

**Fourth Edition
January 2012**

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- health plans, health systems, health care organizations, hospitals and integrated health care delivery systems;
- medical specialty and professional societies;
- researchers;
- federal, state and local government health care policy makers and specialists; and
- employee benefit managers.

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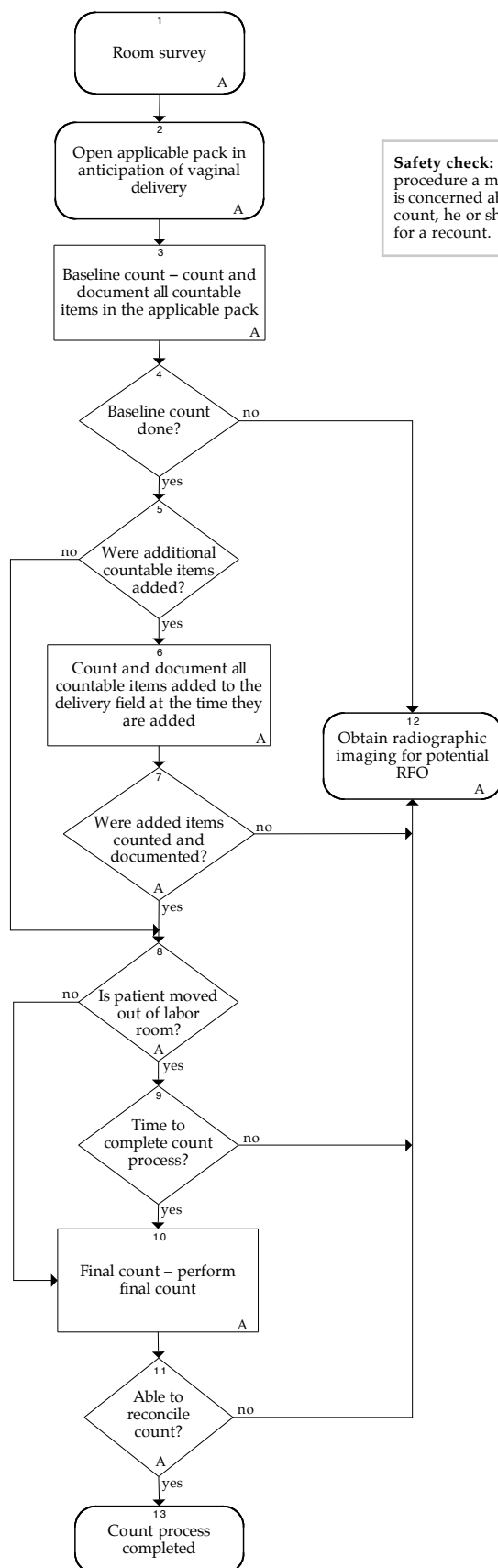
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Prevention of Unintentionally Retained Foreign Objects During Vaginal Deliveries

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All algorithm boxes with an "A" and those that refer to other algorithm boxes link to annotation content.

Text in blue throughout the document also provides links.



Safety check: If at any time during the procedure a member of the L&D team is concerned about the accuracy of the count, he or she is empowered to call for a recount.

A = Annotation

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Disclosure of Potential Conflict of Interest

In the interest of full disclosure, ICSI has adopted a policy of revealing relationships work group members have with companies that sell products or services that are relevant to this protocol topic. It is not assumed that these financial interests will have an adverse impact on content. They are simply noted here to fully inform users of the protocol.

Stephanie Doty, RN, holds personal stock with 3M.

Doug Creedon, MD, is the treasurer for the Minnesota section of the American Congress of Obstetrics and Gynecology.

No other work group members have potential conflicts of interest to disclose.

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Description of Evidence Grading

A consistent and defined process is used for literature search and review for the development and revision of ICSI Protocols. Literature search terms for the current revision of this document include retained foreign objects and labor and delivery from May 2009 through June 2011.

Individual research reports are assigned a letter indicating the class of report based on design type: A, B, C, D, M, R, X.

Evidence citations are listed in the document utilizing this format: (*Author, YYYY [report class]; Author, YYYY [report class] – in chronological order, most recent date first*). A full explanation of ICSI's Evidence Grading System can be found on the ICSI Web site at <http://www.icsi.org>.

Class	Description
Primary Reports of New Data Collections	
A	Randomized, controlled trial
B	Cohort-study
C	Non-randomized trial with concurrent or historical controls Case-control study Study of sensitivity and specificity of a diagnostic test Population-based descriptive study
D	Cross-sectional study Case series Case report
Reports that Synthesize or Reflect upon Collections of Primary Reports	
M	Meta-analysis Systematic review Decision analysis Cost-effectiveness analysis
R	Consensus statement Consensus report Narrative review
X	Medical opinion

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Foreword

Introduction

For as long as the medical community has been assisting women in performing vaginal deliveries, we have had the risk and misfortune of unintentionally retained foreign objects. Many measures have been instituted to mitigate the likelihood of an unintentionally retained item, but unfortunately they continue to occur.

Professional organizations such as The Joint Commission (*Joint Commission International Center for Patient Safety, 2006 [R]*), and Controlled Risk Insurance Company/Risk Management Foundation for Obstetrical Providers (*Controlled Risk Insurance Company/Risk Management Foundation, 2006 [R]*) have developed guidelines for the prevention of retained items during vaginal deliveries.

The Joint Commission categorizes the unintended retention of a foreign body after a vaginal delivery as a sentinel event. This categorization requires health care organizations to conduct a root cause analysis and to develop a corrective action plan designed to reduce the probability of a repeat occurrence. Per The Joint Commission's Sentinel Event Report dated June 2011, unintentionally retained foreign objects were the most frequently reviewed category in 2010 and through the first half of 2011. In 2010 there were 133 events reported, which is up from 119 in 2009. Through the first half of 2011, 76 events were reported which, when annualized, would exceed the 2010 rate by nearly 20 events.

In the first seven reporting periods (June 2003–October 2010), the Minnesota Department of Health's Adverse Health Events Report showed 434 surgical events with 221 of those involving unintentionally retained foreign objects. In the most recent reporting period (October 2009 to October 2010), 34 unintentionally retained foreign objects were reported, three of which were sponges following vaginal delivery (*Adverse Health Events in Minnesota Seventh Annual Public Report, 2011 [NA]*).

A significant challenge faced by the work group in developing the protocol was the definition of "retained." A number of sources were consulted and found to be in conflict or non-specific. When developing the protocol's definition, the work group considered the potentially retained object's size, location of the patient within the facility, procedure time frames, the delivery stages and The Joint Commission's definition of when an object is considered retained.

Another challenge faced by the work group was the limited number of relevant peer-reviewed research studies to guide the development of the overall protocol. Therefore, in creating the document the work group relied upon expert opinion, real-life experiences and expertise.

Commercial aviation safety experts faced the same lack of evidence when they developed their now generally accepted standard operating procedures aimed at eliminating commercial airplane accidents. Aviation has shown that by broadly and systematically employing processes such as standardized procedures to minimize variation, communication techniques like crew resource management, and minimizing distractions during critical steps, safety and reliability can be improved (*Helmreich, 2000 [R]*).

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Scope and Target Population

This protocol will describe the necessary steps, which if implemented, should prevent the unintentional retention of foreign objects during vaginal deliveries.

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Aim

1. Eliminate the number or rate of unintentionally retained foreign objects left following a vaginal delivery.

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Clinical Highlights

- Sponges/soft goods, sharps and miscellaneous items will be counted for vaginal deliveries. (*Annotation #3; Aim #1*)
- Sponges/soft goods with radiopaque markers are the only soft goods that will be present on the delivery field. (*Annotation #3; Aim #1*)
- Establishing accurate count processes for the baseline and final counts are all critical steps in preventing an unintentionally retained intra-delivery foreign object during vaginal deliveries. If the baseline count is not accurately performed before using countable items, all subsequent counts should be considered compromised. For compromised and unreconciled counts, a radiograph shall be obtained to ensure that a foreign object has not been unintentionally retained. (*Annotations #3, 6, 10, 12; Aim #1*)
- Good communication is necessary before and during the procedure, when staff changes and/or at hand-offs, e.g., transitioning to the operating room. (*Annotation #3; Aim #1*)

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Implementation Recommendation Highlights

The following system changes were identified by the work group as key strategies for health care systems to incorporate in support of the implementation of this protocol.

1. The work group recommends that a standardized method, such as use of either a count worksheet or a whiteboard, be used in Labor and Delivery to keep track of baseline, ongoing and final counts. This method can then be used for final documentation or dictation of the medical record and/or submission into an electronic medical record.
2. The Labor and Delivery room needs to have a dedicated receptacle or location for all used sponges/soft goods in order to ensure accuracy of the count process. This must be in a location where staff can retrieve these items and not be co-mingled with the waste bucket at the foot of the bed.
3. The counting process must include a registered nurse and another person trained in the counting process.
4. Active support for the implementation of this protocol from administrative and medical leadership is essential.
5. Establish and/or maintain processes for ongoing training, measurement and feedback for all involved staff.
6. Evaluation of count practices should include performance improvement audits. This is to ensure that count processes are being followed and not merely documented. Trends identified with audits can be used for ongoing training, measurement and feedback for all staff (*Murdock, 2008 [X]*).
7. Red rules* should be established, followed by staff and physicians and supported by leadership (see below for specific red rules suggested for this protocol).

* Red rules are the few key rules created by the facility to prevent/address specific actions that pose the highest level of consequence and risk to patients or staff. The intention is to develop solid habits around these rules so that they are followed consistently and accurately each time. Individual responsibility to adhere to each red rule is imperative to ensure a safe environment and consistent delivery of the desired care process.

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Suggested red rules for Labor and Delivery:

1. All sponges and sharps will be counted for every vaginal delivery.
2. Only radiopaque sponges/soft goods will be present on Labor and Delivery trays or enter the delivery field.
3. If the count cannot be reconciled, imaging must be done.

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Related ICSI Scientific Documents

Guideline

- [Management of Labor Guideline](#)

Protocol

- [Perioperative Protocol](#)

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Definitions and Specifications

Baseline count: The initial count of countable items (sponges, sharps, instruments). It is completed before the items are used.

Countable items: Any item that could be unintentionally left behind after a vaginal delivery and is subject to the count process. This includes:

- **Miscellaneous items:** Includes fetal scalp electrodes, intrauterine pressure catheters and non-radiopaque items such as umbilical tapes, vacuum sponges and other small items.
- **Sharps:** Items with edges or points capable of cutting or puncturing. In the context of a vaginal delivery, sharps include, but are not limited to, suture needles and hypodermic needles.
- **Sponges/soft goods:** Includes such items as gauze pads, vaginal packs or laparotomy sponges used to absorb fluids, protect tissues or apply pressure or traction.

Count documentation: A standardized form used in the count process. This may be on paper, a whiteboard or electronic format. Organizations may or may not choose to store specific count information for future retrieval.

- **Paper:** A paper count sheet may be used in organizations where the use of a whiteboard is not possible either due to space limitations and/or the inability of all the team members to visualize the board.
 - The paper form should be a standardized, preformatted form specific to vaginal deliveries.
 - Whenever feasible, a countable item should be preprinted on the form to minimize legibility or omission errors.

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- **Whiteboard:** A preformatted, dry-erase board directly viewable by the entire Labor and Delivery team that is used to document sponges/soft goods, sharps and miscellaneous items counts. The ability of the entire team to visualize the count information and assist in the correct identification of tucked and unaccounted-for items enhances safety and reduces the risk of errors (*France, 2005 [D]*).
 - The whiteboard should use standard columns, rows and categories to record counts. In addition to the count, the whiteboard should include the patient's name and other pertinent or patient-unique information.

Final count: The count conducted at the end of the delivery to account for all used, countable items. The final count is preferably performed before the physician or midwife leaves the patient's room.

Notification: If an unintentionally retained foreign object is found during a patient examination in a clinic, emergency department, or during a subsequent hospitalization, the facility that performed the original procedure should be notified.

Permanent staff change count: Count completed when there is a permanent staff change of the Labor and Delivery nurse during the delivery.

Post-delivery imaging: Radiographic images obtained within the Labor and Delivery suite, usually with portable imaging equipment.

Radiology room imaging: Radiographic images obtained in a radiology room with a fixed tube and moving grid.

Safety check: Critical step essential for reliably preventing an unintentionally retained foreign object.

Structured hand-off: Standardized method of communication to improve the exchange of information during care transitions.

Vaginal delivery retained foreign object (RFO): An object unintentionally retained after the end of the immediate recovery period (one to two hours post-delivery). This does not include packing intentionally placed for the purpose of controlling hemorrhage unless the packing is not removed as intended prior to the patient's discharge.

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Special Considerations

- **Temporary Packing of the Genital Tract After a Vaginal Delivery and Beyond the Immediate Recovery Period** – When the genital tract is packed post-delivery and the packing is intentionally kept in place beyond the immediate recovery period (one to two hours after delivery), the risk for an unintentionally retained foreign object increases. Strict adherence to the count process and documentation and communication of all packed materials, and reliable implementation of procedures to ensure removal of packing prior to discharge are important for the prevention of an unintentionally retained item. Imaging is recommended only when the final count cannot be reconciled.
- **Equipment Components** – It is important to conduct an examination of all equipment used during the vaginal delivery to ensure that the equipment is intact and no incidental pieces and instruments are unintentionally retained.

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Protocol

The Prevention of Unintentionally Retained Foreign Objects During Vaginal Delivery Protocol is limited to patients who present with an anticipated vaginal delivery.

Counts Compromised – Continue to Follow the Labor and Delivery Retained Foreign Object Prevention Process

When a mother's and/or fetus's condition becomes critical/emergent and/or there is not adequate time or staff to perform the steps of the protocol, counts should be considered compromised. The Labor and Delivery team should continue to follow the retained foreign object prevention process and at the conclusion of the procedure, obtain radiographic imaging to detect a potentially retained foreign object.

Room Survey

Perform Count Process

- Items included in the count process are:
 - Sponges/soft goods – only radiopaque sponges will be present in the Labor and Delivery tray or the delivery field
 - Sharps
 - Miscellaneous items, including those that are non-radiopaque
- The count process will be performed at the following times:
 - Immediately before the delivery pack is used (baseline count)
 - When additional items are added to the delivery field
 - At the end of the delivery (final count)
 - Any time a member of the Labor and Delivery team is concerned about the accuracy of the count
 - Whenever there is a permanent staff change of the Labor and Delivery nurse (permanent staff change count)
- The count process will be performed in the follow manner:
 - Two individuals, one of whom must be a registered nurse, will directly view and will verbally count each item. These individuals must be trained in the counting process.
 - The Labor and Delivery nurse will document the number and type of sponges/soft goods, sharps and miscellaneous items on a preformatted whiteboard **or** other standardized, preformatted documentation record. The second person involved in the count process will verbally confirm the number.
 - Sponges/soft goods and sharps will be counted prior to entering the delivery field.
 - Sponges/soft goods will be separated, counted and documented individually.
 - Sponges/soft goods will have visual verification that the radiographic-detectible indicator is present.
 - Used sharps will be counted as each sharp is placed into the needle box by the physician/nurse midwife.
 - Used sponges will be counted after retrieving them from the designated basin.
 - Used sponges/soft goods will be separated, unballied and/or pulled apart prior to being counted.
 - Sharps and miscellaneous items will be inspected for broken or missing pieces during the baseline and final count.
- Post-procedure tasks include:
 - No items will be removed from the Labor and Delivery area until all counts have been reconciled and inspections completed.
 - Countable items that accompany the infant out of the Labor and Delivery area will be communicated to the Labor and Delivery nurse and documented on the count sheet.
 - After all counts have been reconciled, all items will be removed from the Labor and Delivery area.

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Transfer to Surgery

- Not all transfers to surgery are emergent, so there may be ample time to perform and reconcile the vaginal delivery final count.
- If the mother and/or fetus's condition become critical, or the mother's condition becomes critical immediately following a vaginal delivery and transfer to surgery, the count process is considered compromised and the mother is at increased risk for a retained foreign object. If the mother's condition allows, portable imaging should be obtained to rule out the possibility of an unintentionally retained foreign object.
- Any countable items that accompany the mother to the surgical suite will be documented in the patient's record and verbally communicated to the surgical team.

Reconciliation Process for a Count Discrepancy

- When a discrepancy is identified, the number and type of missing item is reported to the provider by the Labor and Delivery nurse.
- A manual inspection of the Labor and Delivery suite is conducted, including a visual inspection of the area surrounding the delivery field, the floor, linens, and trash receptacle.
- The count is repeated and verified. A discrepancy must never be resolved by using the number listed on open packages.
- Special attention should be paid to items that can stick together, such as sponges/soft goods. Sponges/soft goods will be unballled and separated for counting.
- If the mother's condition permits, the genital tract should be explored, with special attention paid to the location of where the missing item might be retained.
- Post-delivery imaging should be obtained if the counts cannot be reconciled.
 - The physician and/or radiologist should review the films before the end of the immediate recovery period (one to two hours).
- If the count cannot be reconciled after all the steps above are completed, attempts to reconcile the count and the outcomes of those attempts will be documented per the organization's policy.

Radiographic Image for Potential Retained Foreign Objects

- Radiographic imaging, whether a portable image obtained in the Labor and Delivery suite or a post-delivery image performed in a radiographic room, is not a substitute for performing an accurate count process and methodical genital tract exploration.
- Portable imaging considerations and limitations include:
 - patient condition,
 - size and type of retained object,
 - whether the item is radiopaque,
 - placement options of the radiographic film cassettes under the Labor and Delivery table limiting the imaging field included on the radiographic image,
 - lower tube power, and
 - availability of equipment and staff.
- Portable radiographic imaging should be obtained when:
 - counts cannot be reconciled,
 - the missing item is radiopaque,
 - the patient's condition did not allow for the count process to be followed (rushed counts, incomplete counts), or
 - a member of the Labor and Delivery team has concerns about the accuracy of the count that cannot be resolved.

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- Radiographic imaging requests include the following information:
 - Callback number and physician name
 - Location and status of patient (e.g., post-delivery recovery, Caesarean room)
 - Number and type of item missing
 - Details of the delivery as appropriate
- The radiology technologist will review the images for quality and repeat imaging as necessary.
- The physician will review the image to check for adequate coverage of the genital tract prior to the film being sent to the radiologist for interpretation.
- The radiologist and physician should simultaneously review the radiographic image especially with a negative read, both verbally and visually, to correlate the anatomical coverage of the images.
- The film should be reviewed before the end of the immediate recovery period (one to two hours).
- If a radiologist is not immediately available, the preliminary interpretation of the radiographic image is the responsibility of the physician.
- When a nurse midwife is the delivering provider, if an unintentionally retained item is visualized on radiographic image, the nurse midwife may attempt to retrieve the item prior to physician collaboration. If the item is retrievable and the count is correct, no further action is needed. If the count is still incorrect, physician collaboration shall be obtained in the immediate recovery period.
- A post-delivery radiographic image should be taken in a radiographic room with fixed radiographic equipment and moving grid when:
 - the patient's condition did not allow for portable radiographic imaging,
 - the entire anatomic area could not be captured with a portable radiographic imaging, or
 - the portable radiographic imaging failed to locate the potentially retained foreign object.

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Algorithm Annotations

Labor and Delivery Retained Foreign Objects Prevention Protocol Annotations

The Prevention of Unintentionally Retained Foreign Objects During Vaginal Delivery Protocol is limited to patients who present with an anticipated vaginal delivery.

The counting recommendations outlined in this protocol are based on consensus statements and guidelines of American College of Obstetricians and Gynecologists and the American Academy of Pediatrics. In addition, articles on communication, teamwork, multitasking and interruptions and their relationship to unanticipated events are referenced. This protocol has identified staff responsible for various steps based on their scope of practice and licensing requirements. Direct and explicit language (e.g., will, must) has been incorporated to reduce variation and to identify the steps of the protocol where variation could significantly increase the risk for an unintentionally retained object (*American College of Obstetrics and Gynecologists, 2006 [R]; AORN, 2006 [R]; Controlled Risk Insurance Company/Risk Management Foundation, 2006 [R]; Eldrige, 2006 [NA]; Haig, 2006 [D]; Harder, 2006 [D]; Joint Commission International Center for Patient Safety, 2006 [R]; American College of Surgeons, 2005 [R]; Council on Surgical and Perioperative Safety, 2005 [R]; ECRI, 2005 [R]; Gibbs, 2005 [R]; Brennan, 2004 [C]; Leonard, 2004 [D]; Lingard, 2004 [D]; Vincent, 2004 [R]; Thomas, 2000 [C]; Leape, 1991 [C]*).

Accurately accounting for all items that could potentially become unintentionally retained is a shared responsibility of the entire Labor and Delivery team. The ultimate responsibility for prevention of an unintentionally retained foreign object lies with the provider performing the procedure.

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1. Room survey

A designated person performs a room survey to ensure that all evidence (e.g., count record, patient ID stickers) from the previous delivery has been removed. The room survey is completed before the next patient arrives in the room.

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2. Open Applicable Pack in Anticipation of Vaginal Delivery

Ideally the pack should be opened only when it is known the pack will need to be utilized and immediately before use; however, the work group acknowledges that this may not be possible in all cases. As a result, facilities are encouraged to establish guidelines related to the amount of time a pack may be open prior to use in light of the following considerations:

- The need to keep the open pack in direct observation by staff at all times
- Direct correlation between the amount of time the pack is open and risk of infection

In order to reduce waste and cost, it is recommended that, whenever possible, facilities develop a process for opening items only when they are needed by the delivering provider.

Organizations may elect to have separate delivery packs for routine versus precipitous deliveries, considering the variation with respect to these presentations. Additionally, it is recommended that facilities consider the financial and logistical benefits of eliminating countable items from the delivery pack.

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3. Baseline Count – Count and Document All Countable Items in the Applicable Pack

The timing and frequency of the count process in Labor and Delivery are different from the process in the surgical suite. Frequently, countable items are not used during or after a delivery. Items that are not opened during the delivery do not need to be counted.

What Items Will Be Included in the Count Process:

It is the work group's recommendation that all non-radiopaque items on the delivery tray or within the delivery field be counted. In addition, the following items will be counted:

Sponges/soft goods: Sponges and soft goods that require counting include such items as gauze pads, vaginal packs or laparotomy sponges used to absorb fluids, protect tissues or apply pressure or traction.

Only radiopaque sponges/soft goods will be present on the delivery tray or within the delivery field (*AORN, 2006 [R]; Controlled Risk Insurance Company/Risk Management Foundation, 2006 [R]; American College of Surgeons, 2005 [R]; Council on Surgical and Perioperative Safety, 2005 [R]*).

Sponges/soft goods will have visual verification that the radiographic-detectable indicator is present prior to being placed in the delivery field.

RayTec/laparotomy sponges will not be cut into pieces (*AORN, 2006 [R]; American College of Surgeons, 2005 [R]*).

Radiopaque sponges/soft goods that are placed in the genital tract should have a detection "tail" that can be clipped to the patient's drapes (*Controlled Risk Insurance Company/Risk Management Foundation, 2006 [R]*).

Sharps: Sharps that require counting include items with edges or points capable of cutting or puncturing such as suture needles and hypodermic needles (*AORN, 2006 [R]; American College of Surgeons, 2005 [R]; Council on Surgical and Perioperative Safety, 2005 [R]*).

Miscellaneous items: Miscellaneous items that must be either counted or accounted for include fetal scalp electrodes, intrauterine pressure catheters and non-radiopaque items such as umbilical tapes, vacuum sponges and other small items (*AORN, 2006 [R]*). The internal fetal scalp electrode must be accounted for at the time of delivery. Should the patient have the electrode in place prior to delivery and it is still in place at the time of delivery, the nurse and provider should account for it along with the sponge count.

When the Count Process Will Be Performed (*AORN, 2006 [R]*):

- Immediately before the delivery tray is used (baseline count) (*Controlled Risk Insurance Company/Risk Management Foundation, 2006 [R]*).
- When countable items are added to the delivery field.
- At the end of the delivery:
 - For sharps, the final count will be performed at the end of the case by counting each sharp placed into a needle box by the provider.
 - For sponges/soft goods and miscellaneous items, the final count will be performed at the end of the procedure by counting each item that was placed into the designated basin (*Controlled Risk Insurance Company/Risk Management Foundation, 2006 [R]; Varner, 1986 [R]*). Sponges/soft goods **WILL NOT** be placed in the container that is used to collect and manage body fluids during the delivery until after the final count has been performed and reconciled.

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Algorithm Annotations

- If the delivering provider is called away for an emergency, the final count will be completed by the Labor and Delivery nurse and a second person trained in the count process.
- Anytime a member of the Labor and Delivery team has concerns about the accuracy of the count, even when the counts appear correct.
- Whenever there is a permanent staff change of the Labor and Delivery nurse.
 - All visible items will be counted and all items in use in the delivery field will be accounted for.

When a count is not required:

- If there is a permanent change in a member of the Labor and Delivery team other than the Labor and Delivery nurse. A structured hand-off is required but a count is not.
- When the Labor and Delivery nurse change is temporary (e.g., lunch break). A structured hand-off is required but a count is not.

How the Count Process Will Be Performed:

- Two individuals, one of whom will be a registered nurse, will directly view and verbally count each item. These individuals must be trained in the counting process (*AORN, 2006 [R]; Controlled Risk Insurance Company/Risk Management Foundation, 2006 [R]; Council on Surgical and Perioperative Safety, 2005 [R]*). The second person may be another registered nurse, the provider, a Labor and Delivery technician, or a nursing assistant.
- Distractions and interruptions should be minimized during the count process (*ACOG, 2006 [R]; American College of Surgeons, 2005 [R]*). If the count process is interrupted in a particular category (e.g., laparotomy sponges, sutures), the count of that particular category will start over.
- Any countable items, when opened, will be counted and documented prior to entering the delivery field.
- The Labor and Delivery nurse will document the number and type of sponges/soft goods, sharps and miscellaneous items on the preformatted count sheet **or** whiteboard. The other person involved in the count process will confirm the number.
 - The work group does **NOT** recommend keeping two concurrent count records.
- Sponges/soft goods will be separated, counted and documented individually (*AORN, 2006 [R]*).
- Every sponge/soft good will be visually inspected to verify that the radiographic-detectable indicator is present (*AORN, 2006 [R]; Controlled Risk Insurance Company/Risk Management Foundation, 2006 [R]; American College of Surgeons, 2005 [R]; Council of Surgical and Perioperative Safety, 2005 [R]*).
 - If the indicator is not present, the entire package of sponges/soft goods will be removed from the room and given to the designated person for follow-up with the manufacturer (*AORN, 2006 [R]*).
- When the labeling on the package does not match the number of items in the package, they will be removed from the room and given to the designated person for follow-up with the manufacturer (*AORN, 2006 [R]*).
- Sponges/soft goods used by anesthesia will not enter the delivery field or be mixed in with sponges/soft goods used and counted during the delivery process.

For specific information related to the final count, Refer to [Annotation #10, "Final Count – Perform Final Count."](#)

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6. Count and Document All Countable Items Added to the Delivery Field at the Time They Are Added

If any additional countable items are added to the delivery field after the baseline count but before the final count, they will be counted in the same manner as the baseline count. Additional counted items will be added to the count on the count sheet or whiteboard. Final count will equal baseline counted items plus all added items.

Additional instructions regarding fetal scalp electrode documentation: Whenever a fetal scalp electrode is placed onto the fetal scalp, the person placing the fetal scalp electrode inspects it for structural integrity and completeness, and verbally announces its placement to the Labor and Delivery nurse. The Labor and Delivery nurse documents the fetal scalp electrode on the count worksheet. When the fetal scalp electrode is removed, the person removing it inspects it for structural integrity and completeness, and verbally announces its removal so the count worksheet can be updated appropriately.

***NOTE:** When a fetal scalp electrode is removed from the fetal scalp, the Labor and Delivery nurse will draw a line across (i.e., cross out) the fetal scalp electrode on the count worksheet and will write "removed" following the entry.

Countable items: Any item that could be unintentionally left behind after a vaginal delivery and is subject to the count process. This includes:

- **Miscellaneous items:** Includes fetal scalp electrodes, intrauterine pressure catheters, non-radiopaque items such as umbilical tapes, vacuum sponges and other small items.
- **Sharps:** Items with edges or points capable of cutting or puncturing. In the context of a vaginal delivery, sharps include, but are not limited to, suture needles and hypodermic needles.
- **Sponges:** Soft goods such as gauze pads, vaginal packs or laparotomy sponges used to absorb fluids, protect tissues or apply pressure or traction.

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7. Were Added Items Counted and Documented?

Refer to [Annotation #3, "Baseline Count – Count and Document all Countable Items in the Applicable Pack,"](#) for how to perform the count process.

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8. Is Patient Moved Out of Labor Room?

Emergency Transfer to Surgery During or Immediately After a Vaginal Delivery – When a mother's and/or fetus's condition becomes critical during the delivery, or the mother's condition becomes critical immediately following a vaginal delivery and transfer to surgery is required, there may not be adequate time for staff to perform the final vaginal delivery count. In this situation, all counts are considered compromised and the mother is at increased risk for an unintentionally retained foreign object. If the mother's condition allows, imaging should be obtained prior to leaving the operating room to rule out the possibility of an unintentionally retained foreign object.

Any countable items used during the vaginal delivery that accompany the patient to surgery will need to be documented in the patient's record and verbally communicated to the surgical team.

If the transfer to surgery is not emergent, and there is time to perform and reconcile the vaginal delivery final count before the mother leaves the Labor and Delivery room, this is the preferred method. The subsequent surgical procedure is considered separately from the vaginal delivery procedure; therefore, the count process for surgery is to be used.

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10. Final Count – Perform Final Count

The final count should be performed before the provider leaves the room. If the delivering provider is called away for an emergency, the final count will be completed by two members of the Labor and Delivery team who have been trained in the counting process. One member of the final count team will be a registered nurse.

Final count process:

- Used sharps will be counted at the end of the procedure by counting each sharp as the provider places it into a needle box.
- Used sponges/soft goods will be placed in the designated basin – **NOT** in the container that is used to collect and manage body fluids during Labor and Delivery until after the final counts have been performed and reconciled.
- Used sponges/soft goods will be separated, unballied and/or pulled apart before counting to aid the count process.
- Sponges/soft goods will be counted at the end of the procedure (*Controlled Risk Insurance Company/ Risk Management Foundation, 2006 [R]*).
- All sharps and miscellaneous items, such as fetal scalp electrodes, will be inspected for broken or missing pieces.
- Any items dropped during the procedure will be retrieved, shown to the person responsible for counting, and isolated from the delivery field.
- Any items intentionally left in a patient will be documented on the procedure record and communicated verbally to the next caregiver. The patient will also be informed.
- No sponges/soft goods, sharps or miscellaneous items will be removed from the Labor and Delivery area until all counts have been performed and reconciled (*AORN, 2006 [R]*).
- Countable items that accompany the infant out of the Labor and Delivery area will be communicated to the Labor and Delivery nurse and documented on the count sheet (*AORN, 2006 [R]*); *Council on Surgical and Perioperative Safety, 2005 [R]*).
- After all counts have been reconciled, all delivery tray items will be removed from the Labor and Delivery area before setup begins for the next procedure.

For other counting information, refer to [Annotation #3, "Baseline Count – Count and Document All Countable Items in the Applicable Pack."](#)

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11. Able to Reconcile Count?

Reconciliation Process for a Count Discrepancy

When a discrepancy is identified, the Labor and Delivery nurse will report the number and type of missing item to the delivering provider.

The following steps should be performed (*AORN, 2006 [R]*):

- Make a visual inspection of the Labor and Delivery suite, including a visual inspection of the area surrounding the delivery field, the floor, linens, and trash receptacles.
- Repeat the count and verify that there is still a discrepancy. A discrepancy must never be resolved by using the number listed on opened packages.

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Algorithm Annotations

- Special attention should be paid to items that can stick together, such as sponges/soft goods. Sponges/soft goods will be separated and unballled and/or pulled apart for counting.
- If the mother's condition permits, the genital tract should be explored, with special attention paid to the location of where that particular item may be retained (*Controlled Risk Insurance Company/Risk Management Foundation, 2006 [R]*).

If the counts cannot be reconciled:

- Post-delivery imaging should be obtained if counts cannot be reconciled (*Controlled Risk Insurance Company/Risk Management Foundation, 2006 [R]*).
 - The physician and/or radiologist should review the films before the end of the immediate recovery period (one to two hours). See Annotation # 12, "Obtain Radiographic Imaging for Potential Retained Foreign Objects."

Unreconciled count:

- If the count cannot be reconciled after all the steps above are completed, attempts to reconcile the count and the outcomes of those attempts will be documented per the organization's policy.

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12. Obtain Radiographic Imaging for Potential Retained Foreign Object

Portable radiographic imaging obtained in the Labor and Delivery room or a post-delivery image obtained in a radiographic room can be used to exclude the possibility of a retained foreign object. However, radiographic imaging is not a substitute for performing an accurate count process and a thorough genital tract exploration (*AORN, 2006 [R]*; *Controlled Risk Insurance Company/Risk Management Foundation, 2006 [R]*; *Council on Surgical and Perioperative Safety, 2005 [R]*).

Portable radiographic imaging can be performed in the Labor and Delivery room and, if the retained item is identified and removed, allows reconciliation of a discrepancy before the patient is transferred to a new room. This added convenience, however, comes at a cost. Portable machines have lower power, which results in less penetration and thus poorer image quality. In addition, placement of the film cassette might be restricted with portable machines, and this could result in sub-optimal capture of the anatomic field.

The highest quality radiographic imaging is obtained in a radiographic room with fixed radiographic equipment and moving grid.

Radiographic imaging should be obtained when:

- counts cannot be reconciled,
- the patient's condition does not allow for the count process to be followed (rushed counts, incomplete counts), or
- a member of the Labor and Delivery team has a concern about the accuracy of the count that cannot be resolved.

Radiographic imaging in a room with fixed equipment and moving grid should be obtained when:

- the patient's condition did not allow for a portable radiographic image to be obtained,
- the entire anatomic area could not be visualized on the portable radiographic image, or
- the portable radiographic image failed to locate the potentially retained foreign object and the count could not be reconciled.

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Radiographic imaging requests should include the following information:

- Callback number and clinician name (e.g., certified nurse midwife, collaborating physician)
- Location and status of patient (e.g., post-delivery recovery, Caesarean room)
- Number and type of item missing
- Details of the delivery, as appropriate

Before a radiologist interprets the radiographic images:

- the radiology technologist will review the radiographic image for quality and repeat the imaging as necessary, and
- when available, a Labor and Delivery physician will review the radiographic image to check for adequate anatomic coverage of the genital tract.

If a retained foreign object is identified on an image, even prior to the formal read by the radiologist, the midwife or Labor and Delivery physician should attempt to retrieve the retained item. If the item is retrieved and this makes the count correct, no further action is needed except to document the events in the medical record.

If initial review does not reveal a retained foreign object, or the Labor and Delivery physician is not able to verify adequate anatomic coverage on a portable image, an image in a radiographic room with fixed equipment and moving grid should be obtained once the patient is stable for transport.

For a negative film with a discrepancy in the count, the work group recommends that the radiologist and Labor and Delivery physician simultaneously review the radiographic image, ensuring adequate anatomic coverage and adequate film quality before declaring the film negative.

The films should be reviewed before the end of the immediate recovery period (one to two hours).

If a radiologist is not immediately available, the preliminary interpretation of the radiographic images used to identify a potentially retained foreign object is the responsibility of a Labor and Delivery physician because interpretation of radiographic films generally falls outside the scope of practice of nurses and certified nurse midwives.

Final reporting of radiologic imaging results should be completed in accordance with appropriate state and federal requirements (*ACR Practice Guideline, 2005 [R]*).

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This section provides resources, strategies and measurement for use in closing the gap between current clinical practice and the recommendations set forth in the protocol.

The subdivisions of this section are:

- Aims and Measures
 - Measurement Specifications
- Implementation Recommendations
- Resources
- Resources Table

Aim and Measures

1. Eliminate the number or rate of unintentionally retained foreign objects left following a vaginal delivery.

Measures for accomplishing this aim:

Outcome Measure:

- a. Rate, number and type of unintentionally retained foreign objects following a vaginal delivery.

Process measures:

- b. Percentage of vaginal deliveries where a baseline count was conducted.
- c. Percentage of vaginal deliveries where a final count was conducted.
- d. Percentage of cases where final counts were not reconciled with baseline counts and imaging was performed.

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Measurement Specifications

Measurement #1a

Number and type of unintentionally retained foreign objects during Labor and Delivery

or

Rate and type of unintentionally retained foreign objects during Labor and Delivery

Population Definition

Patients of all ages who have a vaginal delivery

Data of Interest

and type of unintentionally retained foreign objects in Labor and Delivery (reported as a raw number)

$$\frac{\text{\# and type of unintentionally retained foreign objects in Labor and Delivery}}{\text{Total \# of vaginal deliveries}} \times N$$

N is determined based on the size of the denominator

If denominator is less than 100, use a rate of per 100

If denominator is greater than 100 but less than 1,000, use rate of per 1,000

If denominator is greater than 1,000 but less than 10,000, use a rate of per 10,000

If denominator is greater than 10,000 but less than 100,000, use a rate of per 100,000

Numerator/Denominator Definitions

Numerator: Number and type of object unintentionally retained after the Labor and Delivery recovery period (one to two hours) following a vaginal delivery.

Denominator: Number of total vaginal deliveries.

Definition: Vaginal delivery includes labor and delivery and the end of the immediate recovery period (one to two hours) after vaginal delivery.

Method/Source of Data Collection

Unintentionally retained foreign object event data reported through an incident report or sentinel event report.

Total deliveries can be collected through a unit log or hospital billing.

Retrospective collection of any measures associated with documentation can be done by randomly sampling patient charts, or all charts can be reviewed for all deliveries.

Concurrent collection of numerator data can also be done through direct observation either by a quality/safety advocate or "secret shopper," defined as someone who has a dual function on the team but the observation and measurement function is not known.

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Sample Size

A sample size of 25 per month is recommended if collecting data through sampling. Can also look at the total number of vaginal deliveries. If less than 25 vaginal deliveries per month, use the total number of deliveries.

Time Frame Pertaining to Data Collection

Monthly or quarterly if caseload and/or event numbers are small.

Notes

This is an outcome measure, and improvement is noted as increase in the rate.

Retained foreign objects found in the clinic need to be reported to the hospital where the patient delivered. It is the responsibility of the hospital to report an event to the state and to perform a root cause analysis.

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Measurement #1b

Percentage of vaginal deliveries where a baseline count was conducted.

Population Definition

Patients of all ages who have a vaginal delivery.

Data of Interest

$$\frac{\text{\# of baseline counts}}{\text{Total \# of vaginal deliveries}}$$

Numerator/Denominator Definitions

Numerator: Number of baseline counts.

Denominator: Number of vaginal deliveries.

Definition: Vaginal delivery includes labor and delivery and the end of the immediate recovery period (one to two hours) after vaginal delivery.

Method/Source of Data Collection

Determine the number of total vaginal deliveries from unit logs or hospital billings. Out of that number, determine the number deliveries that had baseline counts done.

This information can also be collected by random sampling of patient charts to determine whether baseline counts were done.

Concurrent collection of numerator data can also be done through direct observation either by a quality/safety advocate or "secret shopper," defined as someone who has a dual function on the team but the observation and measurement function is not known.

Sample Size

A sample size of 25 per month is recommended if collecting data through sampling. Can also look at the total number of vaginal deliveries. If less than 25 total vaginal deliveries per month, use the total number of deliveries.

Time Frame Pertaining to Data Collection

Monthly.

Notes

This is a process measure, and improvement is noted as increase in the rate.

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Measurement #1c

Percentage of vaginal deliveries where a final count was conducted.

Population Definition

Patients who have a vaginal delivery.

Data of Interest

$$\frac{\text{\# of deliveries where final counts were done}}{\text{Total \# of vaginal deliveries with baseline counts done}}$$

Numerator/Denominator Definitions

Numerator: Number of vaginal deliveries where final counts were done.

Denominator: Number of vaginal deliveries with baseline counts done.

Definition: Vaginal delivery includes labor and delivery and the end of the immediate recovery period (one to two hours) after vaginal delivery.

Method/Source of Data Collection

Determine the number of vaginal deliveries from unit logs or hospital billings. Out of that number, determine the number deliveries that had baseline counts done. Then determine if the final counts were done for those deliveries.

This information can also be collected by random sampling of patient charts to determine whether final counts were done.

Sample Size

A sample size of 25 per month is recommended if collecting data through sampling. Can also look at the total number of vaginal deliveries. If less than 25 total vaginal deliveries per month, use the total number of deliveries.

Time Frame Pertaining to Data Collection

Monthly.

Notes

This is a process measure, and improvement is noted as increase in the rate.

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Measurement #1d

Percentage of cases where final counts were not reconciled with baseline counts and imaging was performed.

Population Definition

Patients who have a vaginal delivery.

Data of Interest

$$\frac{\# \text{ of cases where final counts were not reconciled with baseline counts for which imaging was performed}}{\text{Total \# of vaginal deliveries with baseline and final counts done}}$$

Numerator/Denominator Definitions

Numerator: Number of vaginal deliveries where final counts were not reconciled with baseline counts and imaging was performed.

Denominator: Number of total vaginal deliveries with baseline and final counts done.

Definition: Vaginal delivery includes labor and delivery and the end of the immediate recovery period (one to two hours) after vaginal delivery.

Method/Source of Data Collection

Determine the number of total vaginal deliveries from unit logs or hospital billings. Out of that number, determine the number deliveries that had baseline and final counts done. Then determine if the final counts were reconciled and if not, determine if imaging was performed.

This information can also be collected by random sampling of patient charts to determine whether baseline counts were done and whether the counts were reconciled and if not, determine if imaging was performed.

Sample Size

A sample size of 25 per month is recommended if collecting data through sampling. Can also look at the total number of vaginal deliveries. If less than 25 total vaginal deliveries per month, use the total number of deliveries.

Time Frame Pertaining to Data Collection

Monthly.

Notes

This is a process measure, and improvement is noted as increase in the rate. To gain further understanding as to why a sentinel event occurred and imaging needed to be done (final counts were not reconciled with the baseline counts), it is recommended that a hospital do Root Cause Analysis (RCA) of processes that led to the sentinel event. Understanding the process that led to a sentinel event will help the clinical team fix the process for future deliveries and thus decrease the likelihood of another sentinel event.

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Implementation Recommendations

Prior to implementation, it is important to consider current organizational infrastructure that address the following:

- System and process design
- Training and education
- Culture and the need to shift values, beliefs and behaviors of the organization

The following system changes were identified by the protocol work group as key strategies for health care systems to incorporate in support of the implementation of this protocol.

1. The work group recommends that a standardized method, such as use of either a count worksheet or a whiteboard, be used in Labor and Delivery to keep track of baseline, ongoing and final counts. This method can then be used for final documentation or dictation of the medical record and/or submission into an electronic medical record.
2. The Labor and Delivery room needs to have a dedicated receptacle or location for all used sponges/soft goods in order to ensure accuracy of the count process. This must be in a location where staff can retrieve these items and not be co-mingled with the waste bucket at the foot of the bed.
3. The counting process must include a registered nurse and another person trained in the counting process.
4. Active support for the implementation of this protocol from administrative and medical leadership is essential.
5. Establish and/or maintain processes for ongoing training, measurement and feedback for all involved staff.
6. Evaluation of count practices should include performance improvement audits. This is to ensure that count processes are being followed and not merely documented. Trends identified with audits can be used for ongoing training, measurement and feedback for all staff (*Murdock, 2008 [X]*).
7. Red rules* should be established, followed by staff and physicians and supported by leadership (see below for specific red rules suggested for this protocol).

* Red rules are the few key rules created by the facility to prevent/address specific actions that pose the highest level of consequence and risk to patients or staff. The intention is to develop solid habits around these rules so that they are followed consistently and accurately each time. Individual responsibility to adhere to each red rule is imperative to ensure a safe environment and consistent delivery of the desired care process.

Suggested red rules for Labor and Delivery:

1. All sponges and sharps will be counted for every vaginal delivery.
2. Only radiopaque sponges/soft goods will be present on Labor and Delivery trays or enter the delivery field.
3. If the count cannot be reconciled, imaging must be done.

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Resources

Criteria for Selecting Resources

The following resources were selected by the protocol work group as additional resources for providers and/or patients. The following criteria were considered in selecting these resources.

- The site contains information specific to the topic of the protocol.
- The content is supported by evidence-based research.
- The content includes the source/author and contact information.
- The content clearly states revision dates or the date the information was published.
- The content is clear about potential biases, noting conflict of interest and/or disclaimers as appropriate.

Resources Available to ICSI Members Only

ICSI has knowledge resources that are *only* available to ICSI members (these are indicated with an asterisk in far left-hand column of the Resources Table). In addition to the resources listed in the table, ICSI members have access to a broad range of materials including tool kits on Continuous Quality Improvement processes and Rapid Cycling that can be helpful. To obtain copies of these or other Resources, go to [Education and Quality Improvement](#) on the ICSI Web site. To access these materials on the Web site, you must be logged in as an ICSI member.

The resources in the table on the next page that are not reserved for ICSI members are available to the public free-of-charge unless otherwise indicated.

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Resources Table

*	Author/Organization	Title/Description	Audience	Web Sites/Order Information
	American College of Obstetricians and Gynecologist	American College of Obstetricians and Gynecologists is a private, voluntary, non-profit membership organization comprised of professionals providing health care for women. Multiple educational resources	Health Care Professionals	http://www.acog.org
	The Joint Commission	The Joint Commission evaluates and accredits health care organization and programs in the United States	Health Care Professionals	http://www.jointcommission.org
	Minnesota Hospital Association	Minnesota Hospital Association Patient Safety Call to Action: Road Map to Preventing Retained Objects in Vaginal Deliveries		http://www.mnhospitals.org

* Available to ICSI members only.

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The subdivisions of this section are:

- References
- Appendix

References

Links are provided for those new references added to this edition (author name is highlighted in blue).

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Appendix A – Incorporating Human Factors Systems Design into Work Process Design

Two large population-based studies of medical injury published in 1991 and 2000 led to the initiation of many efforts to reduce medical error. The first of the studies, the Harvard Medical Practice Study (HMPS), examined the outcomes of 30,121 randomly chosen patient cases from 51 hospitals in New York State in 1984 (*Brennan, 1991 [C]; Leape, 1991 [C]*). In the second, the Utah and Colorado Medical Practice Study (UCMPS), the records of 14,052 randomly selected hospitalizations from 28 hospitals in Utah and Colorado in 1992 were reviewed (*Thomas, 2000 [C]*). Similar results were found in both studies, and extrapolation from the results of the most recent of the studies, the UCMPS, indicates that approximately 44,000 deaths recorded in 1997 in the USA could have occurred as a result of preventable adverse events. Many efforts to reduce medical error that were initiated as a result of these studies have included Human Factors methodology to investigate and improve health care systems.

Human Factors emphasizes designing systems and producing work processes that enhance human performance. Human Factors Systems Design considers weaknesses and strengths in the entire medical delivery process from diagnosis through the prescription and delivery of treatment, and includes examining the work processes of, for example, surgeons, anesthesiologists, nurses, scrub technicians, phlebotomists, pharmacists and health unit coordinators.

Human Factors Systems Design focuses on how the work process and performance of health care providers are affected by issues such as work space design; the functionality and ease of using electronic medical records systems; distractions and interruptions; workload; the complexity, length and urgency of procedures; fatigue and personal stress; intra- and inter-departmental communication issues; staffing requirements; the use of float staff; shift changes; staff competencies; and training.

Human Factors Systems Design seeks to identify the probable and potential causes of errors and to identify factors contributing to safety gaps in medical processes. Then design improvements, based on Human Factors principles, are developed so that the errors and safety gaps are addressed without introducing problems elsewhere in the system. The goal is to foster better work environments, minimize potential errors, improve patient care, and enhance patient safety.

Communication Factors and Events

In root cause analysis findings submitted to The Joint Commission in the 10 years from 1995 to 2005, the number one reason identified as causal in all sentinel events was communication (*Joint Commission of Accreditation Organization, 2006 [C]*). In 2006, in an attempt to address these findings, The Joint Commission required accredited organizations to implement a national patient safety goal related to communication. While organizations have been given flexibility in determining how to meet the expectations of this goal, many have adopted SBAR (situation, background, assessment and recommendation) as one way of improving communication. While SBAR has its origins in the nuclear power and commercial aviation industries, it has been successfully adapted to the medical community (*Haig, 2006 [D]*).

One of the benefits of this communication model is that it addresses the different ways in which physicians are trained to communicate versus other health care professionals, especially nurses (*Leonard, 2004 [D]*).

One mechanism to decrease events, including retained items, is the use of pre-procedural briefings. The purpose of a briefing is to ensure that all the members of the team are working toward a common goal and are aware of any concerns the provider may have related to the procedure. The briefing also provides a platform for any member of the team to raise a misgiving (*ECRI, 2005 [R]*). At the conclusion of the procedure, team members can debrief the process to identify what went well, what could have been done differently, and what can be done the next time (*ECRI, 2005 [R]*).

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Both communication methodologies promote the use of "stop the line." Again, developed outside the health care industry, this concept allows any member of the team to speak up about a patient safety concern at any time during the procedure. Implementing a "stop the line" process requires a culture that promotes and rewards behaviors consistent with patient safety efforts. No matter the outcome, the willingness of the individual to raise a concern is directly related to the organization's administrative support of the action.

(Harder, 2006 [D]; Lingard, 2004 [D])

Distractions, Environmental Factors and Events

When an event occurs, one of the contributing factors that is explored is the environment. Noise in the procedure room, including music, can interfere with the team's ability to communicate, increase stress levels and adversely affect motor skills (*Vincent, 2004 [R]*). Distractions (e.g., pagers in the Labor and Delivery room) and interruptions by individuals not directly involved should be kept to a minimum, especially during critical stages of a procedure (*ACOG, 2006 [R]*). Other factors that should be taken into consideration when evaluating the environment are adequate lighting in the room for team members to see clearly and read labels, unpleasant odors that may be a direct result of the procedure being performed, or the room temperature. While the latter two factors may be outside the direct control of the team members, nonetheless they should be taken into consideration and recognized as a risk factor for an event.

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Prevention of Unintentionally Retained Foreign Objects During Vaginal Deliveries

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ICSI Document Development and Revision Process

Overview

Since 1993, the Institute for Clinical Systems Improvement (ICSI) has developed more than 60 evidence-based health care documents that support best practices for the prevention, diagnosis, treatment or management of a given symptom, disease or condition for patients.

Document Development and Revision Process

The development process is based on a number of long-proven approaches. ICSI staff first conducts a literature search to identify pertinent clinical trials, meta-analysis, systematic reviews, regulatory statements and other professional protocols. The literature is reviewed and graded based on the ICSI Evidence Grading System.

ICSI facilitators identify gaps between current and optimal practices. The work group uses this information to develop or revise the clinical flow and algorithm, drafting of annotations and identification of the literature citations. ICSI staff reviews existing regulatory and standard measures and drafts outcome and process measures for work group consideration. The work group gives consideration to the importance of changing systems and physician behavior so that outcomes such as health status, patient and provider satisfaction, and cost/utilization are maximized.

Medical groups, who are members of ICSI, review each protocol as part of the revision process. The medical groups provide feedback on new literature, identify areas needing clarification, offer recommended changes, outline successful implementation strategies and list barriers to implementation. A summary of the feedback from all medical groups is provided to the protocol work group for use in the revision of the protocol.

Implementation Recommendations and Measures

Each protocol includes implementation strategies related to key clinical recommendations. In addition, ICSI offers protocol-derived measures. Assisted by measurement consultants on the protocol development work group, ICSI's measures flow from each protocol's clinical recommendations and implementation strategies. Most regulatory and publicly reported measures are included but, more importantly, measures are recommended to assist medical groups with implementation; thus, both process and outcomes measures are offered.

Document Revision Cycle

Scientific documents are revised every 12-24 months as indicated by changes in clinical practice and literature. Each ICSI staff monitors major peer-reviewed journals every month for the protocols for which they are responsible. Work group members are also asked to provide any pertinent literature through check-ins with the work group mid-cycle and annually to determine if there have been changes in the evidence significant enough to warrant document revision earlier than scheduled. This process complements the exhaustive literature search that is done on the subject prior to development of the first version of a protocol.

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