



# **Guidelines for Validation of Selected AHRQ Quality Indicators**

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## **PSI 5: Foreign Body Left in During Procedure**



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of  
Selected AHRQ Quality Indicators  
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## Getting started

Prior to starting data abstraction, familiarize yourself with the medical record, pertinent health information policies and procedures specific for your medical center, as well as the specific Patient Safety Indicator (PSI) abstraction guideline and instrument.

Review the “Getting Started” document (AHRQ\_Pilot\_Getting\_Started.doc).

The abstraction Instrument is provided as Appendix A of this document.

## General Instructions for Completing the AHRQ Study Record

**Please complete all data fields:** All data fields must be completed to enable submission of a Patient Record to the AHRQ Patient Safety Indicator (PSI) Database. If you do not have the information for a given field, check the “Not Documented” box. Except as noted, avoid leaving any questions blank. Most questions that relate to specific findings or data elements default to “no” if left unchecked.

We assume that if a finding is not documented in the medical records that it does not occur. Questions that relate to specific times, physical findings or laboratory values generally can be answered with “9”, “99”, “999”, “99:99” etc., if the necessary information is missing or un-interpretable. If you believe that a question should be answered in this manner, but the computer entry system does not allow for it, contact your supervisor.

Use leading “zeros” to complete a number string **EXCEPT** for DRG and/or procedure codes. For example, if given a double digit entry and the number of events to be entered is less than 10, precede the entry with a zero (e.g., 07 for 7). ENTER all DRG and procedure codes as written with careful consideration of the decimal point. Do not right or left margin adjust and do not add any additional digits including ‘zeros’. For example, 38.9 should be entered as [ \_ 3 8.9 \_ ].

**Date/time:** All dates are recorded in the [MM/DD/YYYY] format. All times are recorded using a 24-hour clock (or military time) [ \_ \_ : \_ \_ ]. To convert clock time to military time, with the exception of midnight and noon, add 12 to any time after noon. For estimating time, use time anchors such as important events, television shows or other references to narrow the time window.

**Information sources:** All information entered into the database must be gleaned from the medical record. Many hospitals are in the process of converting from paper to an electronic medical record (EMR or eMR). It is acceptable to use a combination of sources, as long as the record retrieved was

an approved component of the record system at the time care was rendered. It is permissible to obtain missing reports. For example, if the patient had a MRI but the final MRI report is missing. It is acceptable to access the report on-line or to obtain a copy from the radiology department. Electronic generated reports used for diagnoses should contain an electronic signature.

**Conflicting information:** For conflicting information in the record, document the finding of the most senior member of the patient care team. The hierarchy from most senior to junior is as follows:

- Primary, attending or consulting physician
- Chief or senior resident (e.g., generally 3<sup>rd</sup> or 4<sup>th</sup> year or higher depending on specialty)
- Junior resident (e.g. 2<sup>nd</sup> year or PG2)
- Intern (e.g., 1st year or PG1)
- Medical student (with MD signature)
- Physician extender [physician assistant (PA), Nurse Practitioner (NP), mid-wife, or advanced practice RN [clinical nurse specialists (CNS), certified registered nurse anesthetists (CRNA) or other]
- PA student or NP student (with physician signature)
- RN (registered nurse with or without further certifications regardless of level of entry into practice such as ASN, BSN, MSN, etc).
- Other licensed and applied healthcare professionals such as a licensed practical nurse (LPN), vocational nurse (LVN) nurse, physical therapist (PT), dietician, etc.
- Unlicensed assistive personnel (e.g., physical therapy aid, nutritional aid, laboratory assistant, nursing assistant or nursing aid).

Notes completed by students should not be used for review unless cosigned by a physician or other appropriate level staff. Medical student notes are often labeled MS3, MSIII, MS4, MSIV, or AI (acting intern). Residents notes may be labeled as R4, R3, R2, R1 or RPN” (for resident progress note with the corresponding year of training), PG4, PG3 etc., or PGY4, PGY3 respectively (for postgraduate year ); or HO3, HO4, etc. (for house officer followed by the training year). The more senior resident in a leadership role may use the title “chief resident”.

Several types of inconsistencies may occur in the medical record. Except as described in subsequent sections, inconsistencies should be resolved as follows:

- a. If two notes are directly contradictory (e.g., one physician describes the patient’s medical problem as stable but another specially states unstable), record the findings of the more senior person. If the contradictory notes are written by individuals at the same level (e.g., two attending physicians), record the findings of the person with more specialized

- knowledge and expertise in the specific area (e.g. a surgeon for surgical findings and an internist or cardiologist for cardiopulmonary findings).
- b. If two notes are inconsistent but not directly contradictory (e.g., one physician reports “an accidental laceration of the bladder”, but another “does not report that any accidental laceration occurred”, record the findings of the more senior person. If the inconsistent notes are written by individuals at the same level (e.g., two attending physicians) look for other evidence in the chart (e.g. nursing, laboratory or radiology notes) that corroborates the more specific or serious finding. If such evidence cannot be found, record the findings of the person with more specialized knowledge and expertise.
  - c. If two notes are inconsistent due to omission of relevant information (e.g. one physician states “deep vein thrombosis ” but another does not mention deep vein thrombosis), the note that provides the most specific information relative to that data element should always be used (regardless of seniority).

**Data verification:** Each page of the medical record should contain at least two unique patient identifiers (e.g., medical record number, patient name, date of birth, etc.). While abstracting data, please confirm that each page of the medical record is for the index patient and associated hospital admission. It is not uncommon for portions of the record to be misfiled.

### Case Ascertainment

**Patients included in the AHRQ PI validation database:** This is a retrospective chart review based on a computer randomized sample (without replacement) generated from administrative data. This sample includes patients discharged within the last 12-24 months. Data collection should occur between March 2008 and May 2008. Each hospital participating in the AHRQ PSI Validation Project will receive a computer generated list of patients for data abstraction. This list is subsequently referred to as the sampling list. The sampling list will contain an AHRQ unique patient identification code number as well as the medical record or patient control number to be used for chart identification.

It is extremely important that you include only patients listed on your sampling list. Do not substitute a patient with a like diagnosis. Patients selected for this validation project were sampled based on the following inclusion and exclusion criteria.

### Inclusion criteria

Selected patients should have ALL of the following criteria (denominator):

- A surgical or medical discharge diagnosis (see appendix B and F respectively in the AHRQ Technical Guidelines) **OR** MDC 14 (pregnancy, childbirth, and puerperium) as defined by specific DRGs.
- Be 18 years of age or older

In addition, they should have an ICD-9-CM related code for a foreign body accidentally left in during a procedure. These codes are as follows:

9984 A foreign body accidentally left during a procedure

9987 An acute reactions to a foreign substance accidentally left during a procedure

These codes include adhesions due to a foreign body accidentally left in an operative wound or body cavity during a procedure, an obstruction due to a foreign body accidentally left in operative wound or body cavity during a procedure, and/or a perforation due to foreign body accidentally left in operative wound or body cavity during a procedure. An acute reaction such as aseptic or chemical peritonitis codes to category 9987.

\* A list of all medical and surgical codes are available on the AHRQ Quality Web Site: <http://www.qualityindicators.ahrq.gov>.

### **Exclusion criteria**

Patients on the sampling list should have NONE of the following exclusions:

- An ICD-9-CM code for foreign body left in during a procedure in the principal diagnosis field.
- Complications such as an obstruction or perforation caused by an implanted device intentionally left in the body (996.0-996.5)

For additional information on inclusion and exclusion criteria, refer to the AHRQ technical guidelines.

## COMPLETING THE PATIENT RECORD

### Section 1: Abstractor details

All section 1 items will auto-populate if using the electronic version.

**QUESTION 1.1:** Date abstraction completed

**Abstraction date:** Enter the date of the chart abstraction using the MM/DD/YYYY format.

**QUESTION 1.2:** Abstractor identification number

**Abstractor identification:** Each abstractor will have a unique log-in identifier linked to a unique abstractor identification number. It is essential that each abstractor use their assigned identifier and password when signing into the AHRQ PSI program and in completing data abstraction. For many hospitals this is the abstractor's initials.

### Section 2: Record identification/validation

**QUESTION 2.1:** AHRQ Study identification number

**AHRQ study identification number:** Enter the AHRQ study identification code of the record you are abstracting. This number can be found on the computer generated sampling list. It is important that you have the correct chart before proceeding.

**QUESTION 2.2:** Medical record number/Patient control number

**Medical record number (MRN, MR# or Patient control number):** The medical record/patient control number will be used for audit purposes and patient verification only. If the medical record/patient control number does not match the AHRQ study identification code, do not continue. If the patient has been admitted under more than one medical record number, ensure that the primary and final medical record numbers match the sampling list. If there are any questions regarding the validity of the medical record number(s), notify your supervisor and/or appropriate departments to establish the correct number for the patient. If there is a conflict in the medical record number and AHRQ study number that cannot be easily rectified or resolved, notify the coordinating center.

**Preferred data source:** Admission record.

**QUESTION 2.3:** What is the patient's date of birth?



**Date of birth (DOB):** Use the DOB on the admission or face sheet. Data used for analysis will contain the calculated age. Use a leading zero when entering single digit months (e.g., 03 for March).

**Preferred data source:** Admitting form.

**QUESTION 2.4:** What is the patient's gender?

**Gender (sex):** Enter if the patient is a male or female.

**Preferred data source:** Use the admission or face sheet followed by the physician's admission history and physical followed by the nurse's admission assessment.

**Common Problems/ Questions:** *Often there is conflicting information concerning demographic information. If the data element (e.g., gender, birth date, etc.) is recorded differently on the admission sheet and on other parts of the medical record, check several sources to verify the correct response. If an incorrect demographic is entered on admission, it will appear on all system generated reports until changed (i.e., laboratory test, diagnostic procedures, etc). Use reports that are not automatically generated to verify information (e.g. history and physical).*

**QUESTION 2.5:** What was the date of hospital admission?

**Admission date:** Verify the month, day and year the patient was admitted to the hospital. If there are conflicting times in the medical record, use the time on the face sheet followed by the admitting assessment form. If there are conflicts greater than 24-hour between the sampling lists admit date and chart date, notify the coordinating center.

**Preferred data sources:** Face sheet, Nursing Admission Assessment Record, History and Physical (H&P), pre-operative assessment form if admitted directly to the pre-op area.

**QUESTION 2.6:** What was the discharge date?

**Discharge date:** Enter the month, day and year the patient was discharged from the acute care hospital or index facility. This includes transfer to a non-acute care area associated within some hospital systems (e.g., a sub-acute care unit, long-term care, or rehabilitation area). For patients that expired during hospitalization, use the date the patient was pronounced.

**Preferred data sources:** Face sheet, Nursing Discharge Record, Ambulance transfer record, discharge summary. For patients that expired, use the death certificate or death note followed by the nursing record.

### Section 3: Risk factors

**QUESTION 3.1:** Height

\_\_\_\_.\_\_( cm) or \_\_ ft, \_\_ inches

**QUESTION 3.2:** Weight

\_\_\_\_.\_\_( kg) or \_\_\_\_ . \_\_ pounds (lbs)

**Height and weight:** Enter the patient's baseline height and weight. Use the most accurate dry weight closest to the time of admission. For patients that admitted directly to the surgical holding area, the most accurate dry weight may be the weight obtained in the clinic or outpatient record as part of the pre-operative work-up. For patients admitting to an inpatient area prior to surgery, use the admitting height and weight. Only use a patient stated height and weight as a last resort.

**Preferred data source(s):** Admitting nursing record, pre-operative records.

### Section 4: Ascertainment of event

**QUESTION 4.1:** Did the patient have a foreign body or foreign substance that was unintentionally left in during a procedure or operation during THIS hospitalization.

If NO, describe the circumstances on why you believe this chart was flagged for review in the TEXT BOX provided and END the form.

**Unintentional foreign body/substance:** This indicator targets any foreign body or substance that was accidentally left in an operative wound or body cavity during a procedure that occurred during THIS hospitalization. Presentation may include the presence of adhesions due to a foreign body or substance accidentally left in operative wound or body cavity during a procedure, an obstruction due to foreign body accidentally left in operative wound or body cavity during a procedure, perforation due to foreign body accidentally left in operative wound or body cavity during a procedure, and/or an acute reaction (category code 9987) such as aseptic or chemical peritonitis from a foreign body or substance accidentally or unintentionally left behind during a procedure or operation.

A YES answer may includes both medical and non-medical objects and/or substances. The foreign body may have been present prior to this hospitalization, such as in the case of trauma.

For example: A contaminant from a traumatic pre-hospital injury such as a piece of glass or shrapnel that should have been removed during surgery but was inadvertently left in OR an instrument or sponge that was inadvertently left in the abdominal cavity.

Do not include objects that were purposefully left in either as part of the operation or procedure or procedures to remove unintentionally items from a PRIOR hospitalization. Sometimes foreign objects will be left in during an operation because the risk of removal outweighs the risk of leaving the object behind. These items should illicit a NO response. Also, do not include objects or substances left in due to a complication in the procedure such as part of a broken guide wire that the physician was knowledgeable about but could not retrieve or objects/substances intentionally placed but that migrated or embolized. Examples of a NO response include: polyvinyl alcohol particles that aerosolized into the lungs, a stent that migrated out of the intended blood vessel into the bladder, contrast medium that extravasated into an unintended region and abdominal packing intentionally left for later removal.

Do include objects that were “missed” or “mistakenly” left behind such as shrapnel, a surgical lap sponge and/or surgical instrument that should have been removed prior to incision closure.

If no foreign body or substance was left in during a procedure that occurred during this hospitalization, explain the circumstances for the coding and then END the form. Also END the form if the foreign body or substance was related to a prior admission.

**Foreign medical devices or substances synonyms and inclusions (non inclusive list):**

- Sharps
- Sponges
- Any medical instrument
- Coil
- Stent
- Sutures
- Staples
- Embolic material acrylate
- Cotton fiber
- Gelfoam
- Polyvinyl alcohol particulate
- Packing
- Medical glue or cement

**Common non-medical objects synonyms and inclusions (non-inclusive list):**

- Bullet
- Glass
- Splinter
- Needle

**Preferred data source(s):** Admitting History and Physical, surgical records, physician progress notes, consultative reports.

**QUESTION 4.2:** If Q4.1 = YES, was the foreign body or foreign substance a medical device? IF NO, describe the object in the TEXT BOX provided.

**Device type:** State if the foreign object was a medical device or substance or a non-medical device. See question 4.1 for examples.

**Preferred data source(s):** Surgical reports, progress records, consultative reports, discharge record.

**QUESTION 4.3:** How many unintentional foreign bodies did they patient have?

**Number of unintentional objects:** State the number of unintentional foreign bodies or substances unintentionally left by the healthcare practitioner (question 4.1). As a reminder, do not include objects intentionally left in by a healthcare provider. These would include objects of which the risk of removal is too great and those objects knowingly left-in because of a complication in the procedure (e.g., catheter tip broke and could not be retrieved) and objects such as pacemakers and implants purposefully left in.

**Preferred data source(s):** Surgical reports, progress records, consultative and reports.

**Branching pattern:**

**For each foreign body or foreign substance unintentionally left behind, answer the following question.**

**QUESTION 4.4:** For each unintentional foreign body, was the foreign body related to an operative procedure performed in the operating room?

**Location of procedure:** If the foreign body or substance was left in during a procedure that took place in the operating room, answer YES. IF not, answer no. A NO answer includes those procedures performed at the bedside, in radiology, in special procedure suites, and alike.

Non-operating room procedures are those performed in the following areas:

- Interventional radiology
- Special procedure rooms

- Post-anesthesia care unit
- Any type of Intensive Care Unit (ICU) (e.g., coronary care, surgical ICU, trauma ICU, medical ICU, etc)
- Emergency Department (ED)
- At the patient's bedside

**Branching pattern:**

**If there is more than one retained foreign body or substance, make a copy of pages 4-7 for each additional foreign body or substance NOT related to a procedure performed in the operating room AND make a copy of pages 8-11 for each additional foreign body or substance left-in during a procedure performed in the operative room procedure.**

**For more than one foreign body or substance, state the number of the foreign body/substance at the top of each corresponding page. State the foreign body/substance number that the page is associated with.**

**Answer the ten specific procedure related questions (P1- P10) for each unintentional foreign body or substance not related to an operative procedure performed in the operating room. If the foreign body or substance was related to a surgical procedure, **SKIP** to question S1.**

**QUESTION P.1:** Enter the date that the acute reaction or foreign body was discovered:

**Discovery date:** State the date when the foreign body was discovered and/or that the patient had an acute reaction related to the retained substance/object.

**Preferred data source:** Procedure notes, progress notes, other procedure or diagnostic related records, discharge summary.

**QUESTION P.2:** Enter the date of the procedure associated with the foreign substance

**Procedure date:** List the date that the procedure related to the retaining of the foreign substance/object was performed.

**Preferred data source:** Procedure notes, progress records, discharge summary.

**QUESTION P.3:** How was the foreign body discovered?

**Discovery:** Select the best response on how the foreign body was discovered.

**Preferred data source:** Procedure notes, progress notes, other procedure or diagnostic related records, discharge summary.

**QUESTION P.4:** Select the category which best describes the procedure associated with unintentional foreign body or substance.

**Procedure:** If none of the listed categories describes the causative procedure (e.g., the procedure that lead to the retained foreign body or substance), select other and describe the procedure in the TEXT BOX.

**Preferred data source:** Procedure notes, progress notes, other procedure or diagnostic related records, discharge summary.

**QUESTION P.5:** What was the ICD-9-CM code associated with the selected procedure from Q P.4? If not known describe the procedure in the TEXT box.

**ICD-9-CM Procedure code:** Enter the causative procedure code.

**Preferred data source:** Coding sheet, face sheet, or procedure record.

**QUESTION P.6:** What best describes the foreign body or substance?

**Foreign Body:** Select which item best describes the foreign body. If there is not a good descriptor of the object, select other and describe in the TEXT BOX provided.

**Preferred data source:** Progress notes, procedure record, diagnostic reports, and discharge summary.

**QUESTION P.7:** What was the rank of the person performing the procedure associated with the foreign body or substance (i.e., the person who was inserting or manipulating the needle or device)?

**Provider:** Select the rank of the person who performed the procedure associated with the retained foreign object. This should be the person who actually inserted or manipulated the needle or device. For example, select physician in training if a resident was manipulating the central line catheter when the guidewire was lost. You will then be prompted to select if the resident was working under direct supervision of an attending physician. For this to be selected, the attending physician would have needed to be physically present at the time of the central line placement.

**Preferred data source:** Procedure note, progress note, flow sheets, emergency department record (if performed in the ED), anesthesia records, and discharge summary.

**Branching pattern:**

**If QP.7 = physician (any type), go to QP.8, if not skip to QP.9.**

**QUESTION P.8:** If Q P.7 = physician, what is his/her area of specialty?

**Specialty:** Select the specialty of the physician completing the procedure. For residents and interns, select the service rotation that they were assigned to at the time of the procedure. For example, if the surgical resident was doing a family practice rotation when performing the related procedure, check the hospitalist/internal medicine/family practice selection.

**Preferred data source:** Progress notes, procedure notes, physician orders.

**QUESTION P.9:** What were the circumstances surrounding the event: Select all that apply.

**Circumstances:** Select the most likely causative event leading to the foreign body being retained. Procedure error due to provider includes not following good clinical guidelines or hospital policy and procedure. Patient behavior encompasses an extremely uncooperative behavior such as that seen in alcohol withdrawal to the extent that it increased the risk of procedural complications. To not adequately prepare a patient for a procedures (such as providing clear expectations, adequate pain control, etc.), should be considered a provider level error.

**Preferred data source:** Procedure notes, progress notes, diagnostic reports, nursing records, and discharge summary.

**QUESTION P.10:** Please provide a brief synopsis of how the event occurred based on excerpts from the medical record (TEXT BOX).

**Description:** Please limit the synopsis excerpt to that which will help the reader better understand the events that lead to the retained object such as a variation in the procedure, problems with transposed anatomy, etc.

**Preferred data source:** Procedure notes, progress notes, consultative records, diagnostic reports, and discharge summary.

**Branching instruments:**

**Go to section 5, question 5.1 if there are no further foreign objects or substances.**

**If not, complete questions S 1-18 for EACH device/substance associated with surgery and questions P1-10 for EACH additional device/substance**

**associated with a procedure making sure to designate the device number at the top of each page. Devices should be numbered as they were discovered.**

**The following set of questions (S1-18) should be answered for EACH foreign body or substance left unintentionally left during surgery.**

**QUESTION S.1:** Date of discovery of the foreign body or diagnosis of the acute reaction to a foreign substance accidentally left during an operative procedure.

**Discovery date:** Use physician documentation to establish the date that the foreign body or foreign substance was first discovered to have been left during an operative procedure. This may or may not be the same day as surgery.

**Preferred data source:** Physician progress notes, surgical records.

**QUESTION S.2:** List the start date of the procedure of the operative event most likely associated with retained foreign body or substance.

**Start date:** Use the incision date that the physician started the operative procedure.

**Preferred data source:** Anesthesia records, surgical records.

**QUESTION S.3:** List the start time of the procedure of the operative event most likely associated with retained foreign body or substance.

**Start time:** Use the incision time or the time that the physician actually started the operative procedure.

**Preferred data source:** Anesthesia records, surgical records.

**QUESTION S.4:** List the end date of the procedure of the operative event most likely associated with retained foreign body or substance.

**End date:** Use the end date that the physician closed the operative site.

**Preferred data source:** Anesthesia records, surgical records.

**QUESTION S.5:** List the end time of the procedure of the operative event most likely associated with retained foreign body or substance.

**End time:** Use the incision end time or the time that the physician closed the operative site.

**Preferred data source:** Anesthesia records, surgical records.



**QUESTION S.6:** List all ICD-9-CM procedure codes associated with the operative event most likely associated with retained foreign body or substance. List all of the procedures performed (e.g., all procedures part of a bundle).  
**ICD procedure code:** List the operative procedure that was associated with the retained foreign body or substance. If there was more than one procedure, list all that apply.

**Preferred data source:** Coding sheet, surgical records.

**QUESTION S.7:** Was there an unplanned change in the procedure performed (e.g., a change in the planned procedure)?

**Unplanned change:** State if there was an unplanned change in the procedure performed. Do not include this option if the physician had discussed alternative plans prior to surgery based on intra-operative test results.

**Preferred data source:** Surgical notes, anesthesia records, progress records, discharge summary.

**QUESTION S.8:** Urgency of the surgical procedure.

**Urgency:** Select the urgency of the surgery answering if it was an elective or non-elective case. Emergency surgery requires immediate surgery without time for preparation or resuscitation. An example would be person brought to the ED with multiple gunshot wounds that is bleeding internally and will die without immediate intervention. Urgent surgeries are those that are scheduled as soon as possible, usually within 24 hours. Elective or non-emergent surgeries are those operations that are planned in advance such as a cancer surgery for the following week as to a time that suits both the patient and/or the surgeon.

**Preferred data source:** History and physical, operative records, emergency department records (if applicable).

**QUESTION S.9:** Number of surgical teams involved in the surgical event (e.g., neurosurgical team working on the head and orthopedics working on a fracture would be considered two teams).

**Number of teams:** State the number of distinct surgical teams that participated in the surgery. For example: ENT and plastics would constitute 2 teams. General surgery, plastics, and GYN would count as 3 teams regardless of the number members on each team.

**Preferred data source:** Operative records, surgeon's post-operative reports.

**QUESTION S.10:** Did the surgical team include residents or interns?

**Trainees:** Answer YES if the surgical team included residents, interns, or medical students that participated in the surgery. Do not include if they only observed the surgery.

**Preferred data source:** Operative records.

**QUESTION S.11:** Sponge count(s) performed.

**Sponge count:** State whether the sponge count was performed both pre and post procedure. Given that the count was performed, state if the count agreed.

**Preferred data source:** Operative records.

**QUESTION S.12:** Instrument count(s) performed:

**Instrument count:** State whether the instrument count was performed both pre and post procedure. Given that the count was performed, state if the count agreed. A narrative note stating that there was agreement between the pre and post counts is sufficient for confirmatory response.

**Preferred data source:** Operative records.

**QUESTION S.13:** Needle count(s) performed:

**Needle count:** State whether the needle count was performed both pre and post procedure. Given that the count was performed, state if the count agreed.

**Preferred data source:** Operative records.

**QUESTION S.14:** Was an intra-operative radiographic study performed to look for a potentially retained foreign body?

**Intra-operative studies:** State if an intra-operative X-ray was performed to specifically rule out the presence of a retained foreign object.

**Preferred data source:** Radiology requests, operative records.

**QUESTION S.15:** Was the operative site reopened prior to close of surgery to look for a foreign body or to remove foreign material?

**Exploration:** State if the operative site was reopened to look for or to retrieve a foreign body and/or material. If YES, select if the site was reopened prior to the patient leaving the operating room, and if so, whether the site was reopened prior to skin closure. If the site was reopened after the patient initially left the operating room, state the start date and time of the new procedure.

**QUESTION S.16:** Intra-operative blood loss

**Intra-operative blood loss:** State the blood loss in cc's as documented by the surgeon and then by the anesthesiologist.

**Preferred data source:** Surgeon operative record and anesthesia record respectively.

**QUESTION S.17:** How was the foreign body or foreign substance discovered?

**Mode of discovery:** Select the mode of discovery. For example, if the foreign body was found on a routine X-ray check "during a routine test". If the mode of discovery was related to symptoms, you will be prompted to check the type of symptoms (e.g., mass, infection, reported signs/symptoms such as cramping and/or pain, or an obstruction such as with a bowel obstruction). If the primary symptom is not listed, check other and enter the primary symptom(s) in the TEXT BOX. Other options include discovery at the time of another operation of an unrelated problem or during a surgery that associated with signs and symptoms of the retained object.

**Preferred data source:** Operative records, progress notes, discharge summary.

**QUESTION S.18:** What best describes the foreign body?

**Foreign body:** Select the best description of the foreign body. If none of the listed examples is appropriate, select other.

**Preferred data source:** Operative records, progress notes, discharge summary.

**Section 5: Evaluation and treatment**

**QUESTION 5.1:** Which of the following complications occurred due to the unintentionally retained foreign body or substance? Select all that apply.

**Complications:** Select any and all complications that were directly or indirectly related to the retained foreign body or substance. If the patient developed sepsis, infection, inflammatory process or other acute reaction, you will be prompted to select the specific type. If the patient developed a complication not listed, state the condition in the TEXT BOX provided.

**Preferred data source:** Operative records, progress notes, discharge summary.

**QUESTION 5.2:** Which of the following interventions did the patient undergo because of the unintentionally foreign body or substance? Select all that apply.

**Interventions:** If the listed intervention is not listed, select other and describe the interventions in the TEXT box provided.

**Preferred data source:** Operative records, progress notes, discharge summary.

## Section 6: Outcomes

**QUESTION 6.1:** Does the chart suggest that the patient suffered any adverse effects or consequences from this event? Check all that apply.

**Adverse effects:** Select if the patient had any of the listed adverse effects or consequences from the retained foreign body. An example of a negligible effect would be minor skin irritation.

**Preferred data source:** Progress notes, surgical records, procedure notes.

**QUESTION 6.2:** If the patient expired, was the death related to the unintentionally retained foreign body or substance?

**Death:** Include if the patient died from a complication related to the foreign body such as sepsis or hemorrhage secondary to perforation of a major organ by the retained foreign object or as a complication of therapy related to the foreign body (e.g., died complications of anesthesia related to a second operation to remove the foreign object).

**Preferred data source:** Death record, progress notes, discharge summary.

**QUESTION 6.3:** Was the patient readmitted to your facility within 30 days of discharge?

**Readmission:** State if the patient was readmitted to the acute care hospital within 30-days of discharge. Only include facilities under the same license.

**Preferred data source:** New admission paperwork, such as a face sheet, history and physical, progress notes, etc.

**QUESTION 6.4:** If yes to Q6.3, was the reason for re-admission related to foreign body or substance?

**Reason for readmission:** State if the readmission was related to the foreign body of substance including any related complications. This includes surgery for removal, obstruction, infection, etc.

**Preferred data source:** New history and physical, procedure notes, surgical notes.

**QUESTION 6.5:** If there are special circumstances or comments related to this case that you feel are important that were not captured in the survey please state in the TEXT BOX [limit 200 characters]:

**Special circumstances:** It is not necessary to complete this box. However, if there are important facts related to this case that were not capture in the data abstraction tool that you feel would be important to the validation project, please describe in the TEXT box provided.

**Preferred data source:** Any documentation.
