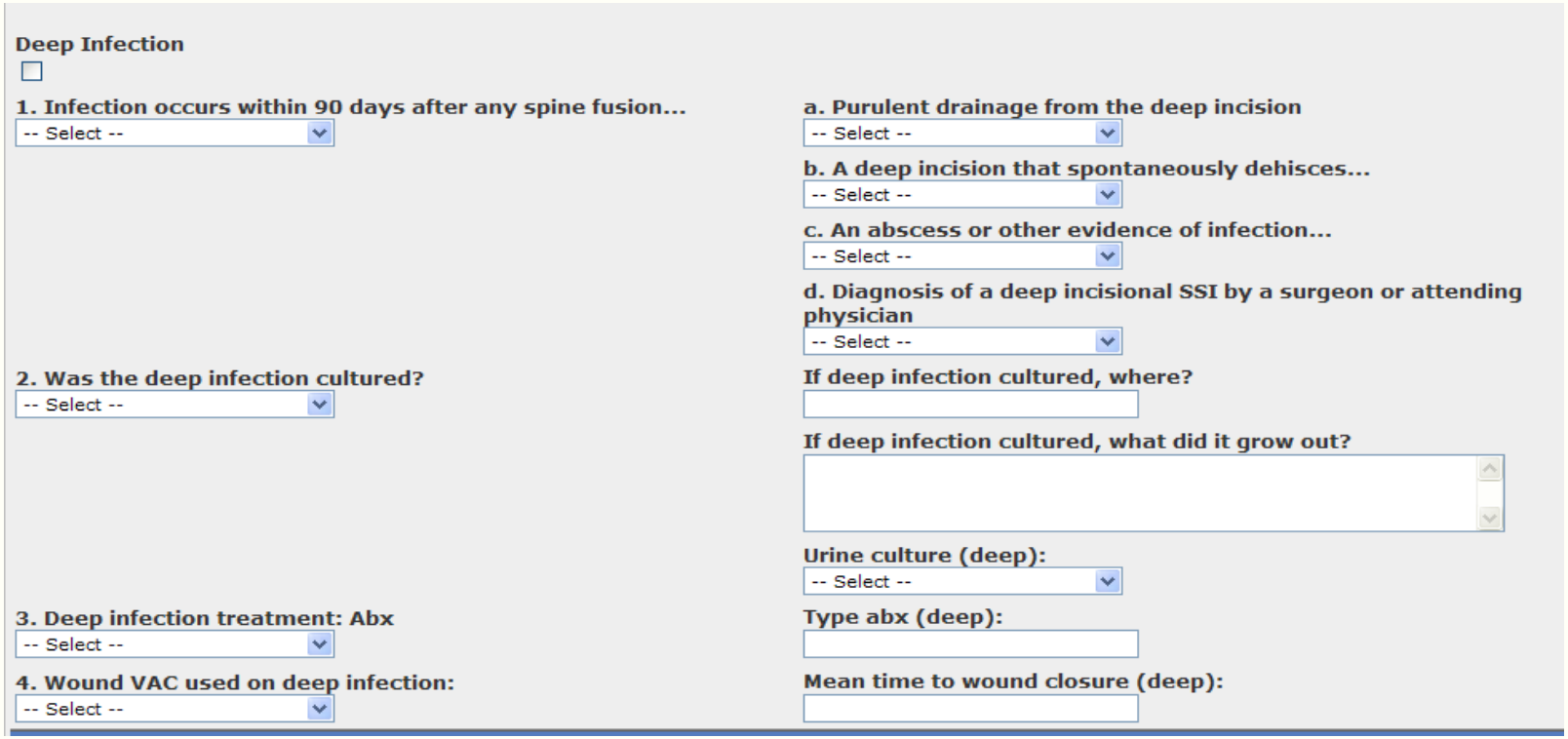
10. **Complication Verified/Date**: This section is to be completed by HSG administrators only, upon verification of complication data. Please do not enter any information in this section.



Pulmonary Complications: Check the appropriate box if Respiratory Failure or SIRS occurred, and indicate the number of days, length of intubation in hours, and length of intubation in days.



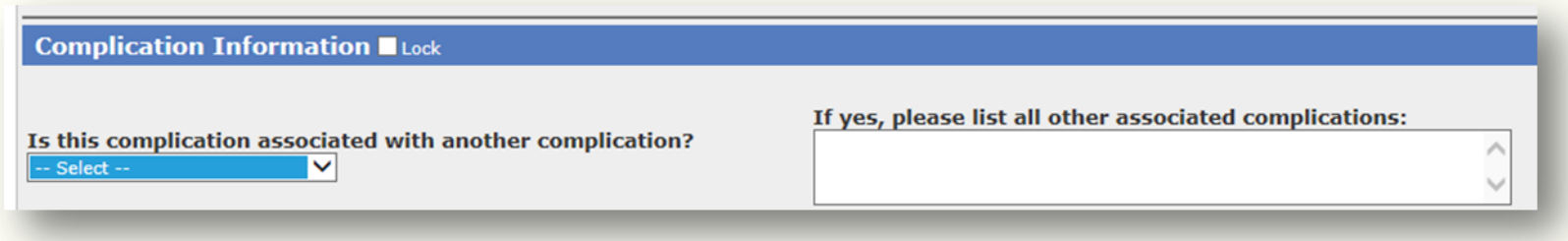
- **Superficial Infection:** check the appropriate box if superficial infection occurred.
- Select from the pull-down menu as to whether the infection occurred **within 30 days after any spinal fusion**, if purulent drainage from superficial incision occurred, if organisms were isolated from an aseptically obtained culture from fluid or tissue or diagnosed by surgeon (must have at least one of these to be SSI).
- Indicate if the superficial infection was cultured, where within the infection site the culture was done, and what grew out of it.
- Indicate if a urine culture was done.
- Indicate if antibiotics (“abx”) were used as treatment and what type of antibiotics were used.
- Select from the pull-down menu if a wound VAC was used.
- Indicate the mean time to wound closure in minutes.



- **Deep Infection:** check the appropriate box if deep infection occurred.
- Select from the pull-down menu as to whether the infection occurred within 90 days after any spinal fusion, if purulent drainage from deep incision occurred, if spontaneously dehisces occurred, an abscess or other evidence of infection occurred, or a diagnosis of a deep incisional SSI by a surgeon or attending physician.
- Indicate if the deep infection was cultured, where within the infection site the culture was done, and what grew out of it.
- Indicate if a urine culture was done.
- Indicate if antibiotics were used as treatment and what type of antibiotics were used.
- Select from the pull-down menu if a wound VAC was used.
- Indicate the mean time to wound closure in minutes.

General Guidelines for Complication Data Collection

- **Related/Associated Complications:**
  - If a patient experiences multiple complications that are related (i.e., broken rods and pseudarthrosis, or bladder retention and UTI) be sure to **report all complications separately and link them by selecting that the complication has other associated complications**. List which complications are associated in the text box.



If you are unsure if complications should be entered or are associated, and if you have an other complication questions, please contact the QA Manager or Database Manager. Either will be glad to help!

General Guidelines Continued

What not to report

1. HSG is NOT interested in capturing the following complications:
   - Anything related to a normal recovery from spine surgery, including, but not limited to:
     - » Back pain within 6 weeks post-op, unless noted as abnormal by the surgeon
     - » Any pain, numbness, or swelling near incisions
     - » Pain or difficulty with walking within 6 weeks post-op timeframe
     - » Normal peri-op course may include pain, fever (if not due to infection), post-op anemia and side effects from pain meds which may include poor PO intake, constipation within the first week of surgery, and narcotic related respiratory depression. We would only want to capture these if they require a major treatment or prolong the hospital stay.
   - Any pre-existing condition or symptoms related to a pre-existing condition should not be included. This applies to conditions that could be complications but are not since they existed in the patient prior to the surgery. Similarly, HSG does not want to capture any subsequent surgeries that are unrelated to the index spine fusion surgery.
   - A complication resulting from an injury or accident that does not affect patient outcome should not be included (i.e., a sport-related injury that elicits back pain but resolves on its own). We DO want to collect any complications resulting from accidents or injuries that require treatment and may affect long-term outcome.

2. All complications will be categorized as either major or minor. Coordinators do not determine major and minor classification but may find this information useful. Minor complications may become major complications if they:

   Prolong hospitalization by more than two days
   Require re-admittance
   Require a surgical intervention

Complication Categories

Death Complication

- **Death**

  Definition: Patient death, either from surgery or otherwise

  Time Frame: Any, intra-or post-op

  Classification: Major

All patient deaths must be reported to your institution's IRB!

Please **record all patient deaths in the database**, not just those directly related to the surgery. Please include cause of death in the note section. It is critical to note whether the death was related to the surgery or not. If the cause is unknown or you are unable to provide specific information, please note this and why you are unable to provide the information (e.g., family withdrew consent).

Gastrointestinal Complications

Most gastrointestinal complications will be minor. Major gastrointestinal complications will require more than two days prolonged hospitalization, re-admittance, or surgery.

- **Cholecystitis** (Minor)
  - **Definition**: Inflammation of the gallbladder which may occur after major surgery
  - **Time Frame**: Up to 1 month post-op
- **Typical Treatments**: Hospitalization, bowel rest, surgery if necessary

- **Bowel Constipation** (Minor)
  - Definition: inability to have a bowel movement
  - Time Frame: no bowel movement after a week
  - Typical Treatments: stool softener, laxatives, fluids, fiber

- **Ileus** (Minor)
  - **Definition**: Gastroparesis, slow to recover bowel function
  - **Time Frame**: Up to 1 month post-op
  - **Typical Treatments**: Hospitalization, bowel rest, TPN

- **Pancreatitis** (Minor)
  - **Definition**: Inflammation of the pancreas which may occur after surgery
  - **Time Frame**: Up to 1 month post-op
  - **Typical Treatments**: Hospitalization, bowel rest, TPN

Gastrointestinal Continued

- **SMA (Superior Mesenteric Artery) Syndrome** (Minor)

  Definition: A rare complication resulting from compression of the duodenum by the abdominal aorta and the superior mesenteric artery in which the patient suffers nausea, vomiting, and pain

  Time Frame: Up to 1 month post-op

  Typical Treatments: NG tube, TPN

- **Toxic Megacolon** (Major)

  Definition: Complication of other intestinal conditions that causes dilation of part of the large intestine

  Time Frame: Up to 1 month post-op

  Typical Treatments: Hospitalization, surgery

- **Other**

  Definition: Any gastrointestinal complication not listed separately

  Time Frame: Up to 1 month post-op

  Typical Treatments: Treatment depends on complication

Instrumentation Complications

Most instrumentation complications are considered minor unless they prolong hospitalization by more than two days, require re-admittance or require another surgery. Many instrumentation complications are associated with neurologic complications. If this is the case, please enter both the neurologic and instrumentation complications separately and note that they are associated (as described on slide 10).

- **Broken Rod** (Minor)
  Definition: A rod break post-operatively
  Time Frame: Any, post-op
  Typical Treatments: Observation, surgery if necessary

- **Broken Screw** (Minor)
  Definition: Screw break post-operatively
  Time Frame: Any, post-op
  Typical Treatments: Observation, surgery if necessary

- **Crosslink Problem** (Minor)
  Definition: Crosslink causing symptoms such as pain
  Time Frame: Any, post-op
  Typical Treatments: Observation, surgery if necessary

- **Loss of Connection Between Implants** (Minor)
  Definition: Rod pulling away from screw, hook, etc.
  Time Frame: Any, post-op
  Typical Treatments: Observation, surgery if necessary

- **Loss of Fixation to Bone** (Minor)
  Definition: Screw, hook, or wire dislodged or loose from bone
  Time Frame: Any, post-op
  Typical Treatments: Observation, surgery if necessary

Instrumentation Complications, cont.

- **Misplaced Instrumentation** (Minor)

  Definition: Screws, hooks, and wires misplaced during surgery (This complication refers to misplaced instrumentation remaining in place after closure. This does not include screws removed/replaced during the index surgery as a result of an EMG trigger without further complications.)

  Time Frame: Any, post-op

  Typical Treatments: Observation, surgery if necessary

- **Prominent Hardware** (Minor)

  Definition: Prominent hardware which may cause symptoms such as pain or bursitis (may also be noted as skin breakdown over hardware)

  Time Frame: Any, post-op

  Typical Treatments: Observation, surgery if necessary

- **Vertebral Fractures** (Major)

  Definition: Any unintentional fracture of bone

  Time Frame: Any, intra- and post-op

  Typical Treatments: Observation, surgery if necessary

- **Other**

  Definition: Any instrumentation complication not listed separately

  Time Frame: Any, post-op

  Typical Treatments: Dependent on complication

Medical Complications

Anaphylactic Reaction (Major)

Definition: an extreme allergic reaction

Time Frame: up to one month post-op (?)

Treatment: epinephrine injection, CPR, IV fluids, antihistamine/steroids

- **Cardiac Arrest /Myocardial Infarction (MI)** (Major)

  Definition: The cessation of normal blood circulation caused by the heart failing to contract effectively

  Time Frame: Any, intra- or post-op

  Typical Treatments: As required

- **Dural Tear/Leak** (may also be called “CSF leak”) (Minor)

  Definition: A tear in the covering of the spinal cord (dura mater) which results in spinal fluid leakage (Patients may experience postural headaches upon standing if the tear is not repaired during surgery.)

  Time Frame: Occurs intra-operatively; if unnoticed during surgery, post-operative symptoms may occur

  Typical Treatments: Repair of tear, bed rest, lumbar drain

- **DVT (Deep Vein Thrombosis)** (Major)

  Definition: A blood clot formed in a deep vein, such as those found in the pelvis or legs

  Time Frame: Up to 3 months post-op

  Typical Treatments: Anticoagulants

Medical Complications, cont.

- **Extensive Blood Loss** (Minor)
  Definition: This will vary depending upon surgeons, amount of levels fused, patient, etc. w/ numbers ranging from 1500—2000 ml lost being noteworthy
  Time Frame: during surgery
  Typical Treatments: transfusion

- **Extremity Fracture** (Minor unless requires cast/other treatment)
  Definition: breaking of bone
  Time Frame: during surgery
  Typical Treatments: rest, splint, cast

- **Hypotension** (Major)
  Definition: Decreased blood pressure that requires pressure support/ICU
  Time Frame: Post-Op
  Typical Treatments: Electrolytes, blood transfusion, none

- **Pressure Ulcers/Skin Problems** (Minor)
  Definition: sores due to interference with circulation
  Time Frame: up to 30 days post-op
  Typical Treatments: varies

Medical Complications, cont.

- **UTI (Urinary Tract Infection)** (Minor)

  Definition: Bacterial infection of the urinary tract

  Time Frame: Post-Op (w/in 30 days)

  Typical Treatments: Antibiotics

- **Other**

  Definition: Any medical complication not listed separately (e.g., SIADH, Vocal Cord Paresis)

  Time Frame: Any, post-op

  Typical Treatments: As required for complication

Neurologic Complications

Please note: Neurologic complications need to be documented in great detail. It is imperative that you clarify whether the complication occurs intra or post-op, the duration of the complication (whether it was immediately correctable or needed its own recovery), and ensure detailed treatment information is provided for both intra-op and post-op! All neurologic complications should be followed for a minimum of one year from the time they are reported, even after resolved, with updates noted at each visit as these are very critical complications.

Reminder: A neuromonitoring change intra-op is not a complication. A physical deficit post-op is.

- **Bladder Incontinence** (Minor)
  - **Definition:** involuntary urination, leakage
  - **Time Frame:** any time post-op
  - **Treatment:** myelography, bed rest, steroids, bladder strengthening therapy, surgery

- **Bladder Retention** (Minor)
  - **Definition:** inability to empty bladder completely (acute/short duration—cannot urinate at all; chronic—long lasting condition)
  - **Time Frame**: any time post-op
  - **Treatment:** bladder drainage, urethral dilation/stint

- **Bowel Incontinence** (Minor)
  - **Definition**: inability to control bowel movement
  - **Time Frame:** any time after surgery
  - **Treatment**: medication, sacral nerve stimulation, surgery

Neurologic Complications, cont.

- **Blindness/Visual Changes** (Major)

  Definition: Any changes in vision or blindness as a result of spine surgery

  Time Frame: Any, post-op

  Typical Treatments: Complication-specific medical management

- **Nerve Root Complications** (Major)

  Definition: Complications originating from the nerve root not related to a spinal cord injury

  Examples include:

  Femoral Cutaneous Neuralgia
  Radiculopathy
  Post- Thoracotomy Syndrome
  Altered Sensation (numbness, hypersensitivity, etc.)
  Foot Drop
  Brachial Plexus injury.

  Be sure to report the nerve root complication type and location in the Notes section in the database (i.e., Patient experiences numbness in right hand.)

  Time Frame: Any, post-op

  Typical Treatments: Complication-specific medical management

- **Spinal Cord Complications** (Major)

  Definition: Any complication relating to a spinal cord injury (Intra-op indication of potential Spinal Cord Injury (SCI) could include a decrease in SSEP/MEP neuromonitoring.) Be sure to list relevant information in the Notes section in the database.

  Time Frame: Any, intra- and post-op

  Typical Treatments: Complication-specific medical management

- **Other** (Please include all available details for "other" complications)

  Definition: Any neurologic complication not listed separately.

  Time Frame: Any, post-op

  Typical Treatments: Complication-specific medical management

Pain Complications

Be sure to include details of pain (location, type, & intensity) in notes section!

- **Back Pain** (Minor)
  Definition: Any pain located on the back
  Time Frame: Any, but please note immediate post-op pain is expected in the first 6 weeks
  Typical Treatments: Observation, PT, NSAIDs or other pain meds

- **Chest Wall Pain** (Minor)
  Definition: Any pain located in the chest or ribs (i.e., costochondritis)
  Time Frame: Any, post-op
  Typical Treatments: Observation

- **Shoulder Pain** (Minor)
  Definition: Pain and discomfort in the shoulders
  Time Frame: Any, post-op
  Typical Treatments: Observation, PT, pain meds

- **Other Pain** (Minor)
  Definition: Pain located in regions other than back, chest, and shoulder
  Time Frame: Any, post-op
  Typical Treatments: Observation, PT, pain meds

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Pulmonary Complications

Pulmonary complications should not be captured unless a treatment is administered. All pulmonary complications need to require a prolonged hospitalization of at least 48 hours & a medical intervention. Oxygen and incentive spirometry are not adequate treatments to justify capturing the aforementioned as complications.

There are several pulmonary complications that may occur in a single patient that are related. Please report each complication as its own complication, check the associated complications box and list which complications are related.

If respiratory failure occurs, please indicate the number of days treatment was needed. If SIRS occurs, please note the length of intubation in hours/days.

- **ARDS (Acute Respiratory Distress Syndrome)** (Major)
  - **Definition**: A severe lung disease which may occur after major surgery, characterized by inflammation of the lungs leading to hypoxemia (decreased oxygen in the blood) and potentially multiple organ failure
  - **Time Frame**: Post-Op
  - **Typical Treatments**: ICU admittance, ventilation

- **Hemothorax/Pneumothorax/Pleural Effusion/Edema** (Minor)
  - **Definition**: Hemothorax is blood in the pleural cavity; Pneumothorax is air or gas in the pleural cavity; Pleural Effusion is fluid in the pleural cavity; edema is fluid in the lungs
  - **Time Frame**: Post-Op
  - **Typical Treatments**: Chest PT, chest tube insertion (be sure to record thoracentisis or bronchotomy)

- **Pneumonia** (Minor)
  - **Definition**: Lung infection; inflammation and fluid accumulation in the lungs
  - **Time Frame**: Post-Op, one month
  - **Typical Treatments**: Antibiotics

- **Pneumothorax Requiring Chest Tube** (Major)
  - **Definition:** collapsed lung requiring insertion of a chest tube
  - **Time Frame:** during surgery; post-op
  - **Typical Treatments:** insertion of chest tube, surgery

Pulmonary Complications, cont.

- **Pulmonary Embolism (PE)** (Major)

  Definition: This occurs when a deep vein thrombus (blood clot) travels to the pulmonary artery of the lungs

  Time Frame: Post-Op , one month

  Typical Treatments: Anti-coagulants, surgical intervention if necessary

- **Respiratory Failure** (Major)

  Definition: Inadequate gas exchange in the lungs; inability to maintain normal ranges of oxygen and carbon dioxide in the blood

  Time Frame: Post-Op, one month

  Typical Treatments: Intubation, ventilation

SIRS (Major)

Definition: Systematic inflammatory response syndrome defined by the presence of two of the following: core temperature >101.3 deg F or <96.8 deg F; 101.3 deg F or <96.8 deg F; mean respiratory rate >18 breaths/min in ages 6-12yrs and >14 breaths/min in ages 13-18yrs, or mechanical ventilation; leukocyte count elevated or depressed to >13.5 or <4.5 for ages 6-12yrs and >11 or <4.5 for ages 12-18yrs

Time Frame: post-op

Fluids: fluids, IV, surgery

- **Unplanned Pleural Invasion** (Minor)

  Definition: This occurs when the surgeon unintentionally invades the pleural cavity during surgery

  Time Frame: Intra-Op

  Typical Treatments: Insertion of a chest tube

- **Other**

  Definition: Any pulmonary complication not listed separately (i.e., Chest Tube Break)

  Time Frame: Post-Op

  Typical Treatments: As required for complication

Pseudarthrosis

(Major)

- **Definition**: Also known as a non-union; refers to a failed spinal fusion where the segments of vertebral bone do not merge over the disc space
  - If it is noted that the patient has both a broken rod and pseudarthrosis, please report ***both*** pseudarthrosis and the broken rod as separate but associated complications.
  - A subsequent surgery to repair pseudarthrosis is considered a *revision surgery* and must be entered into the database as outlined on the following slide.
- **Time Frame**: Any time after the fusion should be complete (about 1 year)
- **Typical Treatments**: Observation, surgery if necessary

Re-Operation/Revision Surgery

Please note that many complications listed in the other sections of this manual can have a re-operation associated with them. The three listed here are examples of specific radiographic complications that are not captured separately, but may be the cause of a re-operation. Only select Re-Operation as a complication if the patient had a re-operation for a complication that is NOT listed under a separate category. When entering a Re-Operation complication, please list the reason for the re-operation under the Notes section in the database.

If the patient has a **revision surgery**, defined as revising or correcting the original instrumentation or surgery, please create a new surgery under the Surgeries tab for that patient. The surgery will be named "Rev 1" for the first revision ("Rev 2" and so on for subsequent revisions), and the coordinator will be responsible for entering the surgical data for the revision surgery. Subsequent surgeries that repair pseudarthrosis or lengthen the instrumentation levels, such as for adding-on, are considered revision surgeries. Enter the complication as usual, and make a note in the Notes section to see additional details under Rev 1 surgery information. Please notify HSG staff when new surgeries are entered.

Re-operations that **do not** qualify as revision surgeries are:

Broken chest tube
I & D
Thoracoplasty
Misplaced instrumentation/Exchange of hardware but no change in levels

The following are example reasons for re-operation and should be documented in the notes section:

- **Adding On/Curve Progression** (Major)
  Definition: Curve added on a level in measurements, or curve magnitude increased enough to require surgery
  Time Frame: Any, post-op

- **Crankshaft** (Major)
  Definition: This occurs when the spine is fused posteriorly yet continues to grow anteriorly, causing progression of the curve
  Time Frame: Any, post-op

- **Progression of Uninstrumented Curve** (Major)
  Definition: The un-instrumented curve has increased enough to require surgery
  Time Frame: Any, post-op

Surgical Site/Incision Complications

There are several complications that occur at the surgical site that may be related. Please remember to enter each complication separately, select that they are related complications, and then list each related complication.

HSG wants to record all infections, whether they be prior to or past 90 days post-op.
Please be sure to enter all culture and antibiotic information for infections.

- **Deep Infection** (Major)

  Definition: An infection involving deep soft tissues of the incision (fascial and muscle layers) which includes one of the following: purulent drainage from the incision, an incision that spontaneously dehisces or is deliberately opened by the surgeon and is culture positive or if not culture positive patient has fever, pain or localized tenderness, an abscess or other evidence of infection found via examination or is diagnosed by a surgeon/attending physician at any point in time after the operation

  Time frame: any point in time following operation

  Typical Treatments: Antibiotics, I&D (This may be performed in office or in the OR. Please note which it is. If in the OR be sure to enter a re-op date.), hardware removal

- **Superficial Infection** (Minor)

  Definition: An infection involving only skin and subcutaneous tissue which will include one of the following: purulent drainage from incision, isolated organisms from culture of fluid or tissue from the incision, a deliberate opening of incision by surgeon and culture positive or not culture positive but patient has pain/tenderness, localized swelling, redness or heat. A surgeon/attending physician can also diagnose a superficial infection.

  Time Frame: Infection occurs within 30 days of the operative procedure

  Typical Treatments: I&D (This may be performed in office or in the OR. Please note which it is. If in the OR be sure to enter a re-op date.), topical or oral antibiotics

Surgical Site/Incision Complications, cont.

Infection Data- Patient had a Superficial or Deep Infection: ☐Yes ☐No

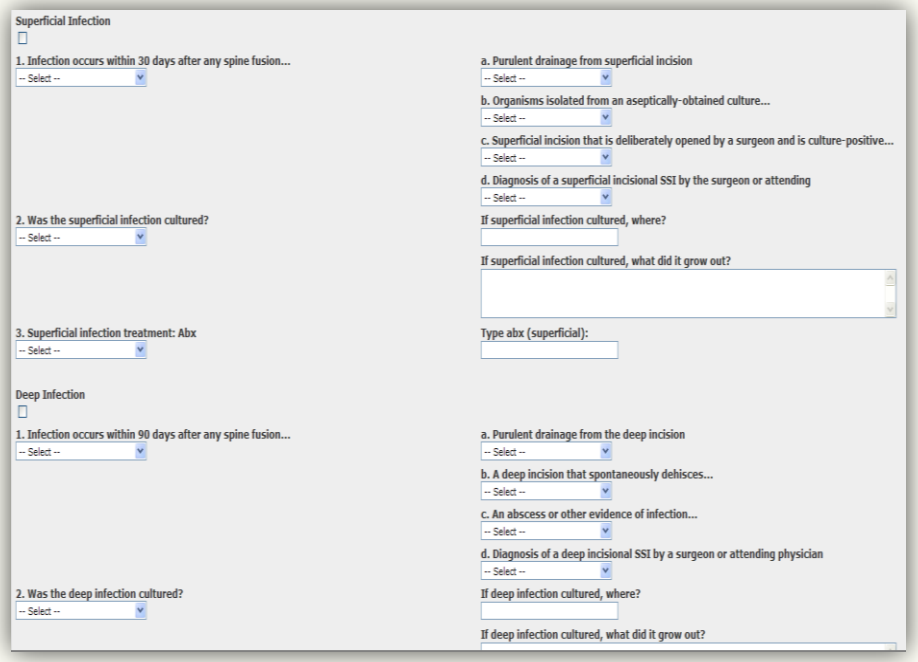
Superficial Infection

1. Infection occurs within 30 days after any spine fusion and involves only skin and subcutaneous tissue of the incision ☐Yes ☐No and patient has at least one of the following:
   a. Purulent drainage from the superficial incision. ☐Yes ☐No
   b. Organisms isolated from an aseptically-obtained culture of fluid or tissue from the superficial incision. ☐Yes ☐No
   c. Superficial incision that is deliberately opened by a surgeon and is culture-positive or not cultured and patient has at least one of the following signs or symptoms: pain or tenderness; localized swelling; redness; or heat. A culture negative finding does not meet this criterion. ☐Yes ☐No
   d. Diagnosis of a superficial incisional SSI by the surgeon or attending. ☐Yes ☐No
2. Was the infection Cultured? ☐Yes ☐No
   If Yes, where?
   If Yes, what did it grow out?
3. Treatment: Abx: ☐Yes ☐No
   Type:_____

Deep Infection

1. Infection occurs within 90 days after any spine fusion and involves deep soft tissues of the incision (e.g., fascial and muscle layers) ☐Yes ☐No and patient has at least one of the following:
   a. Purulent drainage from the deep incision. ☐Yes ☐No
   b. A deep incision that spontaneously dehisces or is deliberately opened by a surgeon and is culture-positive or not cultured and patient has at least one of the following signs or symptoms: fever(>38°C); localized pain or tenderness. A culture-negative finding does not meet this criterion. ☐Yes ☐No
   c. An abscess or other evidence of infection involving the deep incision that is found on direct examination, during invasive procedure, or by histopathologic examination or imaging test. ☐Yes ☐No
   d. Diagnosis of a deep incisional SSI by a surgeon or attending physician. ☐Yes ☐No
2. Was the infection Cultured? ☐Yes ☐No
   If Yes, where?
   If Yes, what did it grow out?
3. Treatment: Abx: ☐Yes ☐No
   Type:_____

- Per the requirements from the CDC, if the patient has a superficial or deep infection please fill out the following section in the case report form and enter the data into the “Superficial/Deep Infection” section under the complication’s “General Information” tab in the database.



Surgical Site/Incision Complications, cont.

- **Dehiscence** (Minor)
  Definition: Wound reopens, ruptures on own (not opened by surgeon)
  Time Frame: Post-Op during healing of incision
  Typical Treatments: Dressing changes, surgery if necessary

- **Prolonged Drainage** (Minor)
  Definition: Prolonged drainage from wound
  Time Frame: Post-Op, past 7 days
  Typical Treatments: Antibiotics, hospitalization, surgery if necessary

- **Seroma** (Minor)
  Definition: A pocket of clear serous fluid that sometimes develops in the body after surgery
  Time Frame: Post-Op
  Typical Treatments: Observation, draining of the fluid

- **Other**
  Definition: Any wound complication not listed separately
  Time Frame: Post-Op
  Typical Treatments: As necessary for complication

Transfusion Complications

- **Reaction** (Minor)
  - **Definition:** allergic response (hives, itching, difficulty breathing, low blood pressure, nausea)
  - **Time Frame:** during transfusion or very soon after
  - **Treatment:** antihistamines, oxygen support, etc.

- **Other** (varies)
  - **Acquired Illness**
    - **Definition:** a transfusion related infection from a virus
    - **Time Frame:** weeks to months after surgery
    - **Treatment:** varies depending upon illness
  - **Fever**
    - **Definition:** high temperature, chills, shaking
    - **Time Frame:** during, right after transfusion
    - **Treatment:** cessation of transfusion
  - **Acute Immune Hemolytic Reaction**
    - **Definition:** immune system attacks new red blood cells
    - **Time Frame:** during, immediately after transfusion
    - **Treatment:** cessation of transfusion, acetaminophen, IV fluids
  - **TRALI (transfusion related acute lung injury)**
    - **Definition:** lungs damaged, difficulty breathing
    - **Time Frame:** 1—6 hours after transfusion
    - **Treatment:** oxygen, mechanical ventilation, ICU